

# 2008

## Annual Report

### CHUGAI PHARMACEUTICAL CO., LTD.





#### << “Kaitai Shinsho” by Genpaku Sugita

Kaitai Shinsho is the first, full-fledged translated text of Western medicine in Japan. The translation was published during the Edo period based on the Dutch version of Anatomische Tabellen, known as Tafel Anatomie in Japan, which was a medical text written by a German doctor, Johann Adam Kulmus. We are committed to pursue the endeavors of our predecessors to bring innovation in human healthcare.

(Akita Prefectural Library Archive)

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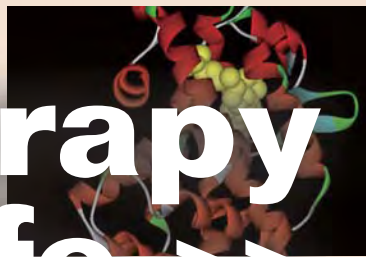
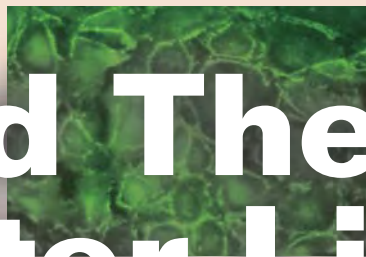
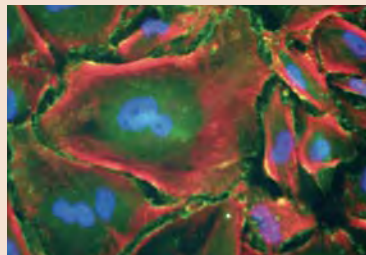
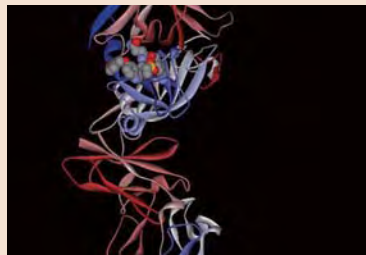
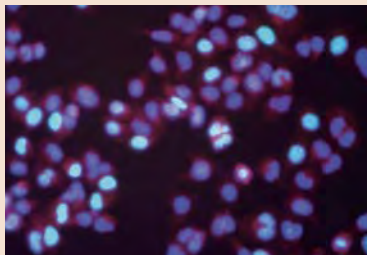
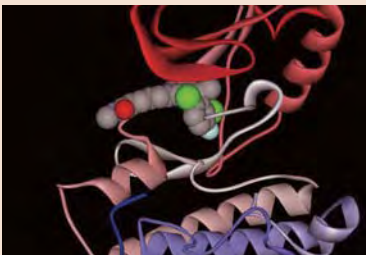
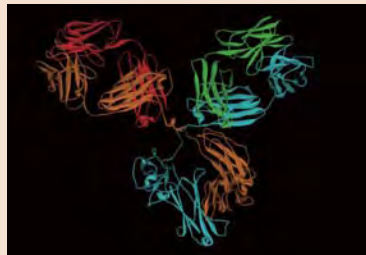
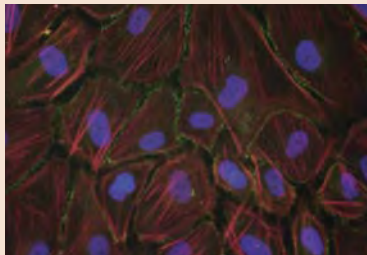
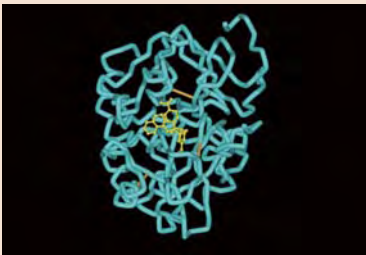
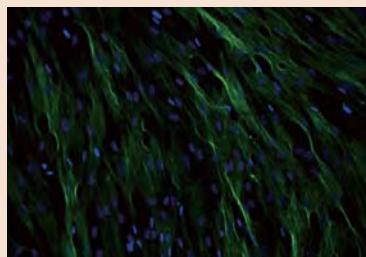
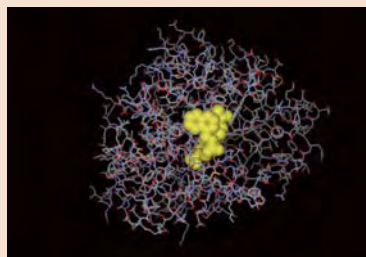
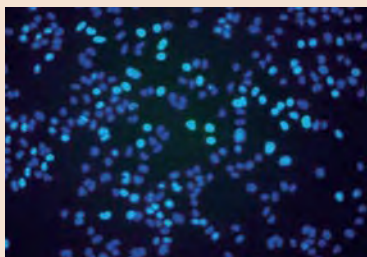
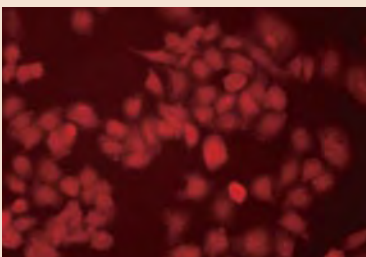
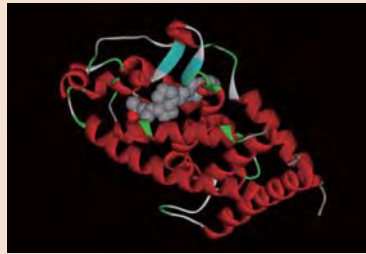
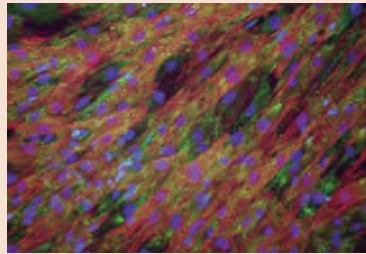
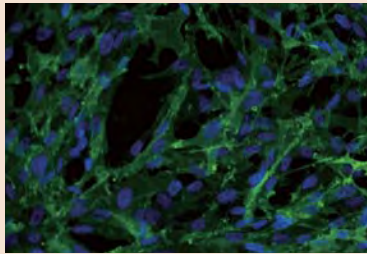
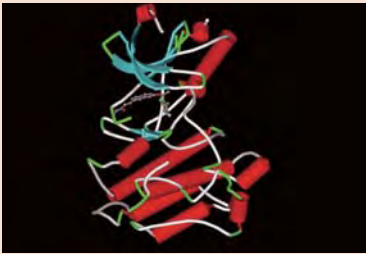
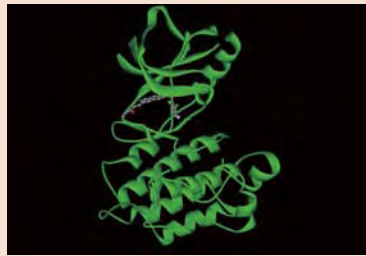
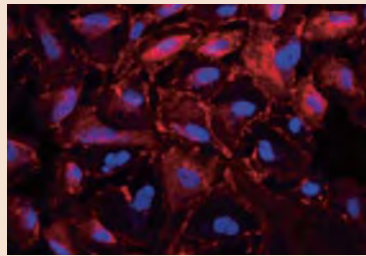
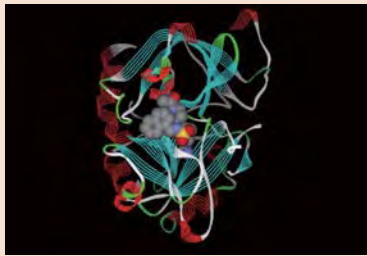
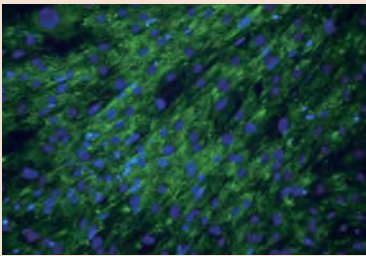
86 >> Shareholders Information

### Forward-Looking Statements

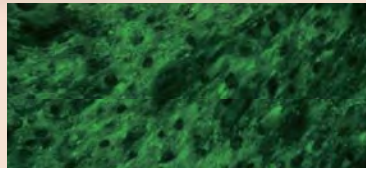
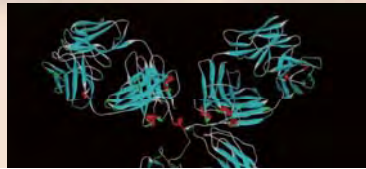
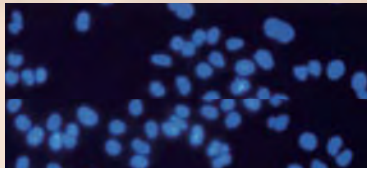
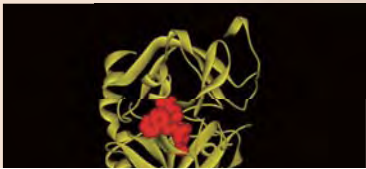
This annual report includes forward-looking statements pertaining to the business and prospects of the Company. These statements reflect the Company's current analysis of existing information and trends. Actual results may differ from expectations based on risks and uncertainties that may affect the Company's businesses.

### Note:

The information regarding pharmaceuticals (including products under development) is not intended for advertising, promotion or medical advice. All trademarks are property of their respective holders.



**Targeted Therapy  
for Better Life >>**

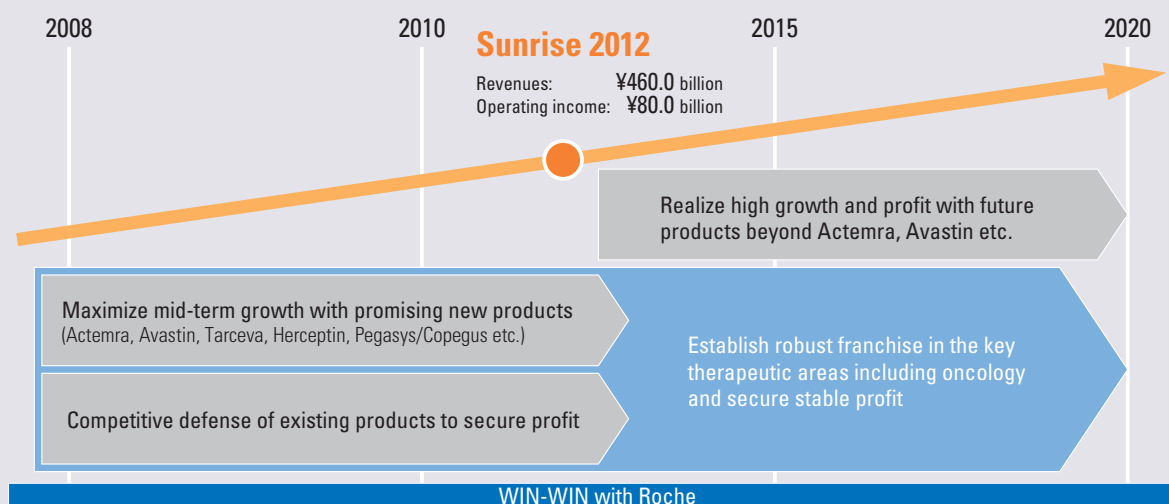


## The Year in Brief 2008

- >> In FY2008 consolidated revenues totaled ¥326.9 billion and operating income totaled ¥51.6 billion (down 5.2% and 22.6%, respectively, from the previous fiscal year). The declines were primarily owing to the completion of deliveries of Tamiflu for the Japanese government's initial stockpiling as well as from the NHI drug price revision in April.
- >> In 2008 a solid foundation was established for our future growth. Actemra, Avastin and other new products marked a steady increase in sales. With the contribution of these future growth drivers, sales excluding Tamiflu recorded the highest in the Company's history. In the oncology field, Chugai seized the No.1 market share\* in the Japanese oncology market for the first time.
- >> Actemra, the first antibody-based drug to originate in Japan, entered the Japanese rheumatoid arthritis market in April 2008. In Europe, the product was jointly launched with Roche in January 2009 as the first step in the global field.

\* IMS Pharmaceutical Market Statistics (Reimbursement price basis), Dec. 2008 MAT.  
The scope of the market is defined by Chugai.

### Medium-to-long-term Growth Strategy by Innovative Drugs





# Financial Highlights

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries / Years ended December 31

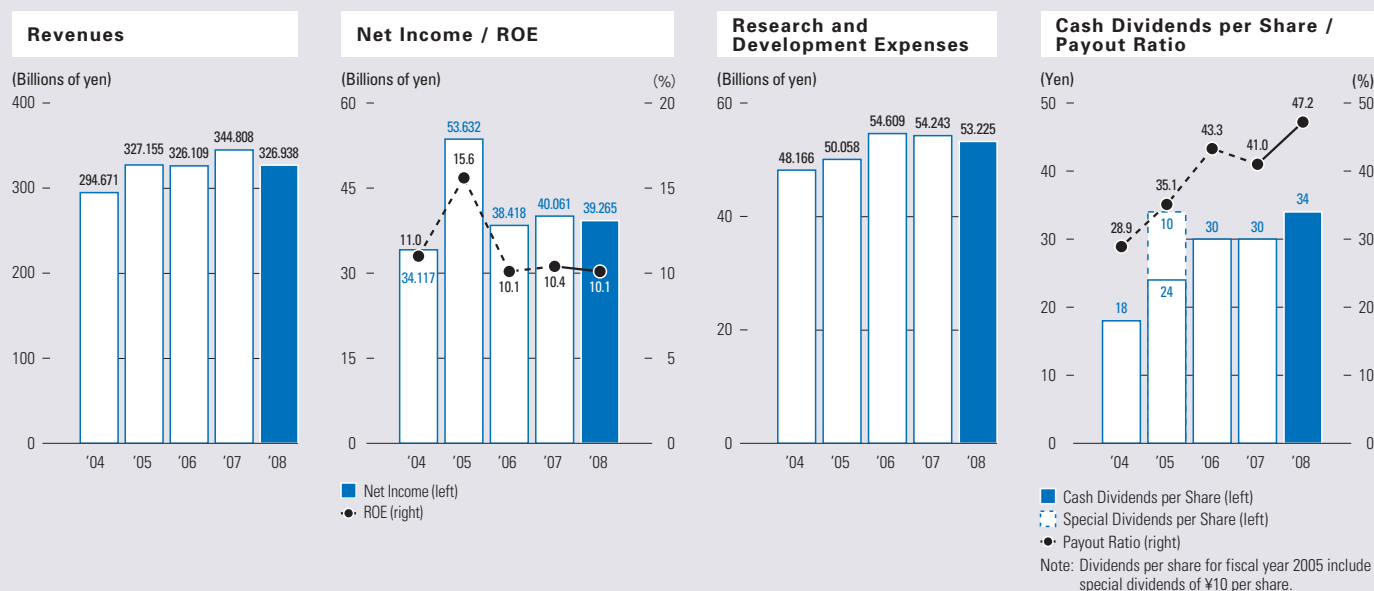
	Millions of yen (Except as otherwise specified)					Thousands of U.S. dollars* <sup>1</sup> (Except as otherwise specified)
	2008	2007	2006	2005	2004	2008
<b>Results for the year:</b>						
Revenues	¥326,938	¥344,808	¥326,109	¥327,155	¥294,671	\$ 3,632,644
Operating income	51,563	66,703	58,347	79,169	51,497	572,922
Income before income taxes and minority interests	63,106	66,428	62,956	86,179	57,488	701,178
Net income	39,265	40,061	38,418	53,632	34,117	436,278
Research and development expenses	53,225	54,243	54,609	50,058	48,166	591,389
<b>Amounts per share: (Yen and U.S. dollars)</b>						
Net income - basic -	¥ 72.07	¥ 73.23	¥ 69.35	¥ 97.00	¥ 62.27	\$ 0.80
Net income - diluted -	72.04	73.16	69.26	96.33	61.34	0.80
Net Assets	725.18	703.80	703.08	665.29	583.61	8.06
Cash dividends* <sup>2</sup>	34.00	30.00	30.00	34.00	18.00	0.38
<b>Financial position at year-end:</b>						
Total assets	¥478,518	¥458,942	¥462,124	¥456,442	¥411,449	\$ 5,316,867
Interest-bearing debt	305	775	1,300	2,549	6,167	3,389
Net Assets	397,067	385,798	389,598	368,306	320,847	4,411,856
Number of shares outstanding	559,685,889	559,636,061	559,493,113	558,655,824	555,004,964	—
Number of employees	6,383	6,257	5,905	5,280	5,313	—
<b>Ratios:</b>						
Operating income to revenues (%)	15.8	19.3	17.9	24.2	17.5	—
Return on equity (%)* <sup>3</sup>	10.1	10.4	10.1	15.6	11.0	—
Shareholders' equity to total assets (%)	82.6	83.5	84.3	80.7	78.0	—
Debt-to-equity ratio (%)	0.1	0.2	0.3	0.7	1.9	—
Interest coverage ratio (Times)* <sup>4</sup>	517.5	461.9	283.0	284.8	169.3	—
Research and development expenses to revenues (%)	16.3	15.7	16.7	15.3	16.3	—

\*<sup>1</sup> The U.S. dollar amounts in the consolidated financial statements as of and for the year ended December 31, 2008 have been translated from Japanese yen amounts at the rate of ¥90 to U.S. \$1.00, the exchange rate prevailing on December 31, 2008.

\*<sup>2</sup> Cash dividends per share are calculated on an unconsolidated basis. Dividends per share for fiscal year 2005 include special dividends of ¥10 per share.

\*<sup>3</sup> ROE = Net income/Shareholders' equity (yearly average) × 100

\*<sup>4</sup> Interest coverage ratio = Net cash provided by operating activities (prior to deductions of interest paid and income taxes paid, and addition of income taxes refunded)/interest paid.



# Dear Shareholders and Investors



Under our Mid-Term Business Plan, “Sunrise 2012,” we have been continuously working to establish a foundation for growth. In FY 2008, we made considerable progress towards this objective with the successful launches of major new products. We will continue to take advantage of our competitive edge in growth areas and biopharmaceuticals to make further advances in our operations and thus meet the expectations of all shareholders.

## FY 2008 Results

### Record-High Sales Excluding Tamiflu Foundation for Growth Established

In FY2008, Chugai reported a decline in both revenues and operating income, with revenues down 5.2% to ¥326.9 billion, and operating income down 22.6% to ¥51.6 billion. The steady expansion of our new product lineup, however, made FY2008 a year in which we solidified our base for the next stage of growth.

The biggest factor for the decline in revenues was the fall in sales of the anti-influenza agent Tamiflu (down ¥30.3 billion, a decrease of 78.3%). Other factors included the NHI price revision in April 2008 and continued competition facing our mainstay product, Epogin, as well as the termination of the marketing collaboration with sanofi-aventis.

Despite the negative impact from these special factors, in 2008 we saw a solid rise in sales of Actemra, an in-house developed driver for future growth, as we obtained its additional indication in Japan for the treatment of rheumatoid arthritis (RA). Other products made steady market penetration, including Avastin, Tarceva, and Copegus—all launched in 2007—as well as Xeloda and Herceptin, which obtained additional indications in 2007 and 2008. As a result, in the oncology field, Chugai seized the top share (15.8%)\*<sup>1</sup> for the first time in the domestic market.

In FY2008, product sales excluding Tamiflu amounted to

¥313.4 billion, an increase of 6.5% from the previous year, the highest level for the Company in history. We also reported non-operating income owing to foreign exchange gain, as well as an extraordinary gain due to the settlement with Roche for co-development costs of Actemra. As a result, recurring profit decreased 15.4% to ¥57.3 billion, and net income decreased 2.0% to ¥39.3 billion.

\*<sup>1</sup> IMS Pharmaceutical Market Statistics (Reimbursement price basis), Dec. 2008 MAT. The scope of the market is defined by Chugai.

### New Policy on Profit Distribution Annual Dividends Raised to ¥34

In FY2008, total dividends paid during the year amounted to ¥34 per share, an increase of ¥4 from the previous year, and the consolidated dividend payout ratio was 47.2%, an increase of 6.2 percentage points from the previous year. Having reviewed our dividend policy, we will now aim to ensure a ratio of around 40%, while keeping dividend amounts stable. In the past, our goal was to ensure stable amounts and a consolidated ratio of 30% or more on average. However, taking into account the importance of further enhancing the return of profits to shareholders, and having achieved an average ratio that greatly exceeds this 30% target over the past five years, we increased the target ratio.



## FY 2009 Outlook

### Increased Sales and Income Expected in FY 2009 Due to Higher Sales of Growth Drivers

In FY2009, we expect revenues of ¥400 billion, up 22.4% year-on-year, driven by further growth of our major products. We project a 7.6% increase in product sales excluding Tamiflu to ¥337.3 billion.

For the year, we forecast sales of Tamiflu to reach ¥53.0 billion, up 531.0%, due to expected resumption of government stockpiling in FY2009 and the ongoing recovery of the prescription rate for seasonal influenza.

Our mainstay product Epogin is expected to continue facing stiff competition, but we will endeavor to maintain sales by expanding sales in the pre-dialysis market. Meanwhile, we are confident that Actemra will become another driver for future growth in addition to Avastin, Herceptin, and Pegasys/Copegus. Actemra, a product expected to become our next major growth driver, was launched in Europe in January 2009, clearing the first step toward becoming a global pharmaceutical product.

On the earnings side, we project a 22.1% increase in operating income to ¥63.0 billion, a 10.8% increase in recurring profit to ¥63.5 billion, and a 1.8% increase in net income to ¥40.0 billion. This is due to higher revenues, despite a 5.7% increase in SG&A owing to sales promotion activities and various post-marketing initiatives, such as safety measures, which are aimed at achieving further market penetration of our major products.

## Chugai's Strategies

### Difficult Business Conditions and a Focus on New Growth Areas

Today, the pharmaceutical industry faces a multitude of challenges. These include continued pressure around the world to reduce medical costs, depletion of new drug candidates, soaring R&D costs, expiration of patents for major products, and generic erosion. In response, leading pharmaceutical companies have embarked on large-scale investment initiatives, including mergers and acquisitions. In 2008, for example, Japanese pharmaceutical companies took actions to acquire overseas biotechnology firms and generic manufacturers. Companies are investing vast amounts for future development in the area of unmet medical needs<sup>\*2</sup>, which is expected to have high growth, as well as in antibody drugs and other biopharmaceuticals. Competition to ensure future growth is becoming increasingly intense.

<sup>\*2</sup> "Unmet medical needs" areas include cancer, rheumatoid arthritis, and chronic hepatitis C, where existing medicines make limited contributions and treatment satisfaction is low.

### Chugai's Foundation for Growth

While various pharmaceutical companies are moving to tap new growth areas to cope with the difficult business environment, Chugai has already begun instituting dramatic transformations aimed for further growth.

Chugai has become the leading biopharmaceutical company in Japan because we took the initiative to develop the



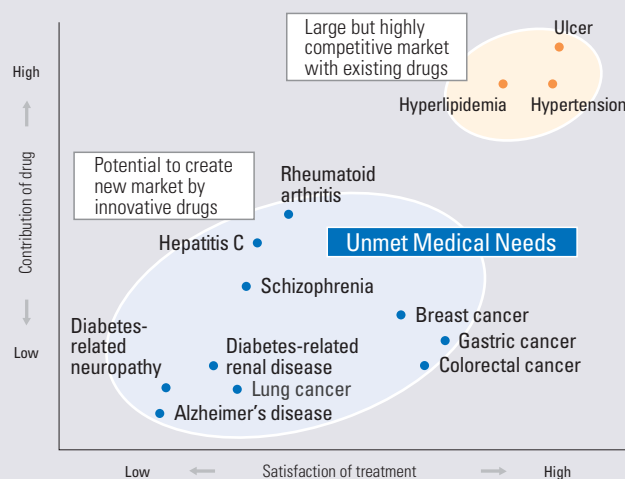
biopharmaceuticals Epogin and Neutrogin early in the 1980s and turned them into major products that are the core of our business. In the ensuing years, we broadened our research to encompass antibodies, resulting in the successful development and launch of the first antibody product originating in Japan, Actemra, an innovative new product drawing high expectation from around the world. In 2008, we commenced clinical development of the next antibody project from Chugai research following Actemra. I am glad to say that we have reached the stage where we possess a firm competitive advantage in the biopharmaceutical field.

Since our strategic alliance with Roche in 2002, we have acquired a rich development pipeline centering on the oncology field. Thus, we have greatly expanded our growth potential in the area of “unmet medical needs” in addition to RA, for which we have Actemra. Innovative new products, such as Avastin and Tarceva, which significantly contribute to medical treatments overseas, have been developed and launched successfully in Japan, dramatically strengthening our product portfolio. FY2008 was the year when we saw the fruits of the strategic alliance, as these new products started to make a full-scale contribution to our business performances.

### Steady Progress of Sunrise 2012, Our Mid-Term Business Plan

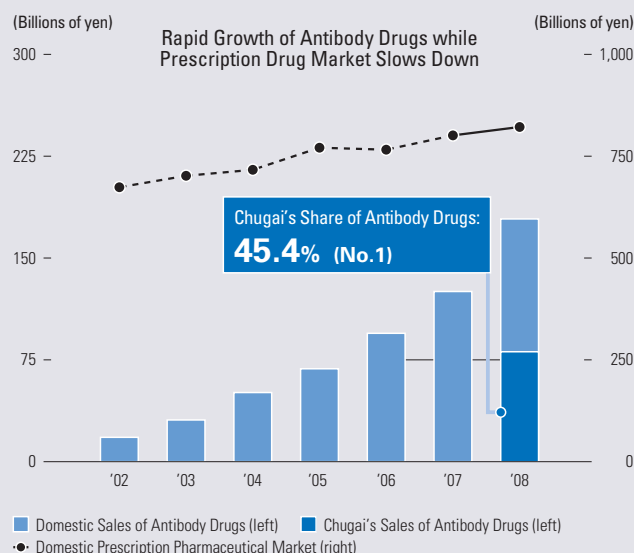
Under our Mid-Term Business Plan, Sunrise 2012, we are targeting ¥460 billion in consolidated revenues and ¥80 bil-

#### Unmet Medical Needs



Source: Report issued by Japan Health Science Foundation (revised by Chugai).

#### Chugai's Presence in the Domestic Antibody Market



Source: IMS Pharmaceutical Market Statistics (Reimbursement price basis), Dec. 2002-2008 MAT, Reproduction without consent is prohibited.  
Note: The scope of the market is defined by Chugai.



lion in operating income by FY2012. Building on our existing base of mainstay products, such as Epogin and Neutrogen, the plan calls for us to establish a firm foundation with our future growth drivers, such as Actemra, Avastin, Tarceva, Herceptin, Xeloda, and Pegasys/Copegus.

In order to achieve these targets, we have placed maximum priority on creating a strategic marketing system that will translate the high potential of our products into stronger earnings. As a result, our new products made steady market penetration in FY2008. We have also made good progress in development projects aimed at strengthening our growth foundation upon which Sunrise 2012 is based. In FY2009, we plan to file for approval of two new

compounds, R744 (overseas product name: Mircera) and ED-71. We will also seek to obtain additional indications for Epogin, Avastin, and Tarceva.

### Aiming for Japan's Top Pharmaceutical Company

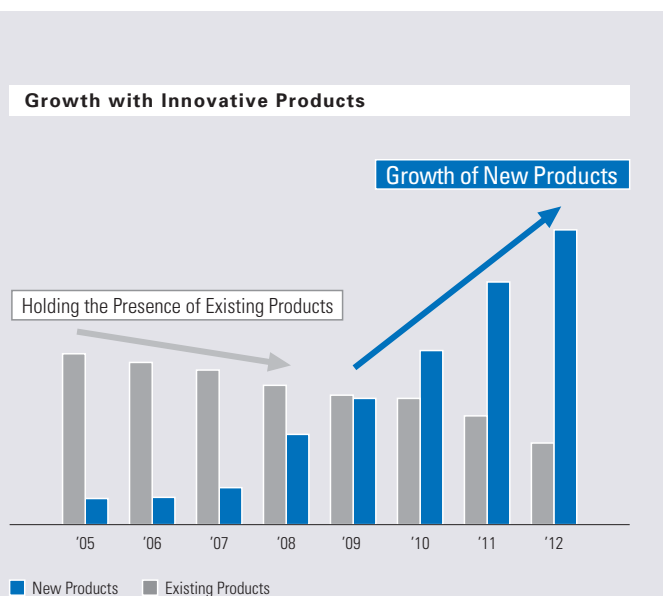
In order to reach the goals of Sunrise 2012 and generate further growth, it is paramount that all employees identify with our objective and take responsibility in their quest to create a top Japanese pharmaceutical company, carrying out proactive initiatives in all business functions. I believe that pursuing such initiatives dynamically and persistently is the key to transform ourselves into our envisioned company with improved business results, higher corporate value, and unshakeable confidence from stakeholders. This will serve as a cornerstone to enable our transformation. Placing our patients first, we will continue to make sincere efforts to meet the expectations of our shareholders through the creation of innovative medical products and services for the benefit of the medical community and human health around the world.

I would like to ask everyone for their continued understanding and support.

March 2008

**Osamu Nagayama**

Chairman, President and CEO





# Special Feature:

## Molecular Targeted Therapy

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# Voyage into Blue Ocean >>

# Molecular Targeted Therapy

Technological innovations have opened up new approaches to a range of diseases not adequately addressed by existing pharmaceutical therapies. Increasingly, molecular targeted therapy is playing a decisive role in treatment advances. Chugai aims to contribute to better medical care through its rich portfolio of innovative targeted therapies.

## Mechanism of Action and Characteristics

Molecular targeted therapy is a new treatment approach resulting from scientific advances which have given us a clearer understanding of the human body and disease mechanisms. With the aim to alleviate symptoms and cure diseases, targeted therapy selectively inhibits activity of specific molecules inside the body that cause occurrence and/or progression of diseases.

Revolutionary therapeutic results from targeted therapy are arriving in various disease areas because of the completely different concept from traditional treatments. In rheumatoid arthritis (RA), clinical benefits of older medicines were not at satisfactory level, and the symptoms of the disease progressed to severe deterioration of the patient's quality of life. Now remission\*<sup>1</sup> is a realistic goal, thanks to targeted therapy, which consequently greatly improves the patient's quality of life. Furthermore, in the treatment of various cancers, the leading cause of death in Japan, a dramatic survival benefit by targeted therapy has been confirmed. Molecular targeted therapy is expected to contribute greatly to the therapeutic areas of "unmet medical needs," where existing drugs make limited contribution and thus treatments have been considered inadequate.

Molecular targeted therapy has different characteristics from existing therapies in terms of safety as well. For example, the wide-ranging adverse effects associated with conventional anti-cancers, which present a major hurdle for continuous treatment, are not as pronounced with targeted therapy. This is because it targets specific molecules that play crucial roles in development of the diseases and thus harms fewer normal cells, while conventional therapies attack both cancerous and normal cells. However, it is known that the targeted agents can be associated with various side effects which are agent and patient specific, and may result in serious consequences. Since the therapeutic experience has not reached a familiar level in Japan yet, unprecedented adverse effects could

possibly occur even if the targeted agent has already become standard treatment outside Japan. To maximize the therapy's value to the patients, it is crucial to ensure proper use by specialized medical professionals with sufficient experience, as well as rigorous safety measures from pharmaceutical companies, which include making the most up-to-date information available to the medical society.

\*<sup>1</sup> State in which patient's symptoms is stably under control by a drug.

## Chugai's Product Portfolio

In 2007 and 2008, Chugai successively launched or expanded the indications of four innovative targeted products: Actemra, Avastin, Tarceva, and Herceptin. In this feature, we profile these four future growth drivers.

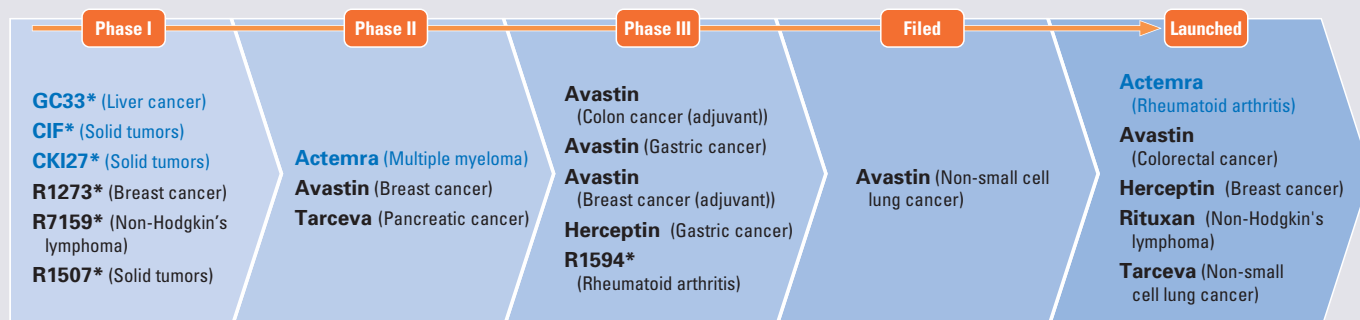
### (1) Actemra

Actemra, the first antibody drug created in Japan, is the result of joint research by Chugai and Osaka University on the role of a protein called interleukin-6 (IL-6), which is part of the human immune system. IL-6 is overexpressed in several autoimmune diseases\*<sup>2</sup> and is therefore thought to be involved in their onset and progression. Actemra targets the IL-6 receptor and blocks signals that are triggered by IL-6 molecules within cells. Based on the excellent outcomes achieved in large-scale clinical trials, Actemra is expected to make a major contribution to the treatment of autoimmune disorders such as Castleman's disease, for which there were hitherto virtually no effective therapies, and rheumatoid arthritis (RA), which often does not respond adequately to the treatments available to date.

Actemra was first approved in Japan for the treatment of Castleman's disease in June 2005. In April 2008, we obtained approval for the additional indications of RA, polyarticular-



## Development Pipeline of Molecular Targeted Drugs



Blue Letters: Developed In-house \*New Molecular Entities

course juvenile idiopathic arthritis, and systemic-onset juvenile idiopathic arthritis. As the first product to demonstrate effectiveness in inhibiting joint damage associated with RA in Japanese patients and with its high remission rate, Actemra has been adopted as the first-line biologic treatment for RA since approval of the additional indications. Besides the clinical benefits, infection is reported as the product's major adverse reaction. As is the case with all new biologic medicines, a post-marketing all-patient registration survey was required as a condition of approval of Actemra. The survey is still ongoing, with approximately 4,900 registered as of mid-February 2009. The adverse reactions seen to date are similar to those observed in pre-approval clinical trials, with no new safety signals.

Overseas, Actemra was approved in the European Union in January 2009 (European product name: RoActemra), and preparations are ongoing to submit materials to the U.S. Food and Drug Administration (FDA) to obtain U.S. approval. (For further information on global development of Actemra, please refer to page 23).

<sup>\*2</sup> Autoimmune diseases: diseases that occur when the immune system, which normally protects the body from foreign substances, attacks the body's own tissues.

## (2) Avastin

Avastin, a humanized anti-VEGF (vascular endothelial growth factor) monoclonal antibody, is the first in a new class of medications called angiogenesis inhibitors. Angiogenesis is the process by which a tumor stimulates the formation of a network of new blood vessels that supplies oxygen and nutrients needed for its growth. Avastin inhibits VEGF, a protein believed to be one of the most potent sources of angiogenesis. In addition to suppressing tumor growth by inhibiting tumor angiogenesis and blocking off its supply of oxygen and nutrients, Avastin is also thought to induce normalization of the dysfunctional blood vessels frequently

present in tumors. This allows chemotherapy drugs, which are given in combination with Avastin, to be delivered more efficiently to the tumor, thus also increasing treatment effectiveness.

In April 2007, Avastin was approved for the treatment of advanced and recurrent colorectal cancer in Japan, and its use in first-line treatment has been steadily increasing. Chugai is committed to patient safety and to promoting the appropriate use of this breakthrough medicine. Overseas clinical trials and experience have shown that treatment with Avastin may be associated with adverse reactions, including gastrointestinal perforation and thrombotic embolism such as pulmonary infarction. After the product was launched, we took steps to ensure that Avastin is administered only by medical institutions with sufficient experience in cancer chemotherapy and qualifications to provide emergency treatment should adverse reactions occur. These institutions also had to be willing to participate in the post-marketing all-patient registration survey that was a condition of marketing approval, as with Actemra. The final results of the survey, announced in October 2008, showed that the safety profile of Avastin in Japanese patients was comparable to that seen in large observational studies carried out overseas.

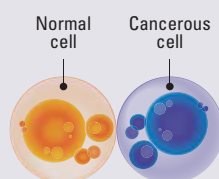
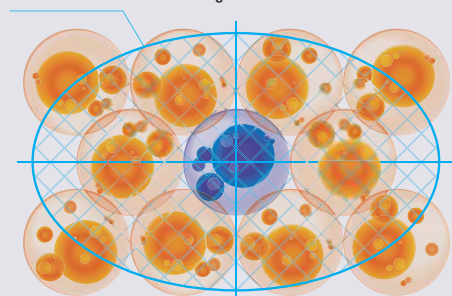
## (3) Tarceva

Tarceva is a small-molecule agent that blocks the formation and growth of cancer cells by targeting a protein called human epidermal growth factor receptor (EGFR). The product has been used overseas as a treatment for non-small cell lung cancer (NSCLC), which accounts for approximately 80% of lung cancers, as well as pancreatic cancer. As both types of cancer are considered to be intractable, Tarceva has been making valuable contribution to patients as an innovative treatment option.

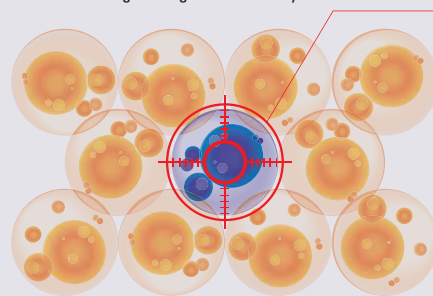
In December 2007, Chugai launched Tarceva in Japan as a treatment for second-line or later treatment of NSCLC. While

**Conventional Therapy vs. Molecular Targeted Therapy — difference in action**

Conventional anti-cancer agents attack both normal and cancerous cells



Targeted agents work only on cancerous cells



providing value to these patients, interstitial lung disease (ILD) has been reported as a serious adverse reaction associated with Tarceva therapy, as with other EGFR inhibitors. Accordingly, in line with its policy of giving top priority to patient safety, Chugai has implemented strict post-marketing safety measures<sup>\*3</sup>. In 2009, Chugai will continue the safety program and also plans to file an application for the additional indication of pancreatic cancer.

<sup>\*3</sup> Our post-marketing safety measures include: (1) confirmation that facilities are capable of providing effective emergency treatment for ILD; (2) confirmation that the treating physician is a member of an association of lung cancer specialists and possesses sufficient experience in lung cancer chemotherapy; (3) the implementation of an all-patient survey required as a condition of approval; and (4) the use of the “Tarceva tablet treatment confirmation form,” which states that a physician meeting the above requirements has informed each patient of the potential risks and benefits of treatment.

#### (4) Herceptin

Herceptin is designed to target and block the effects of human epidermal growth factor receptor type 2 (HER2), a protein which is highly expressed on the surface of certain types of cancer cells. Abnormally high levels of HER2 are detected in approximately one in four breast cancer patients. This type of breast cancer, called HER2-positive breast cancer, is particularly aggressive, fast-growing and likely to relapse, while HER2 negative breast cancer progresses relatively slowly. Herceptin is indicated for the treatment of HER2-positive breast cancer, both as post-operative adjuvant therapy to prevent disease recurrence and for treatment of cancer that has metastasized or relapsed. Testing for HER2-overexpression makes it possible to personalize healthcare for these patients by ensuring optimal treatment selection. Herceptin is used only in patients whose tumors overexpress HER2.

In Japan, Herceptin was launched in June 2001 for HER2-positive metastatic breast cancer. In February 2008, Herceptin was approved for the additional indication of post-operative adjuvant therapy of HER2-positive breast cancer, based on a

two-year interim analysis of a large global study (HERA). The results showed that, with two years of median follow-up, the risk of recurrence and death decreased by 36% and 34%, respectively, in the group treated with Herceptin for one year as compared with the group not receiving the product.

## Outlook

Molecular targeted therapy is expected to remain an important source of innovation in many therapeutic areas. Chugai is investing significant resources in the development of promising new compounds with the potential to become future growth drivers and in additional indications that can help to maximize the value of existing products.

In 2008, we initiated clinical development of three new anticancer compounds originating from Chugai research. GC33 is a humanized monoclonal antibody that targets glypican 3, a protein which is specifically expressed in liver cancer. CKI27 and CIF, both of which are targeted small-molecule agents, have already been licensed to Roche, and are currently under co-development overseas.

In addition, we are conducting clinical trials with four compounds licensed from Roche. In the oncology field, we have R7159 (GA101), an anti-CD20 monoclonal antibody; R1507, an anti-insulin-like growth factor 1 receptor (IGF-1R) monoclonal antibody; and R1273, an antibody that inhibits the pairing (dimerization) of HER2 with other HER receptors. In the bone and joint diseases field, we are developing R1594, an anti-CD20 humanized monoclonal antibody.

Consistent with our mission to create innovative medical products for the benefit of the medical community and human health around the world, Chugai will continue its dynamic research and development activities.



# Review of Operations

At a Glance	page	14
Oncology Field	page	16
Renal Diseases Field	page	20
Bone and Joint Diseases Field	page	22
Others Field	page	26

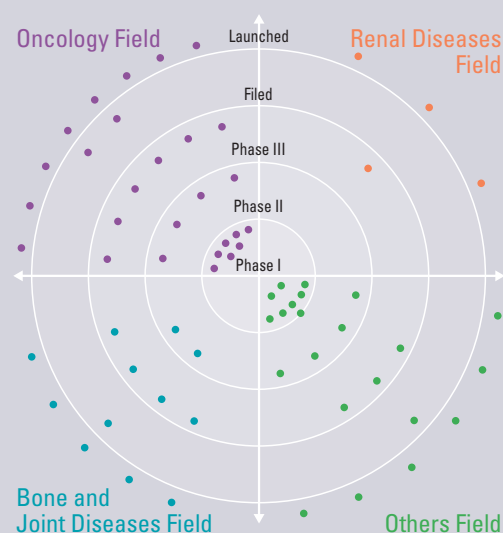
\* For basic information on marketed products and compounds in development, please refer to pages 74-81.



**On  
the Right Track >>**

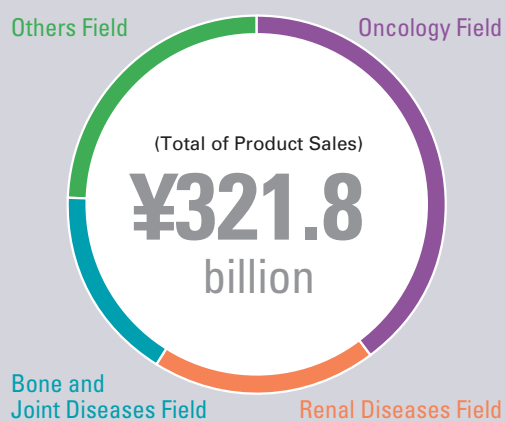
# At a Glance

## Our Pipeline



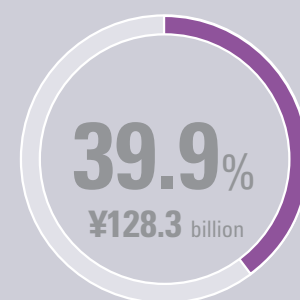
Chugai has the richest oncology pipeline in Japan with eight mainstay products and 19 development projects.

## Sales by Strategic Field



## Percentage to Total Product Sales

### Oncology Field p.16



### Renal Diseases Field p.20



### Bone and Joint Diseases Field p.22



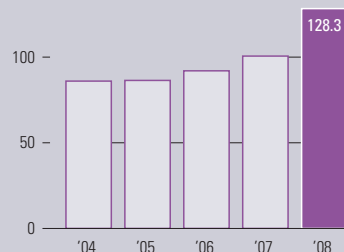
### Others Field p.26



In addition to our three strategic fields of oncology, renal diseases, and bone and joint diseases, we are conducting vigorous R&D activities in diabetes area and infectious diseases area. Our mission is to contribute to medical care by developing innovative drugs that can fulfill patient's unmet medical needs.

**Sales**

(Billions of yen)  
150 –

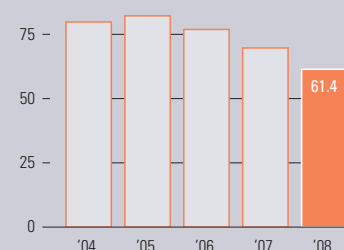
**Major Products**

- Neutrogin (lenograstim)
- Herceptin (trastuzumab)
- Rituxan (rituximab)
- Avastin (bevacizumab)
- Kytril (granisetron)
- Xeloda (capecitabine)
- Tarceva (erlotinib)
- Femara (letrozole)

**Activities (January 2008 - February 4, 2009)**

- Avastin:** Joined global PIII trial for aBC (May 2008), Filed for NSCLC (November 2008)
- Herceptin:** Approval for aBC (February 2008), Approval for modification of manufacturing process for drug substance (to use porcine derived material) (September 2008)
- Xeloda:** Filed for CRC (both monotherapy and combination therapy with Avastin and oxaliplatin) (February 2008)
- Epogin:** Started PIII trial for CIA (June 2008)
- CIF, CK127:** Started overseas PI trial for solid tumors (April and November 2008)
- GC33:** Started overseas PI trial for HCC (October 2008)
- R1507:** Started PI trial for solid tumors (January 2009)
- R7159:** Started PI trial for NHL (October 2008)

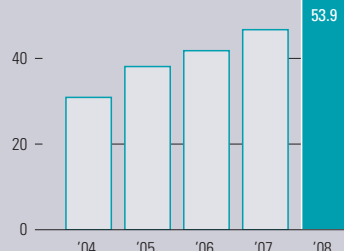
(Billions of yen)  
100 –



- Epogin (epoetin beta)
- Oxarol (maxacalcitol)
- Renagel (sevelamer HCl)

- Epogin:** Filed for modification of manufacturing process for drug substance (serum-free version) (March 2008)

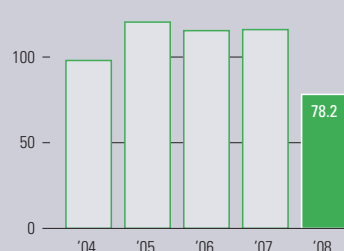
(Billions of yen)  
60 –



- Evista (raloxifene HCl)
- Alfarol (alfacalcidol)
- Suvenyl (sodium hyaluronate)
- Actemra (tocilizumab)

- Actemra:** Approval in Japan for RA, sJIA and pJIA (April 2008), Started PI/II trial for subcutaneous injection (January 2009)  
Signed a toll manufacturing and supply agreement with Genentech in the US (July 2008)  
Received a CRL (Complete Response Letter) from the FDA (U.S. Food and Drug Administration) for US application (September 2008) Details of the FDA's requirement announced (December 2008)
- ED-71:** Approval in Europe for RA (January 2009)  
Signed a co-development and co-marketing agreement with Taisho (May 2008), Confirmed positive results from PIII trial (December 2008)

(Billions of yen)  
150 –



- Sigmart (nicorandil)
- Pegasys (peginterferon alfa-2a)
- Tamiflu (oseltamivir)
- Rocephin (ceftriaxone)
- Copegus (ribavirin)
- Cellcept (mycophenolate mofetil)

- R1678:** Joined global PII trial for schizophrenia (May 2008)
- NA808:** Started PI trial for chronic hepatitis C (October 2008)
- R1579:** Started PI trial for T2D (June 2008)

aBC: adjuvant therapy for breast cancer, BC: breast cancer, CIA: chemotherapy-induced anemia, CRC: colorectal cancer, HCC: hepatocellular carcinoma, NHL: Non-Hodgkin's lymphoma, NSCLC: non-small cell lung cancer, pJIA: polyarticular-course juvenile idiopathic arthritis, RA: rheumatoid arthritis, sJIA: systemic-onset juvenile idiopathic arthritis, T2D: type II diabetes



# Oncology Field




## Sales of Major Products

Product Name (generic name)	Sales (Billions of yen)	Brief Overview	Launch Year in Japan
<b>Neutrogin</b> (lenograstim)	06: 36.1 07: 39.2 08: 37.9	Agent for neutropenia associated with chemotherapy	1991.12
<b>Herceptin</b> (trastuzumab)	06: 14.5 07: 16.1 08: 23.7	Anti-HER2 humanized monoclonal antibody	2001.6 (150mg) 2004.8 (60mg)
<b>Rituxan</b> (rituximab)	06: 18.0 07: 18.6 08: 20.5	Anti-CD20 monoclonal antibody	2001.9
<b>Avastin</b> (bevacizumab)	06: 3.5 07: 20.1 08: 20.1	Anti-vascular endothelial growth factor (VEGF) humanized monoclonal antibody	2007.6
<b>Kytril</b> (granisetron)	06: 12.9 07: 13.6 08: 10.9	5-HT3 receptor antagonist, antiemetic agent	1992.5 2006.6 (bag)
<b>Xeloda</b> (capecitabine)	06: 2.5 07: 2.7 08: 4.8	Antitumor agent	2003.6
<b>Tarceva</b> (erlotinib)	06: 0.2 07: 4.5 08: 4.5	Epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor	2007.12
<b>Femara</b> (letrozole)	06: 0.3 07: 1.0 08: 1.7	Aromatase inhibitor/agent for breast cancer in postmenopausal women	2006.5

## Development Pipeline (As of February 4, 2009)

Development Code (Product Name)	Status Phase I	Phase II	Phase III	Filed	Approved	Indication	Generic Name	Dosage form	Origin (Collaborator)
R340 (Xeloda)				● '08/2		Colorectal cancer	capecitabine	Oral	Roche
			●			Gastric cancer			
R435 (Avastin)				● '08/11		Non-small cell lung cancer	bevacizumab	Injection	Roche / Genentech
			● (Global study)			Colon cancer (adjuvant)			
			● (Global study)			Gastric cancer			
			● (Global study)			Breast cancer (adjuvant)			
		●				Breast cancer			
R597 (Herceptin)			● (Global study)			Gastric cancer	trastuzumab	Injection	Roche / Genentech
EPOCH (Epogin)			●			Chemotherapy-induced anemia	epoetin beta	Injection	In-house
R1415 (Tarceva)		●				Pancreatic cancer	erlotinib	Oral	Roche / Genentech / OSI
R744		●				Chemotherapy-induced anemia	—	Injection	Roche
MRA (Actemra)		● (Overseas)				Multiple myeloma	tocilizumab	Injection	In-house (Roche)
R1273	●					Breast cancer, etc.	pertuzumab	Injection	Roche / Genentech
TP300	● (Overseas)					Colorectal cancer, etc.	—	Injection	In-house
CIF(R7167)	● (Overseas)					Solid tumors	—	Oral	In-house (Roche)
GC33	● (Overseas)					Liver cancer	—	Injection	In-house
R7159 (GA101)	●					Non-Hodgkin's lymphoma	—	Injection	Roche / GlycArt
CKI27 (R7304)	● (Overseas)					Solid tumors	—	Oral	In-house (Roche)
R1507	●					Solid tumors	—	Injection	Roche

● Designates change in status since 2008.



Since 2007, when the Basic Act for Anti-Cancer Measures came into force, there have been rapid advances in cancer care in Japan. Chugai is contributing to ongoing improvements in cancer treatment with a growing portfolio of products that includes groundbreaking targeted anticancer agents, as well as established supportive-care treatments\*<sup>1</sup>. Our goal is to offer the most comprehensive range of products in Japan. In addition, by providing medical professionals with detailed information on the latest developments in cancer care and treatment methods, Chugai aims to strengthen its position as Japan's leading company in the oncology field.

\*<sup>1</sup> Medicines to relieve the adverse reactions of certain cancer treatments.

## Review of 2008 Results

In 2008, combined sales of Chugai's oncology products rose ¥27.7 billion to ¥128.3 billion. The main contributors to this strong growth were the launches of the targeted anti-tumor medicines Avastin and Tarceva in 2007, as well as approvals in 2007 and 2008 of additional indications for Xeloda and Herceptin. Significant advances in cancer treatment in recent years have made the provision of information to the medical community all the more important. In March 2008, therefore, we increased the number of Oncology District Offices to 54, with some 500 oncology medical representatives, to strengthen communication with oncologists and other healthcare professionals. Placing top priority on the safety measures and appropriate use of our products, Chugai continued its broad-based contribution to the ongoing development of cancer care in Japan by promoting awareness of new products with the potential to become standard treatments and emphasizing the clinical benefits of existing products. As a result, in 2008 Chugai achieved its goal of becoming the leading company in this segment, increasing its share of the domestic oncology market to 15.8%\*<sup>2</sup>.

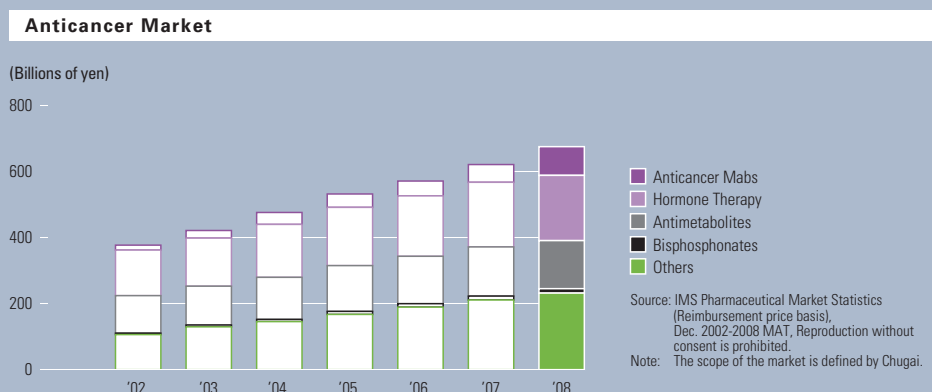
\*<sup>2</sup> IMS Pharmaceutical Market Statistics (Reimbursement price basis), Dec. 2008 MAT. The scope of the market is defined by Chugai.

## New Products and Additional Indications

The two targeted therapies launched in 2007 are achieving steady market penetration. Sales of Avastin, a humanized anti-vascular endothelial growth factor (VEGF) monoclonal antibody, increased 474.3% in its second year on the market to ¥20.1 billion. Avastin has now been adopted by almost all targeted hospitals, and its increased use as a first-line treatment

reflects the steady progress made in positioning the product in the market. In October 2008, the final results of the all-patient registration survey undertaken as part of post-marketing safety measures were announced at the annual meeting of the Japan Society of Clinical Oncology. The findings showed that the product's safety profile in Japanese patients is similar to that seen in major observational studies overseas. Sales of Tarceva, a human epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor launched in December 2007, totaled ¥4.5 billion. Despite the strong market position established by a competing EGFR inhibitor, there has been a steady increase in the usage of Tarceva at earlier stages compared with the competitor product. The post-marketing all-patient registration survey is ongoing. We will continue to promote appropriate use of Tarceva, giving patient safety top priority.

Sales of Xeloda and Herceptin grew significantly in the year under review, helped by approvals for additional indications. In February 2008, marketing approval for Herceptin, an anti-HER2 humanized monoclonal antibody, was expanded to include the post-operative adjuvant treatment of HER2-positive breast cancer. Sales of Herceptin increased 47.2% to ¥23.7 billion for the year. Sales targets were met thanks to steadily increasing recognition of the medicine's benefits in the adjuvant setting. Adoption was initially slower than expected due to the relatively large number of options for the treatment of post-operative breast cancer. In December 2007, Xeloda, a fluoropyrimidine anti-tumor agent, was additionally approved for the post-operative adjuvant therapy of colon cancer. Sales of Xeloda increased 77.8% to ¥4.8 billion in 2008, achieving steady growth in a competitive environment.



### Existing Products

Sales of anti-cancer agents in Chugai's existing product portfolio continue to grow, although maintaining the market presence of supportive care products has become a challenge.

Sales of Rixutan, an anti-CD20 monoclonal antibody, increased 10.2% to ¥20.5 billion, owing to an increase in the number of doses per treatment course. Sales of Femara, an aromatase inhibitor for breast cancer in postmenopausal women, grew 70.0% to ¥1.7 billion. Growth was driven by increased prescriptions of Femara as initial adjuvant therapy following positive data from overseas clinical trials that were released in December 2008. In addition to showing that Femara can prevent the recurrence of breast cancer, they also suggest that the medicine may improve survival when given for a period of five years following surgery. We expect this information to have a continuing positive effect on the domestic market. Sales of Neutrogin (overseas name: Granocyte), a human granulocyte-colony stimulating factor (G-CSF), fell 3.3% to ¥37.9 billion. In Japan, we increased the product's market share by 2.0 percentage points to 42.6%<sup>\*3</sup>, thanks to synergies with our rich oncology franchise and the ongoing provision of information to healthcare professionals. However, domestic sales declined 4.8% to ¥12.0 billion, due to continued contraction of the G-CSF market caused by an increase in outpatient cancer treatment. Overseas, while the sales volume remained steady, exchange rate effects resulted in a 2.6% decline in yen terms to ¥25.9 billion. Sales of Kytril, a 5-HT<sub>3</sub> receptor antagonist antiemetic agent, decreased 19.9% to ¥10.9 billion, as generic erosion outweighed growth in the antiemetic agent market that is being driven by advances in

cancer treatment and enhanced awareness of quality-of-life issues for cancer patients. Several generic competitors have been launched since 2007.

<sup>\*3</sup> IMS Pharmaceutical Market Statistics (Reimbursement price basis), Dec. 2008 MAT.

### 2009 Strategy and Outlook

In 2009, Chugai will focus on positioning newly available products and additional indications as potential new treatment standards, while continuously giving precedence to safety measures and appropriate use. As Japan's leading provider of anticancer and supportive care medicines, we will continue contributing to cancer care by promoting the benefits of our established and new brands.

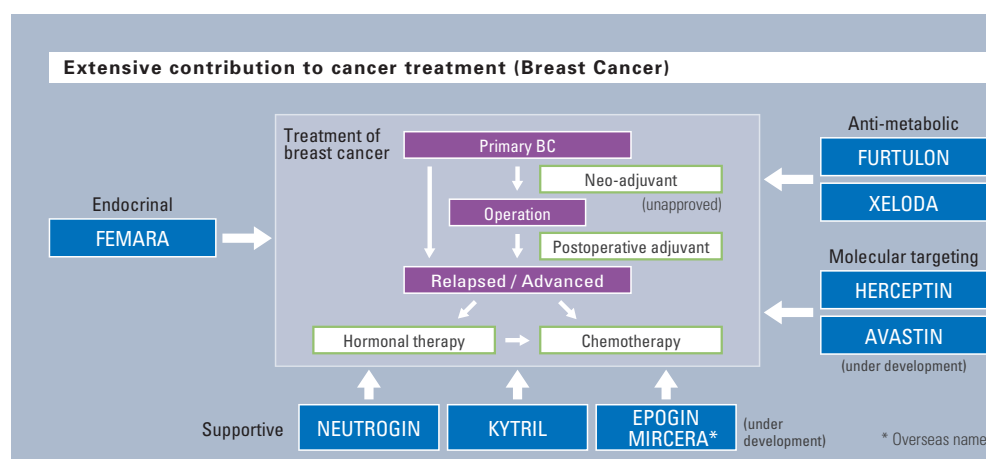
Overseas, biosimilar<sup>\*4</sup> versions of several G-CSF agents were approved in 2008 and are expected to enter the market soon. However, as few clinical data on biosimilars are available, slow adoption by physicians is expected. Chugai will continue working to maintain the market position of Neutrogin by highlighting its solid, established record of safety and efficacy.

<sup>\*4</sup> New versions of biopharmaceutical products after patent expiry. Unlike synthetic agents, they are not chemically identical to the original drug.

### Products Under Development

Chugai is committed to enhancing its contribution to make optimized treatment available for cancer patients. We will continue to expand our product portfolio, focusing on targeted





therapies by developing innovative new compounds and seeking approval for additional indications for existing products.

In 2008, we filed an application to expand the marketing approval of Xeloda to include additional indications for advanced and recurrent colorectal cancer, both as a monotherapy and as a combination therapy with Avastin and oxaliplatin. Compared with conventional treatments, combination therapy with Avastin plus oxaliplatin and oral Xeloda offers both efficacy and cost-effectiveness benefits and reduces the time patients must spend in the hospital. Chugai's application for the additional indication of non-small cell lung cancer for Avastin, also filed in 2008, was designated for priority review in February 2009.

In 2009, Chugai plans to file applications for additional indications for Avastin (breast cancer), Tarceva (pancreatic cancer), and Epogin (chemotherapy-induced anemia). A first filing for Epogin in chemotherapy-induced anemia, in 2005, was withdrawn after the regulatory authorities requested additional clinical trials. With patients and doctors expressing substantial demand for anemia treatment in this setting, we will continue working closely with the authorities to obtain approval.

Other projects designed to enable applications for additional indications are also proceeding as planned. In 2008, we started development of Avastin as a post-operative adjuvant therapy for triple-negative breast cancer<sup>\*5</sup>, in addition to ongoing projects with the medicine in gastric cancer and as post-operative adjuvant therapy for colon cancer. Chugai is participating in global phase III studies with Roche for all three indications. Japan is the lead country in development of Avastin for gastric

cancer, with the highest patient enrollment in the study. Chugai is also collaborating in global phase III studies investigating Xeloda and Herceptin in gastric cancer, with filings for both projects expected by 2010.

In addition to line extensions for existing products, Chugai is also developing new compounds. In 2008, we started development of three compounds from Chugai research, GC33, CKI27, and CIF, and of another two licensed compounds. Phase I clinical trials have already begun overseas with the Chugai compounds: GC33 is a humanized antibody generated by Chugai that targets glypican-3 proteins, which are specifically expressed in liver cancer. Resulting from joint research by Chugai and Tokyo University and clinical proteomics work by PharmaLogicals Research<sup>\*6</sup>, GC33 represents the culmination of many years of basic research by Chugai scientists. CKI27 and CIF, both small-molecule compounds which target specific parts of cancer pathways, have already been licensed to Roche, and Chugai is working with Roche on their development overseas. Also in 2008, Chugai commenced phase I clinical trials with two compounds licensed from Roche: R7159 (GA101), an anti-CD20 antibody, is being developed for non-Hodgkin's lymphoma; R1507, an antibody targeting the insulin-like growth factor-1 receptor (IGF-1R), is being investigated in solid tumor indications.

<sup>\*5</sup> Triple-negative breast cancer is a subtype of breast cancer that does not express the genes for estrogen receptor (ER), progesterone receptor (PR), or HER2.

<sup>\*6</sup> Joint venture established in Singapore by Chugai Pharmaceutical, Mitsui & Co., and the Central Institute for Experimental Animals.

# Renal Diseases Field



## Sales of Major Products

Product Name (generic name)	Sales (Billions of yen)	Brief Overview	Launch Year in Japan
<b>Epogin</b> (epoetin beta)	06 63.4 07 54.8 08 44.9	Agent for anemia associated with end-stage renal disease	1990.4 (ampoule) 2001.5 (syringe)
<b>Oxarol</b> (maxacalcitol)	06 7.6 07 8.7 08 10.0	Agent for secondary hyperparathyroidism in hemodialysis patients	2000.9
<b>Renagel</b> (sevelamer HCl)	06 5.1 07 5.7 08 5.8	Agent for hyperphosphatemia	2003.6

## Development Pipeline (As of February 4, 2009)

Development Code (Product Name)	Status Phase I	Phase II	Phase III	Filed	Approved	Indication	Generic Name	Dosage form	Origin (Collaborator)
R744			●			Renal anemia	—	Injection	Roche

## Review of 2008 Results

In 2008, sales in Chugai's renal diseases field decreased ¥8.3 billion year-on-year to ¥61.4 billion. The major factor in this decline was the continued intense competition faced by Epogin, an agent for the treatment of renal anemia and Chugai's most important profit driver for many years. The market for Epogin and other erythropoietin-stimulating agents (ESAs) has changed radically due to continued cutbacks in medical expenditure (see page 77) since the introduction of a flat-sum reimbursement system for ESAs in April 2006. In addition, a competitor product was launched in July 2007. In response, Chugai has reinforced its customer relations and marketing activities, and is also highlighting the product's outstanding record of safety and efficacy over many years. As a result, we defended Epogin's leading position in the market with a market share of 58.5% (a year-on-year decline of 3.4 percentage points)\*<sup>1</sup> and sales totaled ¥44.9 billion in 2008, in

line with the company's forecast.

Sales increases were recorded in 2008 for Oxarol, a vitamin D analogue for the treatment of secondary hyperparathyroidism, and Renagel, for hyperphosphatemia (both conditions are complications seen in long-term hemodialysis patients) despite NHI drug price reductions. Sales of both medicines were helped by wider recognition in clinical practice of their effectiveness. Treatment guidelines issued by the Japanese Society of Dialysis Therapy advise that vitamin D supplementation and the treatment of hyperphosphatemia can help to increase life expectancy.

\*<sup>1</sup> IMS Pharmaceutical Market Statistics (Reimbursement price basis), Dec. 2008 MAT.

## 2009 Strategy and Outlook

We expect intense competition in our key renal anemia market to continue in 2009. Our sales activities will focus on pre-



Protecting sales of our mainstay product Epogin, Japan's leading treatment for renal anemia in dialysis patients, is a top priority. At the same time, as awareness of the importance of treating anemia in pre-dialysis patients grows, Chugai is committed to expanding sales in this setting, too. In 2009, Chugai plans to file a marketing application for R744 (overseas product name: Mircera), an innovative therapeutic agent for renal anemia. We expect that this novel product and our established reputation will allow us to reinforce our leadership position in this segment.

dialysis patients, in addition to dialysis patients, highlighting the proven safety and efficacy of Epogin.

In recent years, there has been a significant increase in pre-dialysis chronic renal failure in patients with underlying diabetes. The rise in the number of patients with pre-dialysis renal failure has led to calls for earlier treatment of the associated complications. Renal anemia is one of the most frequent complications, and it has a significant impact on patients' quality of life. Until now, treatment of anemia has focused primarily on dialysis patients, with less emphasis given to pre-dialysis patients. However, guidelines issued by the Japanese Society for Dialysis Therapy in September 2008 are helping to raise awareness of the importance of treatment at the pre-dialysis stage. The guidelines state that early diagnosis and treatment of renal anemia can prevent cardiovascular complications and may also delay the need for dialysis.

Chugai will focus on making optimal anemia treatment available in the pre-dialysis renal disease setting, while maintaining its strong presence in the dialysis market.

## Products Under Development

In March 2008, Chugai filed for approval of a serum-free<sup>\*2</sup> manufacturing process for Epogin. Our priority is to ensure patient safety by bringing our product to market as soon as possible.

In 2009, we plan to file for approval of R744 (overseas product name: Mircera), the first continuous erythropoietin receptor activator, for the treatment of renal anemia. R744 is an innovative anti-anemia medication that enables stable and sustained control of hemoglobin with once-monthly maintenance administration. The decrease in treatment frequency is

especially beneficial for pre-dialysis renal anemia patients, as it simplifies their care. R744 is expected to play a significant role in this market, where the number of patients is growing and the importance of anemia treatment is increasingly recognized.

By bringing this next-generation product to market, Chugai aims to strengthen its position — established with Epogin — as Japan's leading supplier of medicines to treat renal anemia.

<sup>\*2</sup> The term "serum-free" indicates that no materials of animal origin, such as bovine serum, are used to manufacture the active ingredient. The resulting product is thus free of risks, such as bovine spongiform encephalopathy (BSE), which may be associated with animal-derived components.

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### 《Response to GCP Violation in Clinical Trial》

In 2008, Chugai confirmed that in the clinical development of R744, which was being tested for the treatment of renal anemia, a former employee of the Company violated GCP (Good Clinical Practice: the implementation criteria for clinical trials as determined by Japan's Health, Labour and Welfare Ministry) by improperly preparing a portion of the required documents. We reported these facts to the medical institutions involved immediately, and confirmed that the persons participating in the clinical trials have not experienced any damage to their health. In response to this incident the company set up an independent investigative committee. After examining and analyzing the cause, Chugai made extensive efforts to prevent a recurrence by strengthening its system to conduct and manage clinical trials, including upgrading education of persons in charge of clinical development, tightening operational controls, and conducting internal training programs.

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# Bone and Joint Diseases Field



## Sales of Major Products

Product Name (generic name)	Sales (Billions of yen)	Brief Overview	Launch Year in Japan
<b>Evista</b> (raloxifene HCl)	06: 13.4 07: 16.0 08: 16.5	Agent for postmenopausal osteoporosis	2004.5
<b>Alfarol</b> (alfacalcidol)	06: 14.6 07: 14.4 08: 13.7	Agent for osteoporosis	1981.9 (capsule, solution) 1994.7 (powder)
<b>Suvenyl</b> (sodium hyaluronate)	06: 9.1 07: 11.0 08: 12.0	Agent for knee pain associated with rheumatoid arthritis, osteoarthritis	2000.8
<b>Actemra</b> (tocilizumab)	06: 0.4 07: 0.5 08: 7.2	Humanized anti IL-6 receptor monoclonal antibody	2005.6 (Castleman's Disease) 2008.4 (Rheumatoid Arthritis)

## Development Pipeline (As of February 4, 2009)

Development Code (Product Name)	Status Phase I	Phase II	Phase III	Filed	Approved	Indication	Generic Name	Dosage form	Origin (Collaborator)
MRA (Actemra)					09/1 (Overseas / EU)	Rheumatoid arthritis	tocilizumab	Injection	In-house (Roche)
				07/11 (Overseas / US)					
			(Overseas)			Systemic-onset juvenile idiopathic arthritis (sJIA)			
		(I / II)				Rheumatoid arthritis (new formulation: subcutaneous injection)			
R1594			(Global study)			Rheumatoid arthritis	ocrelizumab	Injection	Roche / Genentech
ED-71						Osteoporosis	eldecalcitol	Oral	In-house (Taisho Pharmaceutical)
R484			(II / III)			Osteoporosis	ibandronate sodium hydrate	Injection	Roche (Taisho Pharmaceutical)
								Oral	


● Designates change in status since 2008.

## Review of 2008 Results

In 2008, Chugai's sales in the bone and joint disease field increased ¥7.7 billion to ¥53.9 billion. The main revenue driver was steady growth in domestic sales of Actemra, a humanized anti-human IL-6 receptor monoclonal antibody, following its approval in April 2008 for the indications rheumatoid arthritis, polyarticular-course juvenile idiopathic arthritis, and systemic-onset juvenile idiopathic arthritis.

## Rheumatoid Arthritis

With a view to making Actemra one of Chugai's growth drivers, we selected medical representatives (MRs) to specialize in Actemra out of our pool of around 900 general MRs. In their promotional activities, the Actemra Core MRs are giving top priority to patient safety and appropriate use of the product. As the first antibody-based pharmaceutical created in Japan, Actemra already enjoyed a high level of recognition in the medical community before its launch. After the product's market launch, promotional activities



In the field of bone and joint diseases, Chugai focuses on treatments for osteoporosis, osteoarthritis, and rheumatoid arthritis. Following the approval of additional indications for Actemra, the first antibody-based drug to originate in Japan, Chugai entered the domestic rheumatoid arthritis market in 2008, with plans to expand into the global market in 2009. In the osteoporosis field, we aim to better serve medical needs by offering a broad range of therapeutic options, maximizing the value of existing products, and expediting projects in development.

focused on its novel mechanism of action, other key elements of the product profile, and the positive outcomes of clinical trials in Japan and overseas. As a result, physicians quickly became aware of the advantages of Actemra and are already using it as a first-line biologic treatment in many patients. Up to mid-February 2009, approximately 4,900 rheumatoid arthritis patients have been enrolled in an ongoing post-marketing all-patient registration survey. Such surveys form part of the safety programs required in Japan following marketing approval for new biologic medicines. Initial uptake of Actemra in the new indications has been very encouraging, with domestic sales of ¥3.4 billion recorded in 2008. In addition, exports of Actemra to Roche in preparation for launches in overseas markets in 2009 accounted for sales of ¥3.8 billion in the year under review. In July, Chugai signed a toll manufacturing and supply agreement with U.S.-based Genentech, Inc., under which Genentech will manufacture Actemra bulk drug substance at its Vacaville, California, plant. The transfer of technology and other preparations for production of bulk drug substance by Genentech are currently underway. The objectives of this strategy are to establish a supply system that can accommodate future increases in demand, and to minimize potential risk associated with concentrating manufacturing at a single location in Japan.

### Osteoporosis and Osteoarthritis

The osteoporosis market in Japan continued to expand in 2008, reaching around ¥170.0 billion<sup>\*1</sup>, or an increase of 6.6% from the previous year. In an expanding but increasingly competitive environment, slower sales growth of the selective estrogen receptor modulator Evista (a year-on-year increase of 3.1%) compared with 2007 reflected market-share gains by competitor products (weekly bisphosphonate agents). We are focusing pro-

motional activities for Evista on explaining the product's most notable feature, the SERM concept<sup>\*2</sup>. In addition, we are conducting a nationwide treatment adherence program, which emphasizes the importance of patients' continuing to take their osteoporosis medication. Generic erosion resulted in a decrease of 4.9% in sales of the activated vitamin D<sub>3</sub> derivative Alfarol. Chugai's marketing activities continue to highlight the reliability of Alfarol as a foundation treatment for osteoporosis.

The market for Suvenyl, a treatment for osteoarthritis, has grown significantly as a result of increased awareness of the disease. In 2008, sales of Suvenyl rose 9.1% year-on-year, well ahead of the market, thanks to recognition among physicians of the product's clear benefits for patients as a high molecular weight agent.

<sup>\*1</sup> IMS Pharmaceutical Market Statistics (Reimbursement price basis), Dec. 2008 MAT. The scope of the market is defined by Chugai.

<sup>\*2</sup> Use the estrogen-like effect only for blocking the reduction of bone mass, while reducing the occurrence of gynecological side effects which are associated with existing estrogen drugs.

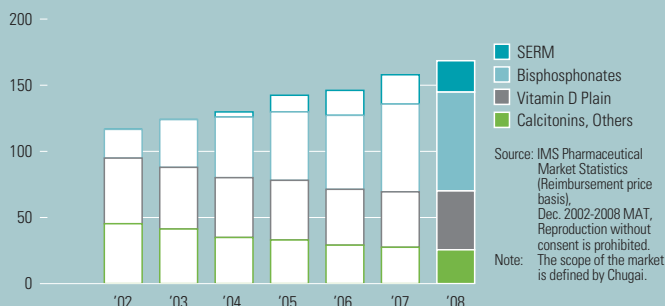
### 2009 Strategy and Outlook

The year ahead will be an important one for Chugai as the global rollout of Actemra (European product name: RoActemra) continues.

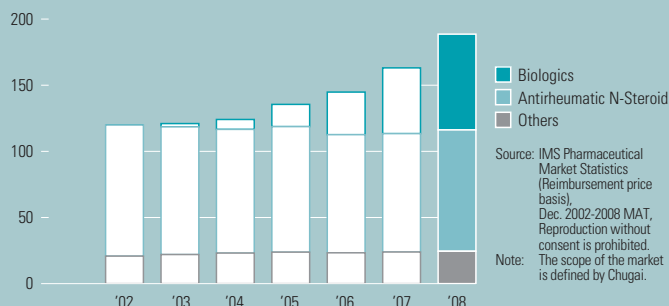
In January 2009, RoActemra was approved in the European Union for the treatment of moderate to severe rheumatoid arthritis in adult patients who have either responded inadequately to, or who were intolerant to, previous therapy with one or more disease modifying anti-rheumatic drugs (DMARDs) or tumor necrosis factor (TNF) antagonists. In these patients, RoActemra can be given as monotherapy in cases of intolerance to methotrexate (MTX) or where continued treatment with MTX is inappropriate. The European

**Osteoporosis Market**

(Billions of yen)

**Rheumatoid Arthritis Market**

(Billions of yen)



rollout of the product started in late January in Germany. Roche and Chugai will copromote RoActemra in the United Kingdom, France, and Germany, where Chugai already has its own sales forces. Chugai has strengthened its European organization in preparation for full rollout in these countries, with marketing activities coordinated by a team drawn from both companies. In addition to sales from exports of bulk drug product, Chugai will receive royalties from Roche from sales of RoActemra and will also share in the profits in countries where it copromotes the product with Roche.

In July 2008, the Arthritis Advisory Committee of the U.S. Food and Drug Administration (FDA) voted ten to one in favor of approving Actemra for the treatment of adult rheumatoid arthritis. In September, Roche received a Complete Response Letter (CRL) requesting additional materials. Then in December 2008, the FDA called for further details, asking that Roche provide additional non-clinical study data and a Risk Evaluation and Mitigation Strategy (REMS) plan<sup>\*3</sup>. Chugai and Roche are currently preparing these materials and expect to submit them to the FDA in the third quarter of 2009<sup>\*4</sup>.

In Japan, Chugai aims to establish Actemra as a first-line biologic for RA. Actemra is the first pharmaceutical product with demonstrated efficacy in inhibiting joint damage associated with rheumatoid arthritis in a Japanese patient population. We are committed to ensuring patient safety and appropriate use of Actemra while promoting its innovative mechanism of action and proven clinical benefits.

Intense competition is expected to continue in the osteoporosis market in 2009. Chugai's activities will be directed towards maintaining our position as a leading company in this field.

<sup>\*4</sup> Additional materials related to production facilities requested in the CRL have already been submitted, and the FDA has indicated that Chugai's Utsunomiya Plant is acceptable for the manufacture of Actemra.

## Products Under Development

As outlined above, 2008 saw significant progress in the overseas development of Actemra. In December, we commenced domestic phase I/II clinical trials investigating R1594, a humanized anti-CD20 monoclonal antibody, in rheumatoid arthritis. Chugai is also participating in a phase III global study with this drug. Our aim in developing R1594, the first agent in its class to be tested in this indication in Japan, is to further expand the treatment options available for patients with rheumatoid arthritis, following Actemra.

In December 2008, positive results were reported from a phase III clinical trial with ED-71, an activated vitamin D<sub>3</sub> derivative being developed for the treatment of osteoporosis. In the trial, a direct comparison of ED-71 versus alfacalcidol, ED-71 was significantly more effective in preventing vertebral fractures and had a similar safety profile. Chugai signed a co-development and co-marketing agreement for the product with Taisho Pharmaceutical Co., Ltd. (Taisho) in May 2008. We expect ED-71 to make a significant contribution as a next-generation product to the treatment of osteoporosis. A marketing application is planned for 2009.

Phase III clinical trials of an injectable form of R484 (overseas product name: Bonviva/Boniva), a bisphosphonate which is also being co-developed with Taisho for osteoporosis, are proceeding smoothly. R484 is an important addition to Chugai's portfolio as the company works to fulfill its aim of offering a range of options for the treatment of osteoporosis.

<sup>\*3</sup> Comprehensive post-marketing safety program based on the U.S. Food and Drug Administration Amendments Act (FDAAA).



## Interview: Launch of RoActemra



General Manager  
Chugai Pharma Marketing Ltd., Germany Branch  
**Dr. Markus Harwart**

Actemra (European product name: RoActemra) received marketing approval in Europe in January 2009. Following approval, the product's European rollout started swiftly with its launch in Germany at the end of the month. In the UK, France and Germany, Chugai Pharma Marketing (CPM) co-promotes RoActemra with Roche. We spoke to Dr. Markus Harwart, the General Manager of CPM Germany (CPMG), about the marketing campaign and cooperation with Roche.

**Q** Could you briefly describe the German RA market?

**A** In Germany, we currently have approximately 800,000 RA patients. About 32,000 new diagnoses are made each year. A newly diagnosed patient usually starts treatment with methotrexate (MTX) or another standard disease-modifying antirheumatic drug (DMARD), either alone or in combination. If this treatment is inadequate or symptoms recur, the patient is moved to a combination of DMARDs and a tumor necrosis factor inhibitor (anti-TNF). Currently, about half the patients on anti-TNFs have to change their treatment within 2 years due to loss of efficacy or the onset of side effects. At this point, most German rheumatologists begin sequential use, or cycling, of anti-TNFs, switching the patient to a second one, then a third, and so on, until they run out of options and start looking for different approaches. In general, the rate of biologic treatment in Germany is low (7–8%),

compared with other EU countries, where it can be as high as 30% or more.

**Q** What are you doing to ensure a smooth launch of RoActemra in Germany?

**A** The main thing is to generate awareness amongst doctors about the truly unique and innovative mechanism of action of RoActemra and its advantages for patients. That is the emphasis of our launch campaign. Our goal is to position RoActemra as the treatment of choice for patients with an inadequate response to anti-TNF therapy, as opposed to TNF cycling, and as the first choice for patients with an inadequate response to DMARD treatment. To achieve these goals, we have to make sure that RoActemra is not perceived as “just another biologic” —with marginally different clinical benefit compared with anti-TNFs— but a completely new alternative that offers distinctive value to patients. In addition, the safety profile of RoActemra has been well characterized in the most comprehensive phase III clinical trial program for any biologic in RA.

**Q** Will there be any post marketing programs to ensure patient safety, like the one in Japan?

**A** Yes. Patient safety is our first priority, and we will do everything necessary to ensure that doctors and patients are well informed and understand how to use RoActemra appropriately. In Germany, there is a regulatory requirement to observe the safety of medications under real-life conditions. For this purpose, we are organizing a Phase IIIb non-interventional study (CLINPROVE), in which we plan to include 2,300 patients at 360 centers for recruitment and follow up periods of 2 years each. Unlike the post-marketing survey currently being conducted in Japan, however, the aim of this survey is not to register and monitor all patients using RoActemra.

**Q** How is collaboration between CPM and Roche developing in Germany?

**A** The collaboration has been mutually beneficial. It has been a positive experience working with Roche Germany. We are equal partners, even though Roche is much bigger than CPMG. We started in February

2007 by setting up a joint steering committee, which decides on national activities and resolves any problems. We maintain close contact through weekly meetings and regular telephone/video conferences. In January 2009, we had a kick-off meeting for our sales-force, which was also attended by colleagues from Chugai headquarters. At the end of the event, they paid me the best compliment by saying that they saw no difference between the Chugai and Roche teams, as the interaction and communication between the two seemed to be based on mutual understanding. We intend to make sure that this continues, so that we maximize the value of RoActemra in this competitive market.

**Q** Could you give us your views on the significance of RoActemra for CPM? Germany is the first EU country to launch the product. What role will Germany play?

**A** The success of RoActemra is vital for CPMG and for CPM. The feedback from doctors who participated in the global phase III trials for RoActemra is very encouraging. What's even more important are the extremely positive reactions we've seen from patients as well — more than 90% of all patients in the studies said they wanted to continue treatment with RoActemra at the end of the trials. The co-promotion of such a product gives us a very promising outlook.

Germany is usually the one of the first countries to launch products after EU approval, so we see ourselves as a trendsetter for the success of RoActemra, and I am sure we'll do our part. We have built a really good team and a solid basis for the launch. Again, collaboration with Roche is going very well, and this is also very important. As a large organization, Roche can achieve things that Chugai might find challenging. But on the other hand, we are small and flexible, and able to make decisions quickly. The combination works very well. I would be very happy if I could report at the end of 2009 that the CPM team has played a key role in the global rollout of RoActemra thanks to our strong partnership with the local Roche affiliates.

# Others Field



## Sales of Major Products

Product Name (generic name)	Sales (Billions of yen)	Brief Overview	Launch Year in Japan
<b>Sigmart</b> (nicorandil)	06 18.0 07 17.9 08 17.0	Anti-anginal agent	1984.4 (capsule) 1993.7 (injection)
<b>Pegasys</b> (peginterferon alfa-2a)	06 5.8 07 6.3 08 9.7	Chronic hepatitis C	2003.12
<b>Tamiflu*</b> (oseltamivir)	06 38.0 (24.4) 07 38.7 (28.5) 08 8.4 (1.3)	Anti-influenza agent	2001.2 (capsule) 2002.7 (dry syrup)
<b>Rocephin</b> (ceftriaxone)	06 5.5 07 5.7 08 5.9	Cephem-type antibiotic	1986.8 (0.5g and 1g IV injection) 2003.6 (1g IV drip bag)
<b>Copegus</b> (ribavirin)	06 2.0 07 08 4.2	Anti-viral agent in combination with Pegasys	2007.3 (2.5mg)
<b>Cellcept</b> (mycophenolate mofetil)	06 3.0 07 3.5 08 4.0	Immunosuppressant	1999.11

\* ( ) Sales for government stockpile.

## Development Pipeline (As of February 4, 2009)

Development Code (Product Name)	Status Phase I	Phase II	Phase III	Filed	Approved	Indication	Generic Name	Dosage form	Origin (Collaborator)
<b>R964</b> (Copegus)			● (II / III)			Compensated liver cirrhosis caused by hepatitis C virus	ribavirin	Oral	Roche
<b>R442</b> (Pegasys)			● (II / III)			Compensated liver cirrhosis caused by hepatitis C virus	peginterferon alfa-2a	Injection	Roche
			● (II / III)			Chronic hepatitis B			
<b>MRA</b> (Actemra)		●				Crohn's disease	tocilizumab	Injection	In-house
	● (Overseas)					Castleman's disease			In-house (Roche)
	● (Overseas)					Systemic lupus erythematosus (SLE)			
<b>NA808</b>	●					Chronic hepatitis C	—	Injection	In-house
	● (Overseas)								
<b>EPOCH</b> (Epogin)				● '02/03		Predeposits of autologous blood transfusion	epoetin beta	Injection	In-house
<b>R1678</b>		● (Global study)				Schizophrenia	—	Oral	Roche
<b>GM-611</b>	● (Completed / Japan)					Diabetic gastroparesis	mitemcinal	Oral	In-house
		● (Overseas)							
		● (Overseas)				Irritable bowel syndrome (IBS)			
<b>R1583</b> (ITM-077)	●					Type II diabetes	tasoglutide	Injection	Roche / Ipsen (Teijin)
<b>CSG452</b> (R7201)	●					Type II diabetes	—	Oral	In-house (Roche)
<b>R1579</b>	●					Type II diabetes	—	Oral	Roche

● Designates change in status since 2008.



Chronic hepatitis C is an area of focus for Chugai, with a product portfolio that includes the pegylated interferon Pegasys and Copegus, an antiviral agent used in combination with Pegasys. We are continuing to expand our presence in this market and maximize the value of both medicines by highlighting the importance of early detection and appropriate therapy, as well as the efficacy of interferon treatment. In addition, Chugai is preparing to enter the field of diabetes, a disease affecting an increasing number of patients worldwide. Our goal is to expand into the global market, both through our own in-house drug discovery activities and collaboration with Roche.

## Review of 2008 Results

In 2008, our sales in the Others Field, which covers all products other than those for oncology, renal diseases, and bone and joint diseases, totaled ¥78.2 billion, a year-on-year decline of ¥37.8 billion. The decrease was primarily due to completion of deliveries of the anti-influenza agent Tamiflu for the Japanese government's initial stockpile, established in readiness for a potential influenza pandemic. In contrast to 2007, when Chugai recorded ¥28.5 billion in sales for government stockpiling, pandemic sales of Tamiflu decreased significantly in 2008, to ¥1.3 billion. Seasonal sales of Tamiflu in the year under review amounted to ¥7.1 billion.

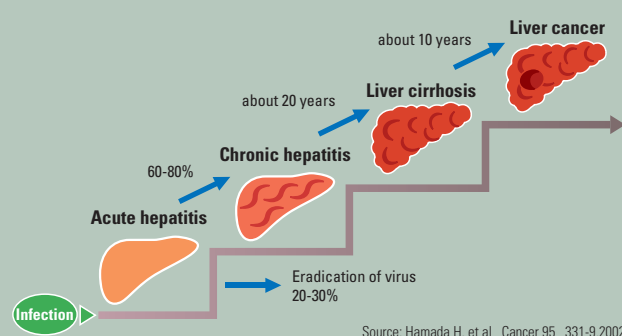
In the chronic hepatitis C segment, the pegylated interferon-based medicine Pegasys and Copegus, an anti-viral agent used in combination with Pegasys, posted solid sales growth in 2008, despite contraction of the peg-interferon market in the early part of the year. Sales of Pegasys totaled ¥9.7 billion, an increase of 50.4%, while the product's market share grew by 7.9 percentage points to 22.0%\*. Sales were driven primarily by approval of Copegus, launched in March 2007, for use in combination with Pegasys. There are an estimated two million people with hepatitis C virus (HCV) infection in Japan. Early detection and appropriate treatment is crucial, as chronic hepatitis C can eventually progress to liver cirrhosis and then liver cancer. In 2008, the Japanese government launched a seven-year program to combat HCV. Part of this initiative is a joint subsidy program introduced by the national and local governments in April 2008 for HCV infected patients receiving interferon treatment. To support education and treatment efforts, Chugai has created a special website, "C-Gata-Kanen (hepatitis C) ZERO" (<http://www.kanzenzero.jp/>), which provides the public with accurate information about the disease and explains the importance of HCV testing and treatment at an early stage. The name of the website was chosen to express Chugai's hope that chronic hep-

atitis C will eventually be eradicated. We aim to contribute to HCV treatment by highlighting the efficacy of combined interferon and antiviral therapy, as provided by Pegasys plus Copegus.

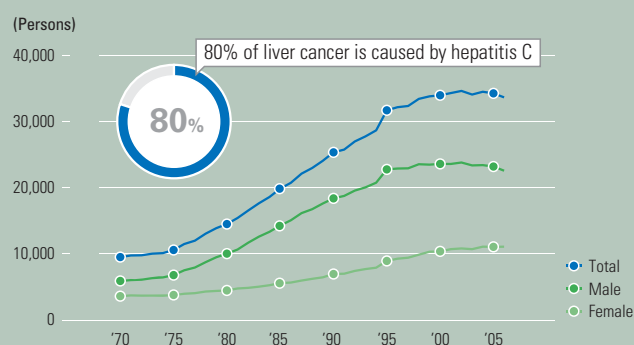
Sales of Sigmart, an anti-anginal agent, declined slightly due to increased competition from generic drugs and the effects of NHI drug price revisions. These factors offset for the positive impact of approval in October 2007 of a label extension for the injectable formulation of Sigmart for acute heart failure.

\* IMS Pharmaceutical Market Statistics (Reimbursement price basis), Dec. 2008 MAT.

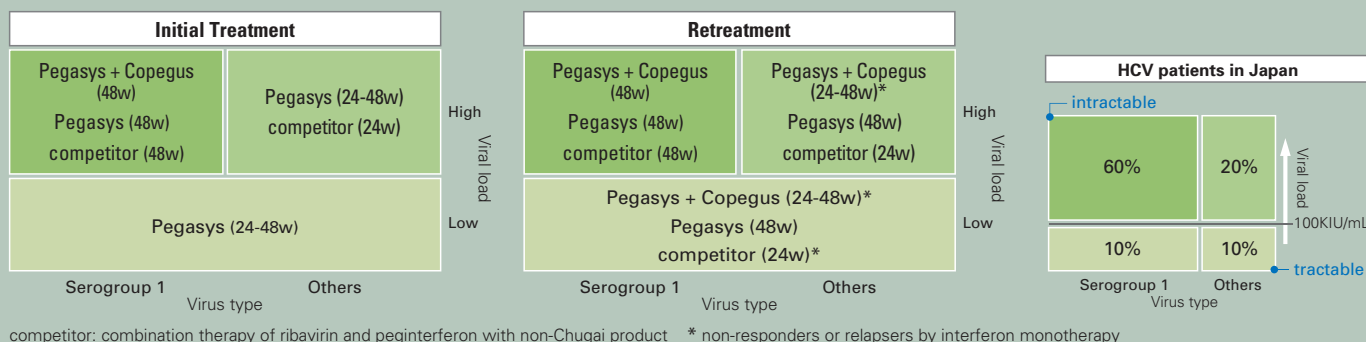
### Progression of Chronic Hepatitis C to Cancer



### Number of Deaths from Liver Cancer



Source: 1. Modified from Vital Statistics of Japan, Center for Cancer Control and Information Services, National Cancer Center, Japan.  
2. Liver Cancer White Paper (H11), The Japan Society of Hepatology.

**Copegus — Expanded Options in HCV Treatment**

## 2009 Strategy and Outlook

In 2009, Chugai plans to intensify its efforts in the field of HCV treatment. Combating HCV infection is becoming a national project, with expansion of the treatment subsidy program mentioned above under discussion. Chugai will continue to provide information to the public and promote the benefits of combination treatment with Pegasys and Copegus, the leading products for hepatitis treatment overseas.

Also in 2009, we expect renewed pandemic sales of Tamiflu, following the government's decision to enlarge its stockpile of the product. In order to enhance national pandemic preparedness, the government has announced plans to stockpile enough anti-influenza drugs over the next few years to cover 45% of the Japanese population, doubling the initial plan.

## Products under Development

In the field of chronic hepatitis C, we started domestic phase I trials with NA808, a small-molecule compound from Chugai research, in October 2008. In addition, Chugai will develop nitazoxanide, a novel compound licensed from U.S.-based Romark Laboratories. The development decision was based on positive results from phase II overseas clinical trials which showed increased efficacy when nitazoxanide is combined with Pegasys and Copegus. The data suggest that this promising candidate may represent a significant advance in the treatment of HCV.

Chugai currently has three compounds in clinical development for diabetes, a new priority field. CSG452, a small-molecule compound developed by Chugai for the treatment of type 2 diabetes, is currently in phase I both in Japan and overseas. Under a licensing agreement signed in 2007, Chugai and

Roche are codeveloping the drug for overseas markets. R1583 is the first once-weekly human glucagon-like peptide 1 (GLP-1) hormone analog. It has shown high efficacy in the phase II clinical trials conducted overseas in 2008, and is currently in phase I clinical trials in Japan. Chugai began domestic phase I testing of R1579, a dipeptidyl peptidase-IV inhibitor (DPP-IV), in 2008. Following a decision by Roche to out-license the product, Chugai is currently considering future plans for development in Japan.

R1678 is a glycine transporter type 1 inhibitor (GlyT1) developed by Roche for the treatment of schizophrenia. Chugai is currently participating in a phase II global study of the compound with Roche.

### 《Restrictions on the Use of Tamiflu in Teenage Patients》

Restrictions on the use of Tamiflu in teenage patients with seasonal influenza have been in force since March 2007. The measure was introduced as a safety precaution following several reports of abnormal behavior in influenza patients who had taken Tamiflu. The interim report of an epidemiological survey published by a working group of the Ministry of Health, Labour and Welfare in July 2008 suggested that there are no findings to date that point to a causal association between Tamiflu and the abnormal behavior of patients taking the drug. The Ministry has concluded that further investigations are needed and has decided to continue restrictions on the use of Tamiflu in teenage patients.



# Organization and Human Resources

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# Learning Organisation >>

# Research

The goal of research at Chugai is to create innovative drug candidates, focusing on oncology and four other strategic fields. We will continue working to develop compounds that contribute to medical care around the world, taking full advantage of our strategic alliance with Roche.

## Basic Policy

Chugai's Research Division undertakes drug-discovery, focusing particularly on five strategic areas: oncology, renal diseases, bone and joint diseases, diabetes, and infectious diseases. Our research organization aims not just to achieve quantitative productivity —the discovery of a certain number of new compounds in a given period— but also to enhance our ability to create innovative medicines over time. To do this, we must increasingly be aware of —and where possible anticipate— developments that may affect the healthcare environment in which new medicines will be used. Accordingly, it is important to consider how existing therapies, the pharmaceutical market environment, the economics of healthcare, and other factors may evolve in the next 10 years. Our overriding goal is to continue developing innovative new therapies that address unmet medical needs and increase patient well-being and quality of life.

## Where We Are

Since the creation of the strategic alliance with Roche in 2002, Chugai's development pipeline has expanded dramatically. We have responded by enhancing our development organization and focusing resources throughout the company to manage a higher number of clinical development projects.

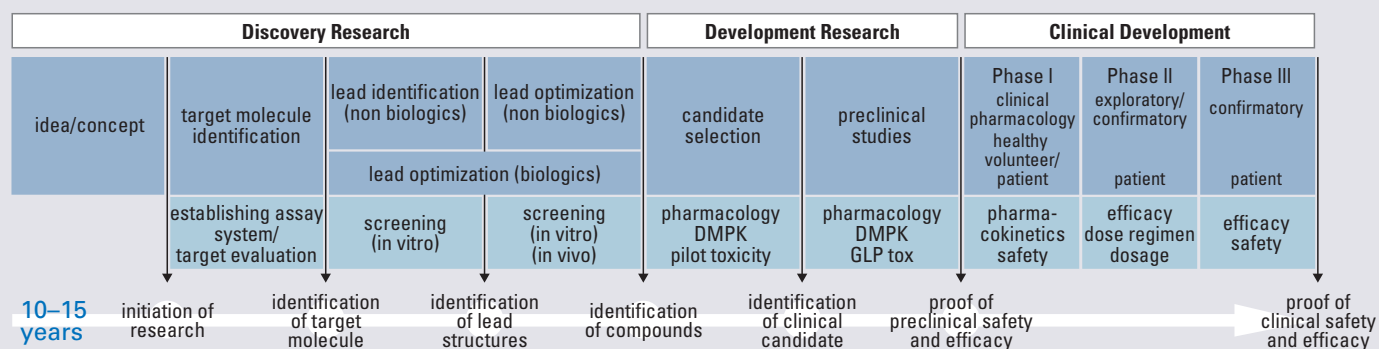
The partnership with Roche has also strengthened Chugai's research organization. Firstly, we were able to realize considerable synergies by merging the research departments of Chugai Pharmaceutical and the former Nippon Roche, each of which offered world-class capabilities in different areas. Chugai's research laboratories pioneered the development of Epogin and

Neutrogin in the 1980s. Since then, the company has established what is widely regarded as Japan's leading biopharmaceutical research organization. Actemra, the first antibody-based medicine to originate from Japan, is the result of cooperation between Chugai and Osaka University. The strength of Nippon Roche, by contrast, lay in the development of small-molecule, chemically synthesized drugs. One of its products, the oral antitumor medication Xeloda, has become a standard treatment for cancer worldwide. The merging of these two organizations thus gave the "New Chugai" highly developed drug-discovery capabilities for both biopharmaceuticals and small molecule-based medicines. Since 2006, six compounds from Chugai research have entered clinical development. Three of these have been licensed to Roche for joint development overseas.

Secondly, the alliance with Roche has enabled Chugai to improve its research infrastructure. Chugai and Roche now share research tools, including a compound library and chemical evaluation database, as well as information on the development of therapeutic antibodies. In addition, access to world-class drug-discovery platforms has enhanced Chugai's research productivity, especially in the areas of lead discovery and optimization.

Finally, competition within the Roche Group is helping us improve our research capabilities further. Chugai's drug candidates are evaluated together with those from other Group members at an early stage. This early competition at a global level has enabled us to bring projects with greater potential to clinical development than was the previously case. This in turn has led to a clear improvement in the quality of our development pipeline.

### Process and Milestones of Drug Development



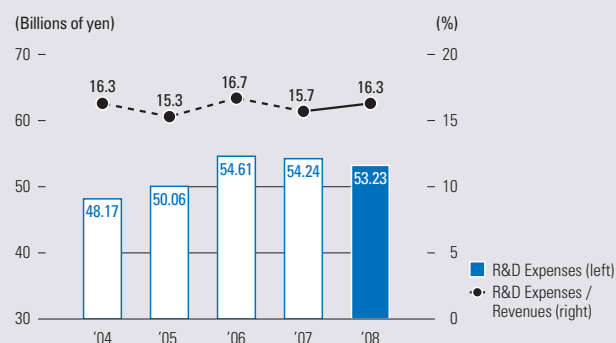
## Outlook and Strategy

Chugai's mission is to dedicate itself to adding exceptional value through the creation of innovative medical products and services for the benefit of the medical community and human health around the world. We are committed to pursuing this goal by strengthening and developing our own research capability and through the advantages we have as a member of the Roche Group.

To maintain our drug-discovery capabilities and create new drug candidates, we need access to the latest technologies. In 2008, we signed a joint research agreement with Chiome Bioscience Inc. to further strengthen our biopharmaceutical research. Collaboration with leading external research organizations also plays a vital role in the development of innovative medicines. Chugai therefore places great importance on alliances with academic and other research organizations in Japan and overseas. GC33, a humanized monoclonal antibody from Chugai laboratories that entered clinical development as an anticancer candidate in 2008, is the product of one such collaboration. It is also testimony to the quality of ongoing basic research by Chugai scientists. GC33 is the result of long-standing collaboration with Tokyo University. Additional research was contributed by PharmaLogicals Research, a Singapore joint venture that is part of Chugai's own growing international research network.

Chugai will continue to develop innovative new drugs that contribute to medical care around the world by enhancing its own research and using the capabilities available to it as a member of the Roche Group.

### R&D Expenses



### Achievements since 2008

	Number of Project	Breakdown		
		New Molecular Entities	Additional Indications	Additional Dosage and Administration / Formulations
Approved	6	—	5	1
Filed	3	—	2	1
Entered Phase III	2	—	2	—
Entered Phase II	2	1	—	1
Started Phase I	7	7	—	—
Suspended Development	1	1	—	—



# Human Resources Strategy

Human resources are the most important factor for realizing our medium to long-term goal of “growth driven through innovative drugs” and establishing our position as a leader in the pharmaceutical industry. Based on this recognition, we promote a human resources strategy, which includes measures that best suite individual employees.

## Basic Policy

In our basic policy, Chugai places human resources (HR) as its core asset to generate growth. We believe that HR is the ultimate source of our competitive advantage, which is necessary in all business functions including R&D, production and marketing, to achieve our envisioned future growth. Guided by this basic policy, we have promoted our HR strategy by setting the qualities desired in our employees. We focus on providing each employee with optimized development programs that extract their best quality.

The ideal employee model, which is the core of our HR strategy, has recently added the new dimension of global competency: the ability to conduct business on an equal footing with other international companies. Not all Chugai employees are involved in global business. However, as the Company extends its reach toward globalization, it is increasingly important for all employees to adopt an international perspective in conducting business. In other words, without limiting their views to their current job description or region they are assigned, employees always need to ask themselves what sort of impact on the Company may rise as a result of their work.

This new initiative stems from our aim, held since the formation of the alliance with Roche in 2002, which is to transform ourselves into a company with a stronger international competitive edge. Looking back over the past several years, we have seen increased tasks conducted on a global basis in every aspect of our business activities, such as a growing number of joint global clinical studies with Roche and the overseas marketing of Actemra starting from 2009. In this environment, development of employees who are competent to work in the global environment continues to be an essential objective.

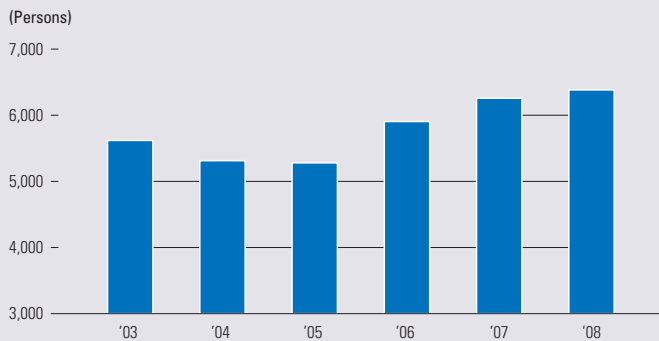
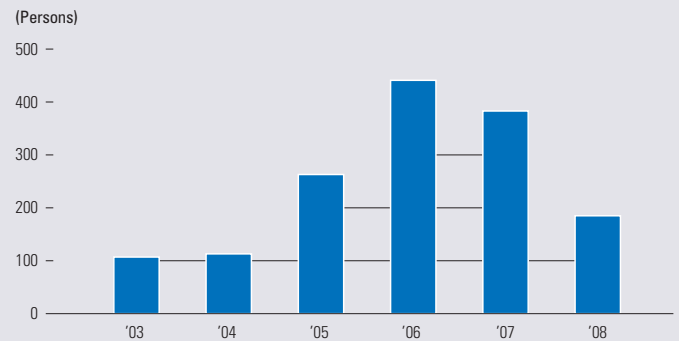
Chugai employees are also expected to obtain a high level of expertise as well as excellent communication skills. We believe that employees with highly professional expertise need to communicate with their colleagues, medical professionals, and many other stakeholders to create new value as well as to maximize the value of our products and development portfolio, and such communications should be maintained throughout our business activities including R&D, production and marketing.

## Where We Are

Since forming the strategic alliance with Roche, Chugai has increased the number of employees substantially to expand its business. Today, there are 6,383 employees\* in the Chugai Group, approximately 1,500 more than in March 2002 before the alliance. Following the merger of Nippon Roche and Chugai, there were some years when we took measures to reduce the number of employees to an optimized level. However, in the short period from 2005 to 2007, we recruited a large number of new graduates, primarily in the product development and sales division, reflecting our accelerated development plan for some major development projects in order to make them available for patients as soon as possible as very promising clinical trial results were obtained.

The demographic structure of employees also changed considerably as the number of employees increased. As a result of the large-scale recruitment of fresh graduates, the proportion of entry-level employees who have worked for less than three years now reaches 20% of the entire workforce. Subsequently, the enhancement of new employee skills has become another important agenda for our HR strategy in recent years in addi-



**Number of Employees (Consolidated)****Number of New Graduates Recruited (Consolidated)**

tion to our medium-to-long-term goal of developing desired HR qualities. To address this issue, we have introduced an on-the-job training (OJT) scheme where mid-career personnel coach new employees. The scheme is designed to prepare new employees to fulfill specialized work without supervision within three years by providing basic job trainings and programs to motivate them to further enhance their skills in view of their future career.

At the same time as providing trainings for new employees, we devoted companywide efforts to the filing and launch of major new products, which are expected to bring further transformation to the Company. Through the companywide business expansion, where employees are required to realize their full potential, junior employees were able to obtain extensive valuable experience at the beginning of their career, which resulted in a rapid development of their skill sets. Also, the OJT scheme had another benefit of raising the overall capabilities of middle and senior-career personnel, who assumed major roles in both the challenging business operations and the training of junior employees at the same time.

The accelerated development of these junior employees also reduced the turnover of those with less than three years of experience with the Company. Recently, many Japanese companies have faced the problem of high turnover among junior employees who lose motivation. We believe our lower attrition rate is the result of our successful strategy for HR development and increased offerings of highly motivating opportunities to junior employees.

\* As of December 31, 2008.

## Outlook and Strategy

Successive market launches of major products have allowed us to achieve the envisioned transformation of the Company, where we believe our HR strategy has played an important role. Going forward, we anticipate further expansion of our business in line with the steady advances in our development projects. In order to build HR that cope with the continuous expansion of our business, we will focus on the further development of the existing work-force rather than another large-scale recruitment of new employees.

Our quality-based HR approach consists of four agendas: (1) building up a strong cadre of future middle-managers who will manage the rapidly increased junior employees in the future, (2) deepening the expertise of seasoned employees, (3) providing career support for female employees who experience life events such as childbirth, and (4) utilizing senior employees.

We have taken a step to build up the cadre of middle-managers, which is the core theme in the aforementioned agendas. In 2008, we started a training program for our mid-career personnel in their early 30s to develop their management skills. This program intends to build leaders who can take actions in line with the Company's strategy on their own account, and team up with different business functions from a broadened point of view.

Taking measures for other agendas as well, we will continue pursuing our HR strategies which will serve as the foundation to bring about further innovative changes to the Company.

# Corporate Governance, Internal Control

Chugai views the enhancement of corporate governance as crucial to achieving sustained business growth.

Based on this recognition, we are working continuously to ensure management transparency and strengthen our internal control system.

## Corporate Governance

### Basic Policy

Chugai is committed to continuously increase corporate value and respond appropriately and fairly to the requests of shareholders and other stakeholders. To fulfill this commitment, we have positioned the enhancement of corporate governance as an important management task and are building a system that emphasizes prompt decision-making, clarification of executive responsibilities, and management transparency.

### Management Decision-Making, Execution and Oversight of Business Operations

#### Board of Directors

Seeking to expedite business operations and clarify executive responsibilities, we have kept separate the business execution function and the decision-making function for the most important management issues. The Board of Directors, which makes decisions on management issues of primary importance, consists of 14 members including seven external directors. Among the directors, one is an Executive Vice President invited from Roche, and four of the external directors are also from the Roche Group. In addition, the Board of Directors is responsible for oversight of the execution of business operations. It receives regular reports on decisions made by the Executive Committee, which consists of the president and key executive officers.

#### Executive Officer System

Chugai has introduced an executive officer system, where executive officers are entrusted by the Board of Directors with the authority to conduct business operations. The Executive Committee is the body for executive decision-making and

consists of 11 members including the president, key executive officers, and two full-time auditors.

#### Introduction of Outside Perspectives

With an aim to reflect diverse stakeholders' perspectives in business decisions, Chugai has taken measures to obtain external viewpoints, such as nominating external directors and establishing an advisory board made up of domestic and overseas specialists.

Four of the external directors from the Roche Group provide opinions from a global perspective and contribute to smooth communications between Chugai and Roche. Also, advice and oversight by the other external directors, based on their abundant experience and knowledge as medical specialists or managers, contribute to the management decision-making. Because the residences of the external directors are spread around the world, it is difficult in some cases to have the attendance of all external directors at the board meetings. In 2008, the attendance rate by external directors was as follows: 100% for the two directors in Japan; approximately 50% for one director in the U.S.; and an average of 30% for the four directors from the Roche Group in Europe. Outside of the board meetings, each external director also provides timely advice concerning Chugai's management and business.

Additionally, Chugai has established the International Advisory Council (IAC), an advisory board comprised of domestic and overseas specialists from various fields. Valuable advice is provided by IAC regarding how to cope with changes in global business environment and how to maintain management soundness in business development.

#### Auditing System

Chugai has a board of company auditors, and audits on man-

### Chugai's Investor Relations Website (<http://www.chugai-pharm.co.jp/english/ir/>)



agement and business execution are conducted independently from business operations by four corporate auditors, including two external auditors. To maintain the independence and the effectiveness of audits by corporate auditors, we have put in place a Corporate Auditors' Support Section. Full-time corporate auditors attend the Executive Committee meetings, providing real-time opinions on the execution of business affairs from the standpoint of appropriate corporate governance. The Audit Department, consisting of 10<sup>\*1</sup> members including certified internal auditors, was established as an internal auditing organization. The department audits operational conditions including the compliance status of various organizations within the Company.

Corporate auditors, the Audit Department, and the external accounting auditors work closely together to audit the Company's business activities. The Audit Department reports internal audit plans and results to corporate auditors for their review. Corporate auditors meet with the external accounting auditors six or seven times a year to exchange opinions on such matters as confirmation of audit plans and interim and year-end audit reports. Also, corporate auditors are required to be present when accounting audits are reviewed.

<sup>\*1</sup> As of December 31, 2008.

### Proactive IR Approach

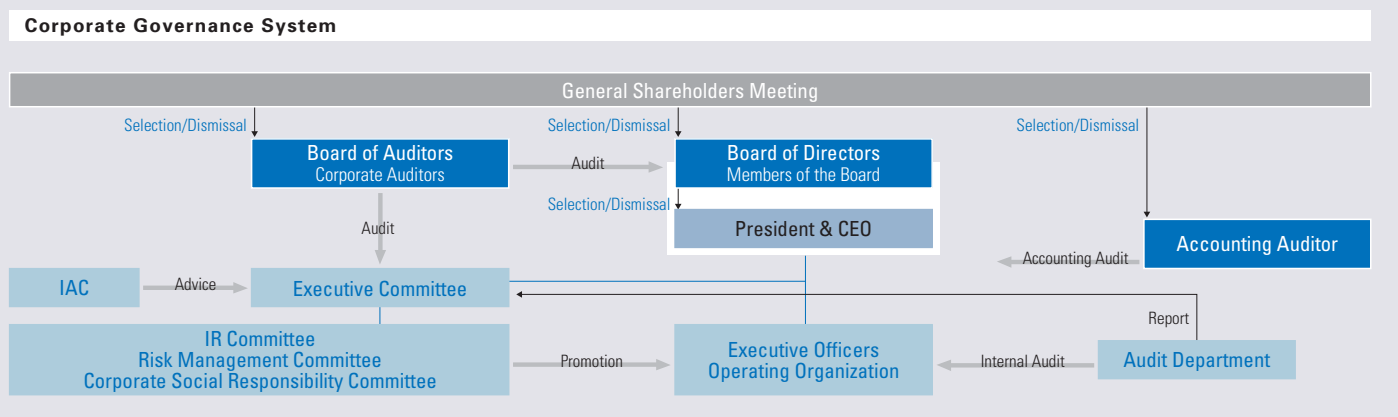
Chugai believes that ensuring management transparency is important to enhance corporate governance. Toward this end, we engage in proactive IR activities for the promotion of mutual understanding with shareholders and investors and the disclosure of information in a timely, appropriate and fair manner. Our IR Committee, chaired by the executive officer in charge of IR activities, formulates our information disclosure policies and supervises disclosure activities.

In IR activities, the Chugai corporate website is utilized as a medium for prompt and fair information disclosure, and press releases, presentations, annual reports, IR calendar, and other IR information are posted there. Our principle is to disclose information simultaneously in Japanese and English, reflecting our priority to impartially communicate with overseas investors just as with domestic investors. To reach a broader stakeholder audience, we also broadcast important IR events, such as financial results and product information meetings, via the website in video and audio formats. As for more direct approaches, we actively meet overseas investors through management roadshows, which toured Europe, the United States, and Asia in 2008. Deeper mutual understanding is obtained in these direct visits where we are able to explain our business status and at the same time receive questions and opinions for our management. In addition, to strengthen our communications with individual investors, we started holding information meetings at the local branches of securities companies in 2008.

### Increase in Roche's Shareholding

The basic agreement establishing the alliance between Chugai and its parent company, Roche, restricts the extent to which Roche may increase its shareholding in Chugai for a period of ten years following the date of the merger of Chugai and Nippon Roche (October 1, 2002)<sup>\*2</sup>. Based on the agreement, Roche made a tender offer for Chugai's shares and increased its shareholding from 50.1% to 59.9% in May 2008.

In addition to our capital ties, we maintain a wide-ranging partnership with Roche that includes joint development of many projects and co-promotion activities in Europe. We view Roche's increased shareholding as a positive measure to further strengthen the good partnership with us. While maintaining the harmonious relationship with Roche, we continue



to manage our business with autonomy and independence as a publicly listed company.

\*2 The restrictions do not apply to increases in Roche's shareholding that result from share repurchases by Chugai.

## Internal Control

### Basic Policy

Chugai believes that maintaining good internal control is crucial to fulfilling its social responsibilities and making appropriate and timely management decisions. With this belief, we strive to enhance our internal control activities across the entire organization. The Chugai Business Conduct Guidelines (Chugai BCG) are our standards for management decision-making and employee behavior. The Corporate Social Responsibility Committee, created under the Executive Committee, together with the Corporate Social Responsibility Department ensure that the guidelines are implemented throughout the Company. They also manage the BCG Hotline, an employee consultation desk established to offer employees advice and support on issues related to the Chugai BCG.

### Compliance

Based on a Board of Directors resolution on the internal control system, Chugai established the Risk Management & Compliance Department in charge of compliance of laws and other rules. The department conducts investigative surveys every quarter on compliance status to ensure companywide observance of laws and regulations. The results of such surveys are reported to the Executive Committee and examined to build and enhance an effective compliance system.

## Financial Reporting

In 2009, we launch the new internal control reporting system based on Japan's Financial Instruments and Exchange Act. The legislative framework is called "J-SOX", and since 2006 we have been united in a companywide effort to go through the necessary process for establishing the new system, such as identification of internal control risks and documentation and monitoring of internal control activities. In 2008, we confirmed that no major internal control problems exist through the initial trial evaluations conducted in close cooperation with our external auditor. Fully prepared for the new system, in 2009 we are confident to be certified in self evaluation and external audit. We will continue to manage the new system in a steady manner to keep up the evaluation.

## Risk Management

Chugai has established Risk Management Regulations to prevent the emergence of risks that could affect the Company's business activities as well as to take prompt and appropriate measures to address problems that may arise. We have also established a Risk Management Committee, created under the Executive Committee, and Division Risk Management Committees. The Risk Management Committee draws up a list of risks facing each division based on information provided by the Division Risk Management Committees, and specifies risks that may significantly affect the management as all company-wide risk issues. Subsequently, the Committee submits a progress report to the Executive Committee concerning preventive measures for such risks.



## Director's Comment



Director  
Christopher Murray

I have been serving as a director and Executive Vice President of Chugai since March 2008 with responsibility for Strategic Marketing of the company. This follows Chugai's intent to introduce global capabilities from the Roche Group into its marketing strategies, so that the company could take full advantage of opportunities presented by the current flow of new products from both Chugai and Roche research.

2008 was the year when we saw the benefit of the Chugai/Roche alliance. With the progress towards launch of Actemra in Europe and the USA, we see the first Chugai product moving toward globalisation.

In Japan, the Roche products for oncology

and virology diseases are increasingly important within the Chugai portfolio.

The challenge in Strategic Marketing is how to realise the full potential of the current and future portfolio. Ensuring continued above market growth rates and sustaining existing levels of profitability can only be achieved through the vigorous implementation of focused marketing plans for all products.

People are critical to the success of the marketing of the products. The continued development of our staff in sales and marketing is a pre-requisite for achievement of our ambitious sales plans and for Chugai to be a leading pharmaceutical company.

## Auditor's Comment

The business environment surrounding Japanese companies has changed radically in recent years and it is necessary for the companies to take prompt actions to address issues arising inside and outside Japan, especially in the following two areas. First, there is even greater pressure on companies than before to strengthen corporate governance and fulfill their social responsibilities in the aftermath of the frequent scandals on falsified product labeling. Second, there is the loss of trust in the accounting system, triggered by the Enron and WorldCom accounting scandals in the United States. Companies must take thorough measures to address these issues, in addition to responding to the dramatic changes in the economic environment.

Against this background, Chugai has two challenges in common with other Japanese companies. First, we must establish and manage an internal control system required by Japan's Financial Instruments and Exchange Act. Second, we need to keep up with sequential changes in accounting rules which come from the nationwide movement towards more credible and better integrated accounting system. Moreover, we have two special factors unique to our company. First, we must remember that we belong to the pharmaceutical industry, which is directly related to people's lives. Second is the large size of Roche's sharehold-

ing ratio of Chugai.

While the companies face the challenging environment, corporate auditors now must assume broader and deeper responsibilities than ever before. I understand this reflects the greater public expectations for corporate auditors. Fortunately, Chugai's four corporate auditors all have expertise and a wealth of business experience in different fields. Our corporate auditors are assigned independently from each other, and I am happy to say that we are also an ideal composition as a team.

I believe the legislative requirement for an internal control system, which is a priority issue, has now been satisfied in Chugai with the smooth launch of the system. I can say with confidence that the new system reinforced our risk management scheme and consequently our corporate governance system has been further enhanced.

As for the changes in accounting rules, I expect more new rules to emerge in the future with the "IFRS by 2011" in sight. This is an inter-sector commitment to bring Japanese accounting standards in line with international standards by 2011. It is said that the current gap between the two accounting standards still remains wide, and significant efforts from Japanese corporations will be required to close the gap in the short term. To overcome the challenge, we must make joint endeavors in



Corporate Auditor  
Yasunori Fujii

Chugai as well, and corporate auditors are ready to pursue the commitment with executives and accounting managers.

Roche increased its shareholding in Chugai in 2008 exercising their rights provided by the Basic Alliance Agreement. Generally speaking, an increase in shareholding implies confidence in the future potential of the company. However, it may also be interpreted as an increase in the potential risk where Chugai jeopardizes interests of minority shareholders. If that appears to be the case, I will be forthright in my recommendations to Chugai's top management from the standpoint of equal benefit of all shareholders.

# Corporate Social Responsibility (CSR)

Chugai is committed to making a contribution to society by creating innovative drugs. At the same time, we conduct active social action programs to meet the expectations of our diverse stakeholders, taking responsibility as a good corporate citizen.

## Benefiting Patients

**Development and Supply of Innovative Drugs:** Specialized in prescription drugs, we aim to create innovative products that contribute to worldwide medical care, with focus on the five therapeutic areas of oncology, renal diseases, bone and joint diseases, diabetes, and infectious diseases. In 2008, we launched Actemra, our in-house product, for patients suffering from rheumatoid arthritis (RA). Actemra is expected to play a major role as a new treatment option for this serious disease, especially for patients who responded inadequately to previous therapies.

**Providing Free Drugs for Intractable Disease:** Through the non-profit organization Shuhei Ogita Fund, Chugai has been supplying Picibanil free of charge to children around the world suffering from lymphangioma, a rare and intractable disease that significantly impedes their growth for 18 consecutive years.

**Disease Awareness Activities:** Since 2005, Chugai has participated in the Pink Ribbon Movement, which promotes the early detection, diagnosis, and treatment of breast cancer. Chronic hepatitis C, is a disease where early detection and treatment is important to prevent development into liver cancer. To promote that fact and eliminate the disease, we have been conducting a disease awareness campaign called “Kanen Zero” through the mass media including television and newspapers, as well as open seminars for the public.

## Benefiting Society

**Sponsoring University Lectures on Pharmaceutical Industry:** Chugai offers lectures on the pharmaceutical industry for students and the general public at Shizuoka Sangyo University. This is part of our social program at Fujieda City, where Fujieda Plant is located. Up until now we have held 12 lectures, with the aim of deepening people’s understanding of the industry and business activities of the Chugai Group.

## Benefiting Employees

**Supporting the Career Development that Satisfies Every Employee:** The Career Support Center was established to help employees develop careers to maximize their potential. In 2008, we started a new career development scheme in order to evaluate and reward employees with specific expertises more appropriately. Previously, we noted cases where such employees lost opportunities to fully utilize their skills as a result of their promotion to management positions. The new system opens up venues where employees can pursue careers as specialists in accordance with their aspirations and qualifications.

## Benefiting the Environment

**Global Warming Prevention Activities:** Chugai is working hard to achieve its goal of reducing group-wide carbon-dioxide emission to the 2003 level by the end of 2012. As a part of the measures, we plan to install photovoltaic power generation facilities with an output of 100 kilowatts or higher by 2012. In 2008, we installed a 30-kilowatt photovoltaic power generation facility in our Ukima Plant. In ongoing efforts to reduce carbon-dioxide emission, we have also purchased two million kilowatt-hours of Green Power Certificates.

### Chugai Pharmaceutical Co., Ltd. Corporate Social Responsibility Report '08



For further information concerning Chugai’s CSR activities, please refer to the Corporate Social Responsibility Report, CSR '08. The report presents Chugai’s corporate policies, including its Mission Statement and corporate governance policy, and provides stakeholders with an update on CSR initiatives and environmental protection activities undertaken in 2008.

\* The full report is on our website:  
<http://www.chugai-pharm.co.jp/english/corporate/csr>

# Board of Directors/ Corporate Auditors

(As of March 25, 2009)



Representative Director  
**Osamu Nagayama**



Representative Director  
**Motoo Ueno**



Director  
**Ryuzo Kodama**



Director  
**Dr. Tatsumi Yamazaki**



Director  
**Harutaka Fujita**



Director  
**Christopher Murray**



Director  
**Naotaka Nakamura**



Director  
**Dr. Etsuro Ogata**  
Director Emeritus of The Cancer  
Institute Hospital of JFCR



Director  
**Mitsuo Ohashi**  
Chairman of the Board,  
SHOWA DENKO K.K.



Director  
**Abraham E. Cohen**  
Chairman of Chugai Pharma USA



Director  
**Dr. Severin Schwan**  
Chief Executive Officer, Roche



Director  
**William M. Burns**  
CEO of the Pharmaceuticals  
Division, Roche



Director  
**Prof. Jonathan K.C.  
Knowles**  
Head of Global Research, Roche



Director  
**Dr. Erich Hunziker**  
Chief Financial Officer, Roche



Auditor  
**Shigetoshi Matsumoto**  
(full-time)



Auditor  
**Dr. Yasuhiro Tsuji**  
(full-time)



Auditor  
**Yasunori Fujii**  
Special Assigned Professor of  
Shizuoka Sangyo University



Auditor  
**Toshio Kobayashi**  
Partner, The Law Offices of  
Nagashima Ohno & Tsunematsu  
Visiting Professor, University of  
Tokyo Graduate Schools for Law  
and Politics



# Executive Officers

(As of March 25, 2009)



**Members of the Executive Committee:**

from left (front) Harutaka Fujita, Ryuzo Kodama, Osamu Nagayama, Motoo Ueno, Tatsumi Yamazaki, Christopher Murray  
(back) Shigetoshi Matsumoto, Michiharu Abe, Naotaka Nakamura, Mikio Arisawa, Yasuhiro Tsuji

## Osamu Nagayama

President CEO, COO

## Motoo Ueno

Deputy President Corporate Social Responsibility, Technology & Production

## Ryuzo Kodama

Executive Vice President CFO, System & Corporate Communications

## Dr. Tatsumi Yamazaki

Executive Vice President

## Harutaka Fujita

Executive Vice President  
Corporate Services and Human Resources

## Christopher Murray

Executive Vice President

## Naotaka Nakamura

Senior Vice President  
General Manager of Sales Div.

## Dr. Mikio Arisawa

Senior Vice President  
Head of Portfolio Management Unit, Research

## Tatsuro Kosaka

Senior Vice President Head of Lifecycle Management & Marketing Unit, Overseas Development

## Dr. Stefan M. Manth

Senior Vice President  
Head of Medical Strategy & Science Unit

## Michiharu Abe

Senior Vice President General Manager of Corporate Regulatory Compliance & Quality Assurance Div.

## Dr. Yutaka Tanaka

Senior Vice President General Manager of Clinical Development Div.

## Shunji Yokoyama

Vice President Deputy General Manager of Corporate Regulatory Compliance & Quality Assurance Div. and Head of Drug Safety Unit

## Dr. Hisafumi Okabe

Vice President General Manager of Research Div.

## Dr. Hidetoshi Ushio

Vice President General Manager of Drug Engineering Div.

## Akio Tanaka

Vice President Deputy General Manager of Sales Div. and Head of Oncology Unit

## Shinya Unno

Vice President Deputy General Manager of Sales Div.

## Yoshiro Saito

Vice President Deputy General Manager of Sales Div. and Department Manager of Wholesaler Business Planning Dept.

## Katsuyori Kunii

Vice President Department Manager of Transplantation Immunology Area Medical Business & Science Dept.

## Keiji Shima

Vice President Branch Manager of Tokyo Branch 1

## Tetsuo Minoura

Vice President Branch Manager of Osaka Branch

## Yoshio Itaya

Vice President General Manager of Corporate Planning Dept.

## Yoichi Yamanaka

Vice President General Manager of Corporate Social Responsibility Dept.

## Fumihiko Kamoshida

Vice President General Manager of Legal Dept.

## Masaharu Unno

Vice President General Manager of Secretarial Dept.

## Kotaro Miwa

Vice President General Manager of Human Resources Management Dept.

## Mitsuru Kikuchi

Vice President General Manager of External Affairs Dept.

## Dr. Tatsuo Miyauchi

Vice President Intellectual Property



# Financial Section

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**Laying the  
Ground >>**

# Financial Summary

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

	Millions of yen except per share amount and other statistics						Thousands of U.S. dollars
	Year ended December 31,					Nine months ended December 31,	Year ended December 31,
	2008	2007	2006	2005	2004	2003	2008
<b>Results for the year:</b>							
Revenues	¥326,938	¥344,808	¥326,109	¥327,155	¥294,671	¥232,748	\$3,632,644
Gross profit	199,909	207,515	193,023	207,732	183,563	149,207	2,221,211
Selling, general and administrative expenses	95,121	86,569	80,067	78,505	83,900	62,963	1,056,900
Research and development expenses	53,225	54,243	54,609	50,058	48,166	43,525	591,389
Operating income	51,563	66,703	58,347	79,169	51,497	42,719	572,922
Net income (loss)	39,265	40,061	38,418	53,632	34,117	28,446	436,278
Capital investments	26,570	19,609	16,344	16,129	9,865	11,819	295,222
Depreciation and amortization	20,080	14,914	13,815	16,981	14,383	10,514	223,111
<b>Amounts per share (Yen and U.S. dollars):</b>							
Net income (loss) -basic-	¥ 72.04	¥ 73.23	¥ 69.35	¥ 97.00	¥ 62.27	¥ 51.73	\$ 0.80
Cash dividends*3	34.00	30.00	30.00	34.00	18.00	13.00	0.38
<b>Financial position at year-end:</b>							
Total assets	¥478,518	¥458,942	¥462,124	¥456,442	¥411,449	¥405,197	\$5,316,867
Property, plant and equipment, net	98,346	92,495	85,150	79,460	90,051	91,970	1,092,733
Interest-bearing debt	305	775	1,300	2,549	6,167	10,761	3,389
Total shareholders' equity	401,623	378,734	389,598	368,306	320,847	296,717	4,462,478
<b>Other statistics:</b>							
Number of employees	6,383	6,257	5,905	5,280	5,313	5,619	

\*1 In June 2003, the Company changed its fiscal year-end from March 31 to December 31. As a result of this change, the nine months ended December 31, 2003 are presented as a transitional period.

\*2 The U.S. dollar amounts in the consolidated financial statements as of and for the year ended December 31, 2008 have been translated from Japanese yen amounts at ¥90 = U.S. \$1.00, the exchange rate prevailing on December 31, 2008.

\*3 Dividends per share for fiscal year 2005 include special dividends of ¥10 per share.

Note: The accompanying notes to the consolidated financial statements are an integral part of this summary.

## Management's Discussion & Analysis

### Operating Environment and Chugai's Growth Strategy

During the period under review, the operating environment surrounding the pharmaceutical industry in Japan remained extremely challenging due to continued government policies to reduce medical costs, including bi-annual drug price reduction and the promotion of generic medicines.

In this business climate, we endeavored to engage in aggressive product research and development (R&D) activities to achieve the continued development and acquisition of innovative new drugs, in addition to implementing marketing campaigns based on sound ethical and scientific principles that promote appropriate drug use as well as consumer confidence.

As a result of these R&D activities, we received indication extensions for Herceptin, an anti-HER2-humanized monoclonal antibody, in Japan to cover the adjuvant treatment of post-operative breast cancer patients whose excess HER2 has been confirmed.

In addition, we received additional indications for Actemra, a humanized anti-human IL-6 receptor monoclonal antibody, in Japan to cover the treatment of rheumatoid arthritis, polyarticular-course juvenile arthritis and systemic-onset juvenile idiopathic arthritis. Overseas, we are developing jointly with F. Hoffman-La Roche Ltd. (Headquarters: Switzerland; hereinafter, Roche) for the treatment of rheumatoid arthritis. We also received a request for submission of further materials from the U.S. Food and Drug Administration (FDA) in September for approval of Actemra and are currently working together with Roche to respond to the request. In January 2009, we

received an approval in Europe (European product name: RoActemra). The rollout of the product started in the same month in Germany.

On the organizational front, to strengthen our functions for formulating strategies and plans related to strategic marketing and portfolio management, we have reorganized our consultative meetings for R&D. Under this reorganization, certain functions related to the formulation of strategies and plans have been shifted from the Executive Committee, and authority and responsibility for these functions has been delegated to a newly formed committee. As a result of this organizational change, we are working to significantly accelerate our decision-making functions.

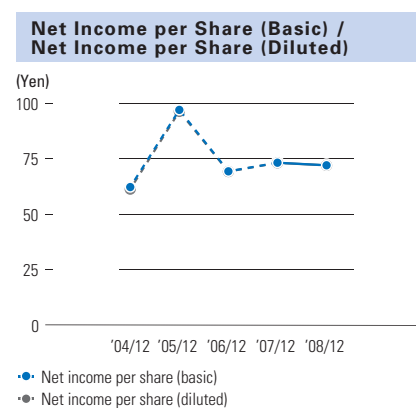
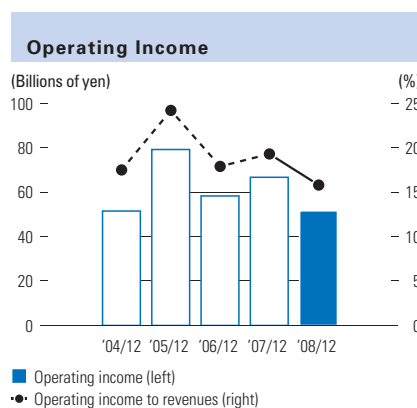
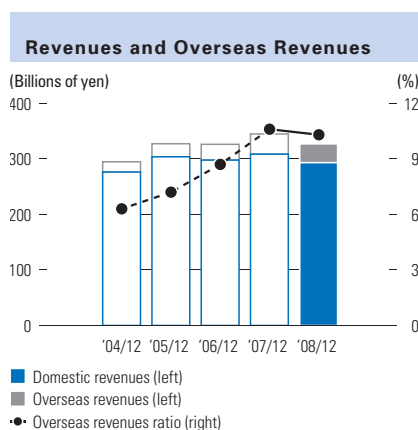
In addition, we are continuing to move forward with our Business Process Reengineering (BPR) Project that commenced in fiscal 2006 and are working to create highly efficient corporate structures. Furthermore, we are working to strengthen internal control functions to secure the rightness of the Company's business. As a result, in terms of revenues, Chugai was ranked fifth in 2008 in the domestic prescription pharmaceutical market with a market share of 4.3%<sup>\*1</sup>.

<sup>\*1</sup> IMS Pharmaceutical Market Statistics (Reimbursement price basis), Dec. 2008 MAT.

### Consolidated Business Results of the Fiscal Year Under Review (January 1, 2008–December 31, 2008)

#### Revenues

Consolidated revenues for the year amounted to ¥326.9 bil-



lion, down 5.2% from the previous fiscal year.

Despite the positive effects of new products and products approved for additional indications, several factors had a negative impact on revenues. These include a decline in sales of the anti-influenza agent Tamiflu mainly owing to the completion of deliveries for the government's stockpile (total sales of Tamiflu fell ¥30.3 billion down from the previous fiscal year), the termination of the Company's marketing collaboration with sanofi-aventis at the end of 2007 (¥11.2 billion down from the previous fiscal year), the NHI drug price revisions in April 2008, the price reduction of the recombinant human erythropoietin Epogin, a mainstay product (¥9.9 billion down from the previous fiscal year), and a decline in royalties and other operating income (¥6.8 billion down from the previous fiscal year).

On the other hand, after the exclusion of the sales of Tamiflu, which vary widely from year to year, total sales amounted to ¥313.4 billion, an increase of 6.5% from the previous fiscal year, the highest level for the Company in history.

Domestic sales excluding Tamiflu rose 6.4%, to ¥279.9 billion from the previous fiscal year. Product sales in the oncolo-

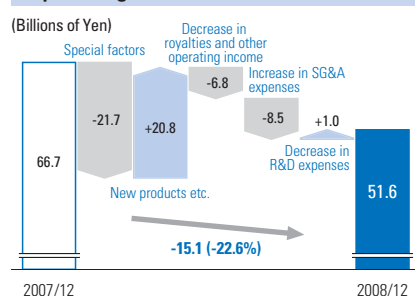
gy field increased 38.2%, to ¥102.3 billion, enabling Chugai to seize the top share (15.8%)\*2 for the first time in the domestic oncology market. This growth was a result of strong performances of Avastin, a anti-vascular endothelial growth factor (VEGF) receptor humanized monoclonal antibody, and Tarceva, a human epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor launched in 2007, as well as additional indications obtained by Herceptin and anti-tumor agent Xeloda. In the renal diseases field, sales declined 11.9% from the previous fiscal year, to ¥61.3 billion, due mainly to fall in sales of Epogin. In the bone and joint diseases field, sales increased 7.3%, to ¥50.0 billion, owing to additional indications for Actemra for the treatment of rheumatoid arthritis. The combined sales of the three strategic fields, oncology, renal diseases as well as bone and joint diseases accounted for 76.3% of our domestic sales, making us a leading company in each of these three fields. Sales in the transplant, immunology, and infectious diseases field excluding Tamiflu increased 35.6%, to ¥24.0 billion, owing to the export of Actemra amounting to ¥3.8 billion. Increased sales of peginterferon alfa-2a Pegasys and anti-viral agent Copegus.

Overseas sales increased 7.4%, to ¥33.5 billion, owing to the reporting of exports of Actemra in the amount of ¥3.8 billion. This was despite the appreciation of the yen, which had a ¥1.9 billion negative impact on sales. Due to a fall in royalties and other operating income, however, total overseas revenues declined 7.2%, to ¥33.8 billion, accounting for 10.3% of the Company's total revenues, a 0.3 percentage point decrease from the previous fiscal year. Royalties and other operating

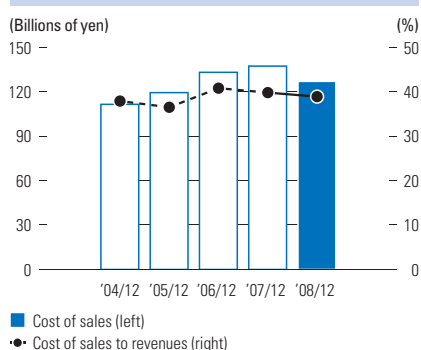
(Billions of yen)

	Non-Consolidated (A)	Consolidated (B)	B/A
Revenues	311.5	326.9	1.05
Operating income	37.1	51.6	1.39
Recurring profit	40.1	57.3	1.43
Net income	29.4	39.3	1.34

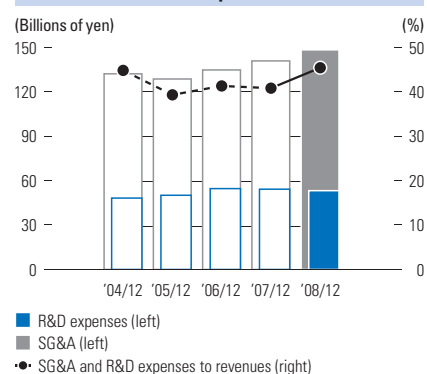
### Operating Income (Year on Year)



### Cost of Sales



### SG&A and R&D Expenses





income in fiscal 2007 included upfront payment income associated with out-licensing to Roche of three development projects from Chugai research, as well as income from milestone payment related to Actemra.

\*<sup>2</sup> IMS Pharmaceutical Market Statistics (NHI reimbursement price basis), Dec. 2008 MAT. The scope of the market is defined by Chugai.

### Cost of Sales and Gross Profit

Cost of sales declined ¥10.3 billion, to ¥127.0 billion from the previous fiscal year, due to the decrease in sales and foreign exchange factors. Foreign exchange factors had approximately a ¥2.0 billion impact on cost of sales, mainly comprised of the reduced purchasing prices of products from Roche, because of the yen's appreciation against the Swiss franc. Gross profit declined 3.7%, to ¥199.9 billion from the previous fiscal year. Within this amount, gross profit on sales declined 0.5%, to ¥194.8 billion from the previous fiscal year. The cost-to-sales ratio (based on sales and excluding royalties and other operating income) improved 1.7 percentage points from the previous fiscal year, to 39.5%, due to a decline in sales of Tamiflu for government's stockpile, which has a relatively high cost-to-sales ratio.

### Operating Income

Operating income totaled ¥51.6 billion, down 22.6% from the previous fiscal year. New products pushed up operating income by around ¥20.8 billion. However, this was outweighed by several negative factors including (1) intensified price competition for Epogin, (2) major decline in sales of Tamiflu for govern-

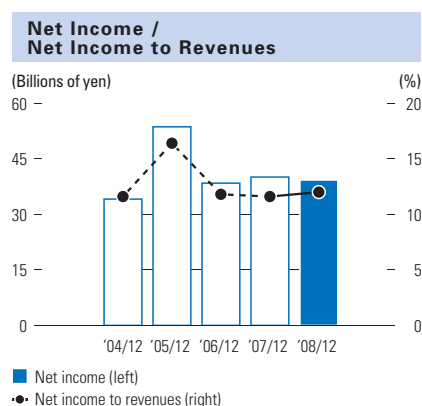
ment's stockpile, and (3) termination of the marketing collaboration with sanofi-aventis. These three special factors had a ¥21.7 billion downward impact on operating income. A ¥6.8 billion decline in royalties and other operating income and a ¥7.5 billion increase in selling, general, and administrative expenses also had a negative effect on operating income.

Selling, general and administrative expenses increased ¥8.5 billion year-on-year. This was mainly due to a rise in costs related to the promotion of new products and products approved for additional indications, an increase in expenses associated with post-marketing surveillance, and an increase in costs related to joint promotion activities of Actemra in Europe.

R&D expenses declined ¥1.0 billion, to ¥53.2 billion from the previous fiscal year. This was due to lower costs for developing Actemra, which entered a new phase, as well as an increase in reimbursement of development expenses for projects developed jointly with Roche.

### Net Income

Net income was down ¥0.8 billion, or 2.0%, to ¥39.3 billion from the previous fiscal year. This limited decline was attributable to an extraordinary gain of ¥6.3 billion on settlement of co-development costs for Actemra with Roche. Extraordinary loss for the year totaled ¥1.4 billion. This included a ¥0.7 billion impairment loss on the disposal of idle real estates and a ¥0.5 billion loss on office realignment costs. As a result, total extraordinary income, net of extraordinary loss, amounted to ¥5.8 billion, a ¥7.1 billion improvement on the previous fiscal year.



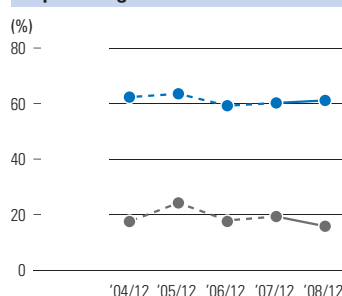
## Profitability (Consolidated Basis)

	Years ended December 31				
	2008	2007	2006	2005	2004
Gross profit ratio (%)	61.1	60.2	59.2	63.5	62.3
Operating income to revenues (%)	15.8	19.3	17.9	24.2	17.5
Return on assets (%)	12.2	14.7	13.3	18.9	12.7
Return on equity (%)	10.1	10.4	10.1	15.6	11.0

Notes: 1. Return on assets = (Operating income + interest and dividend income) / Total assets (yearly average) × 100

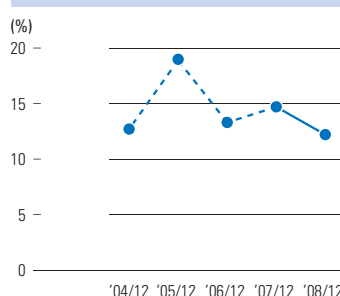
2. Return on equity = Net income / Shareholders' equity (yearly average) × 100

## Gross Profit Ratio / Operating Income to Revenues

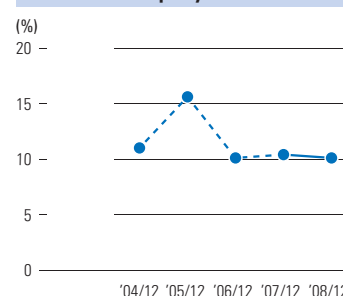


• Gross profit ratio  
• Operating income to revenues

## Return on Assets



## Return on Equity



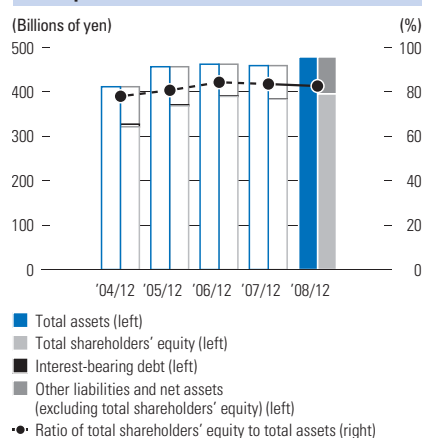
## Financial Position and Cash Flows

## Financial Position

At the end of the fiscal year under review, total assets on a consolidated basis amounted to ¥478.5 billion, an increase of ¥19.6 billion, or 4.3%, from the end of the previous fiscal year. While cash and deposits declined ¥2.4 billion, and marketable securities as well as investment securities declined by ¥10.8 billion and ¥2.4 billion respectively, the increase of ¥23.5 billion in inventories and ¥5.8 billion in tangible fixed assets contributed to the overall increase in total assets.

The increase in inventories resulted from the Company's measure to stock Tamiflu in preparation for resumption of government's stockpile in fiscal 2009. Other factors included increased inventories of Actemra in preparation for rising demand in Japan and shipments to Europe, as well as stockpiling of products associated with the closure of the Kamakura plant. The manufacturing site transfer will begin in the fourth quarter of fiscal year 2009, with completion scheduled for the end of fiscal year 2012. The Kamakura plant will cease production at the end of fiscal year 2010 and close in the first

## Composition of Total Assets



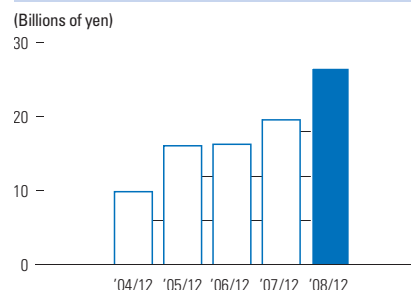
• Ratio of total shareholders' equity to total assets (right)

quarter of fiscal year 2011.

The increase in tangible fixed assets stemmed mainly from capital investments for expansion of three plants: the injection products building No.3 at the Utsunomiya plant, the solid pharmaceutical production lines and related facilities at the Fujieda plant, and the formulation and packaging pilot plant No.2 and the bio-product technology research building No.2 at the Ukima Plant.

The declines in cash and deposits as well as marketable and investment securities resulted from capital investments for the purpose of strengthening its production system (such expenditures peaked in fiscal year 2008 at ¥26.6 billion), as well as to fund its working capital needs.

### Capital Investments



### Stability (Consolidated Basis)

	Years ended December 31				
	2008	2007	2006	2005	2004
Current ratio (%)	438.5	472.5	517.3	418.6	434.0
Fixed assets ratio (%)	34.0	33.7	32.0	34.8	42.6
Interest coverage ratio (times)	517.5	461.9	283.0	284.8	169.3
Debt-to-equity ratio (%)	0.1	0.2	0.3	0.7	1.9
Shareholders' equity to total assets (%)	82.6	83.5	84.3	80.7	78.0
Market value equity ratio (%)	196.2	189.9	294.4	306.7	226.3

Notes: 1. Current ratio = Current assets (fiscal year-end)/Current liabilities (fiscal year-end) × 100

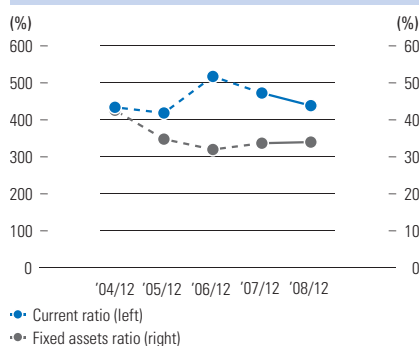
2. Fixed assets ratio = Fixed assets (fiscal year-end)/Shareholders' equity (fiscal year-end) × 100

3. Interest coverage ratio = Net cash provided by operating activities (prior to deductions of interest paid and income taxes paid, and addition of income taxes refunded)/interest paid

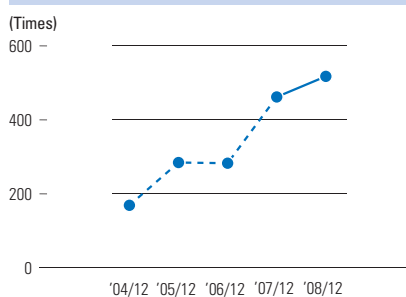
4. Debt-to-equity ratio = Interest-bearing debt (fiscal year-end)/Shareholders' equity (fiscal year-end) × 100

5. Market value equity ratio = Total market capitalization/Total assets (fiscal year-end) × 100

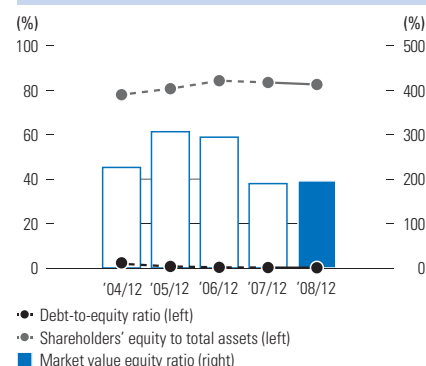
### Current Ratio / Fixed Assets Ratio



### Interest Coverage Ratio



### Debt-to-Equity Ratio / Shareholders' Equity to Total Assets / Market Value Equity Ratio



Total liabilities stood at ¥81.5 billion, ¥8.4 billion or 11.5% higher than the end of the previous fiscal year. This was mainly due to an ¥11.5 billion increase in accounts payable and a ¥3.1 billion rise in accrued expenses, which outweighed a ¥4.9 billion decrease in accrued income taxes. In September 2008, the Company redeemed ¥0.3 billion in corporate bonds, and as a result, reduced its external borrowings to zero.

Net assets rose ¥11.3 billion, to ¥397.1 billion, despite the

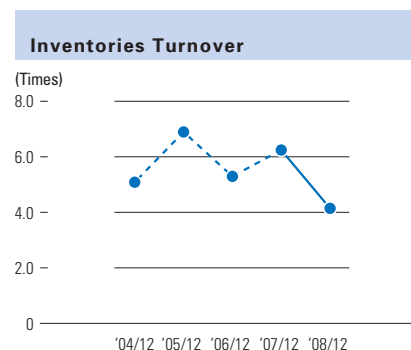
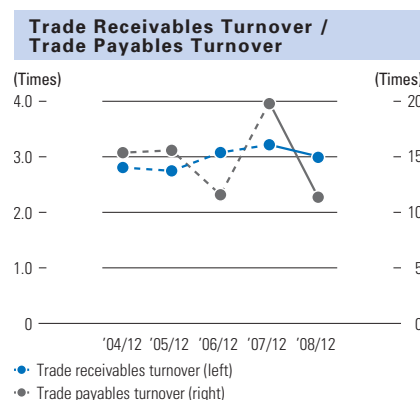
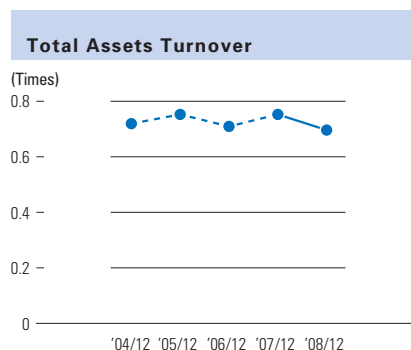
decrease in foreign currency translation adjustments.

The shareholders' equity ratio was 82.6%, a 0.9 percentage point decrease from the previous fiscal year-end. Net working capital (current assets minus current liabilities) totaled ¥265.8 billion, and the current ratio was 438.5% (from 472.5% at the previous fiscal year-end), reflecting the Company's sound financial position.

### Efficiency (Consolidated Basis)

	Years ended December 31				
	2008	2007	2006	2005	2004
Total assets turnover (times)	0.70	0.75	0.71	0.75	0.72
Trade receivables turnover (times)	3.01	3.22	3.08	2.75	2.81
Inventories turnover (times)	4.15	6.25	5.30	6.90	5.09
Trade payables turnover (times)	11.37	19.90	11.59	15.59	15.38

- Notes: 1. Total assets turnover = Revenues/Total assets (yearly average)  
 2. Trade receivables turnover = Revenues/(trade notes receivable + trade accounts receivable)  
 3. Inventories turnover = Revenues/inventories  
 4. Trade payables turnover = Revenues/(trade notes payable + trade accounts payable)





## Cash Flows

Cash and cash equivalents at the end of the fiscal year under review totaled ¥70.7 billion, down ¥3.0 billion from the beginning of the current fiscal year.

Net cash provided by operating activities amounted to ¥39.3 billion, a decline of ¥21.1 billion from the previous fiscal year. This was because of increases in income taxes paid and inventories as well as other factors.

Net cash used in investing activities totaled ¥14.1 billion, ¥6.6 billion greater than the previous fiscal year. This rise in

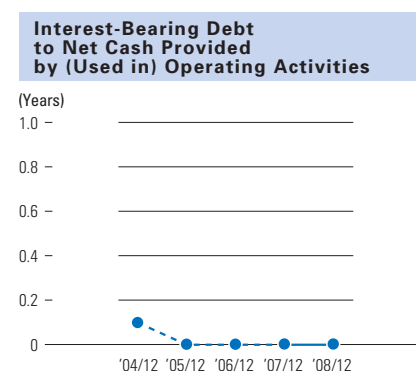
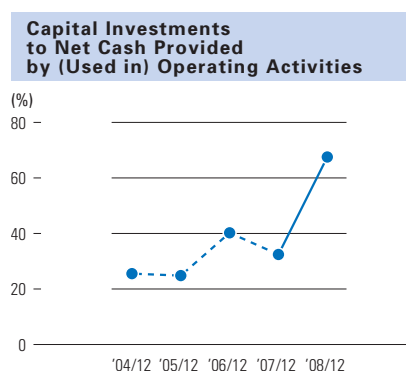
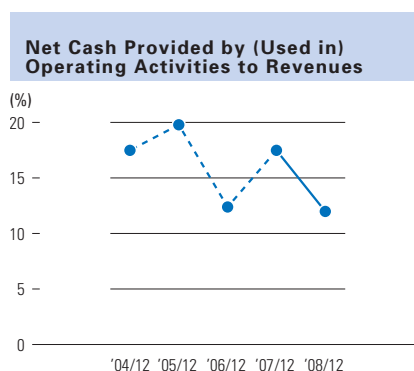
net cash used in investing activities was due to a decline in proceeds from the sales of securities and an increase in purchases of fixed assets.

Net cash used in financing activities amounted to ¥18.4 billion, representing a decrease of ¥28.8 billion from the previous fiscal year. This consisted of ¥16.3 billion in dividend payouts, ¥1.7 billion in dividend payouts of the French joint venture Chugai sanofi-aventis, and ¥0.3 billion in redemption of corporate bonds.

## Cash Flow (Consolidated Basis)

Millions of yen	Years ended December 31				
	2008	2007	2006	2005	2004
Net cash provided by operating activities	39,277	60,365	40,539	64,663	51,495
Net cash used in investing activities	(14,122)	(7,510)	(29,371)	(35,460)	(15,211)
Net cash used in financing activities	(18,361)	(47,173)	(18,797)	(12,557)	(13,718)
Effect of exchange rate changes on cash and cash equivalents	(9,865)	(292)	1,581	354	170
Net increase (decrease) in cash and cash equivalents	(3,071)	5,390	(6,048)	17,000	22,736
Cash and cash equivalents at beginning of year	73,723	68,333	74,381	57,381	36,226
Decrease resulting from exclusion of subsidiaries from consolidation	—	—	—	—	(1,581)
Cash and cash equivalents at end of year	70,652	73,723	68,333	74,381	57,381
Net cash provided by (used in)					
operating activities to revenues (%)	12.0	17.5	12.4	19.8	17.5
Capital investments to net cash provided by (used in) operating activities (%)	67.6	32.5	40.3	24.9	25.6
Interest-bearing debt to net cash provided by (used in) operating activities (years)	0.0	0.0	0.0	0.0	0.1

Note: Interest-bearing debt to net cash provided by (used in) operating activities  
= Interest-bearing debt/net provided by (used in) operating activities (prior to interest and income tax deductions)



## Basic Profit Distribution Policies and Per-Share Data

### Basic Profit Distribution Policies

With regard to income distribution, we aim to stabilize the return of profit for all shareholders. Taking into account of short-term fluctuation in earnings by the effect of the influenza epidemic as well as medium-to-long-term strategic investment funding needs and earnings prospects, we aimed to ensure a consolidated dividend payout ratio of 30% or more on average. To expand the return of profit for all shareholders, we freshly aim to ensure a consolidated dividend payout ratio of around 40% or higher on average.

Internal reserves will be used to fund R&D activities in Japan and overseas as well as for making capital investments related to new products, in order to further enhance corpo-

rate value. At the same time, we will use such reserves to repurchase our shares when it is appropriate to improve shareholder value.

Note that year-end dividends for the fiscal year ended December 31, 2008 are ¥19 per share, bringing total dividends paid during the year to ¥34 per share, up ¥4 from the previous fiscal year. This brings the consolidated dividend payout ratio to 47.2%. For fiscal 2009, we expect annual dividends to be ¥34 per share, including ¥17 for the interim period.

### Per-Share Data

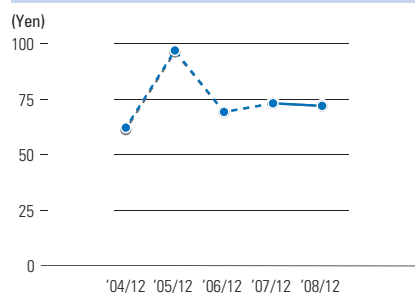
Earnings per share (EPS) for the year under review was ¥72.07, down ¥1.16 from the previous fiscal year. EPS on a fully diluted basis was ¥72.04. Net assets per share (BPS) totaled ¥725.18, up ¥21.38 year-on-year.

### Per Share Data (Consolidated Basis)

Yen	Years ended December 31				
	2008	2007	2006	2005	2004
Net income per share (basic)	72.07	73.23	69.35	97.00	62.27
Net income per share (diluted)	72.04	73.16	69.26	96.33	61.34
Shareholders' equity per share	725.18	703.80	703.08	665.29	583.61
Cash dividends per share	34.00	30.00	30.00	34.00*	18.00
Payout ratio (%)	47.2	41.0	43.3	35.1	28.9

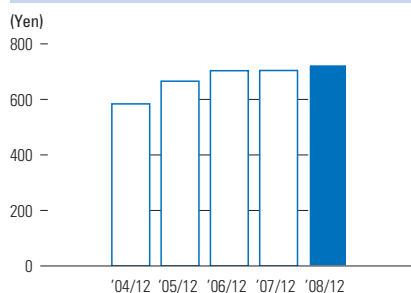
\* Include special dividends of ¥10 per share.

#### Net Income per Share (Basic) / Net Income per Share (Diluted)

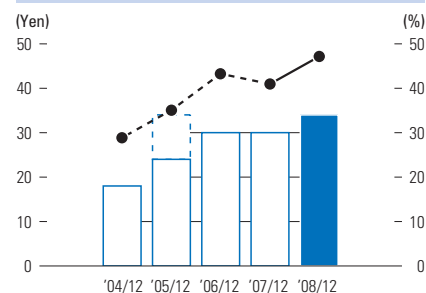


● Net income per share (basic)  
 ● Net income per share (diluted)

#### Shareholders' Equity per Share



#### Cash Dividends per Share / Payout Ratio



■ Cash dividends per share (left)  
 ■ Special dividends per share (left)  
 ● Payout ratio (right)  
 Note: Dividends per share for fiscal year 2005 include special dividends of ¥10 per share.

## Business Risks

Chugai's corporate performance is subject to major impact from a range of possible future events. Below, we list what we consider the principal sources of risk to the development of our business. We recognize the possibility of these risk events actually occurring, and have prepared policies to forestall such risks and take appropriate measures when they do occur. The future risks identified in this section are based on assessments made by the Company as of the end of the consolidated fiscal year under review.

- (1) *New Product Development:* With the goal of becoming a top Japanese pharmaceutical manufacturer capable of continuously delivering innovative new drugs, Chugai aggressively pursues R&D in Japan and overseas. Our development pipeline is well stocked, especially in the fields of oncology, bone and joint diseases, and renal diseases. However, bringing all of them smoothly through to the market from the R&D stages may not be possible, and we expect to have to abandon development in some cases. When such a situation occurs, there is a possibility of major impact on our business performance and financial position, depending on the product under development.
- (2) *Changes in Product Environments:* In recent years, there have been rapid technological advancements in the pharmaceutical industry, and the Company faces fierce competition from pharmaceutical companies in Japan and overseas. The Company's business performance and financial status may be significantly affected by changes in product environments caused by the sale of competing products and genetic products and also by changes in contracts concluded by the Company for the marketing agreement or the licensing of technologies.
- (3) *Side Effects:* Medical products are approved in Japan by the Ministry of Health, Labour and Welfare after stringent screening. However, advances in science and technology and years of careful post-marketing monitoring of pharmaceutical product use mean that side effects are discovered in a good number of drugs. In cases where unexpected side

effects occur after marketing, there is a risk of significant impact on our business performance and financial position.

- (4) *Reform of Japan's medical system:* Japan's medical insurance system is being reformed against a backdrop of rapid demographic change, with a falling birthrate and increasing numbers of aged citizens. As part of this process, measures are being taken to curb medical expenses. Revisions have been made to the system of reimbursement of medical fees, and debate is continuing in such areas as drug price reform. The Company's business performance could be significantly affected by future developments in medical system reform, including drug price reform.
- (5) *Intellectual Property (IP) Rights:* The Company recognizes that it applies intellectual property rights in pursuing its business activities, and takes care to distinguish its own proprietary intellectual property rights and licensing arrangements recognized under law. However, the possibility remains of our infringing on third-party intellectual property rights without being aware of the fact. Major disputes related to intellectual property rights relating to our business could have major impact on our business performance.
- (6) *Strategic Alliance with Roche:* In line with its strategic alliance with Roche, we are the only pharmaceutical partner of Roche in the Japanese market and have introduced many products and projects from Roche. In the event that our strategic alliance with Roche is changed for some reason, such circumstances could have a major impact on the Company's operating results and financial position.
- (7) *Foreign Exchange-Rate Fluctuations:* The Company's business activities include export and import transactions as well as royalties and other operating income denominated in foreign currencies. The Company hedges against exchange risk and similar risk through forward foreign exchange contracts and other means, but it is impossible to completely eliminate such risk, and there is a possibility of non-negligible adverse effects on the Company's business results and financial position from such risk.

## Consolidated Financial Statements:

## Consolidated Balance Sheets

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries / December 31,

Assets	Millions of yen		Thousands of U.S. dollars (Note 4)
	2008	2007	2008
Current assets:			
Cash and cash equivalents (Note 19)	¥ 70,768	¥ 73,168	\$ 786,311
Marketable securities including short-term investments (Note 13)	54,715	65,548	607,944
Receivables:			
Trade notes	24	24	267
Trade accounts	108,435	106,988	1,204,833
Other	6,561	6,442	72,900
Reserve for doubtful accounts	(61)	(53)	(678)
Inventories (Note 5)	78,736	55,187	874,844
Deferred tax assets (Note 10)	21,835	20,467	242,611
Other	3,341	2,036	37,124
Total current assets	344,354	329,807	3,826,156
Property, plant and equipment, at cost (Note 16):			
Land	9,938	9,927	110,422
Buildings and structures	122,969	108,279	1,366,322
Machinery and equipment	111,035	102,244	1,233,722
Construction in progress	5,488	11,983	60,978
	249,430	232,433	2,771,444
Accumulated depreciation (Note 6)	(151,084)	(139,938)	(1,678,711)
Property, plant and equipment, net	98,346	92,495	1,092,733
Investments and other assets:			
Investment securities (Note 13)	14,158	16,603	157,311
Unconsolidated subsidiaries and affiliates	230	230	2,556
Long-term loans	45	65	500
Lease deposits	4,091	4,228	45,456
Deferred tax assets (Note 10)	12,198	8,992	135,533
Other	5,096	6,522	56,622
Total investments and other assets	35,818	36,640	397,978
Total assets	¥ 478,518	¥ 458,942	\$ 5,316,867



Liabilities and net assets	Millions of yen		Thousands of U.S. dollars (Note 4)
	2008	2007	2008
Current liabilities:			
Long-term debt due within one year (Notes 7 and 20)	¥ —	¥ 343	\$ —
Payables (Note 20):			
Trade notes	6	4	67
Trade accounts	28,760	17,321	319,556
Construction	6,035	4,682	67,056
Other	1,019	519	11,322
Income taxes payable (Note 10)	11,382	16,326	126,467
Deferred tax liabilities (Note 10)	—	1	—
Accrued liabilities	29,133	26,458	323,700
Other	2,189	4,144	24,321
Total current liabilities	78,524	69,798	872,489
Long-term liabilities:			
Deferred tax liabilities (Note 10)	1	3	11
Reserve for employees' retirement benefits (Note 11)	2,084	2,604	23,156
Reserve for officers' retirement benefits	773	633	8,589
Other	69	106	766
Total long-term liabilities	2,927	3,346	32,522
Contingent liabilities (Note 17)			
Net assets (Notes 8 and 22):			
Shareholders' equity:			
Common stock, without par value:			
Authorized: 799,805,050 shares			
Issued:			
December 31, 2008 - 559,685,889 shares	72,967	—	810,744
December 31, 2007 - 559,636,061 shares	—	72,948	—
Additional paid-in capital	92,815	92,796	1,031,278
Retained earnings	271,009	248,098	3,011,211
Treasury stock, at cost:			
December 31, 2008 - 14,872,196 shares	(35,168)	—	(390,755)
December 31, 2007 - 14,831,246 shares	—	(35,108)	—
Total shareholders' equity	401,623	378,734	4,462,478
Valuation, translation adjustments and others:			
Net unrealized holding gain on securities	1,355	2,758	15,056
Translation adjustments	(7,889)	1,944	(87,656)
Total valuation, translation adjustments and others	(6,534)	4,702	(72,600)
Stock subscription rights	326	140	3,622
Minority interests in consolidated subsidiaries	1,652	2,222	18,356
Total net assets	397,067	385,798	4,411,856
Total liabilities and net assets	¥ 478,518	¥ 458,942	\$ 5,316,867

See accompanying notes to consolidated financial statements.

## Consolidated Financial Statements:

## Consolidated Statements of Income

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries / Year ended December 31,

	Millions of yen			Thousands of U.S. dollars (Note 4)
	2008	2007	2006	2008
Revenues:				
Sales	¥ 321,836	¥ 332,943	¥ 326,109	\$ 3,575,956
Royalties and other operating income	5,102	11,865	—	56,688
	326,938	344,808	326,109	3,632,644
Cost of sales (Note 20)	127,029	137,293	133,086	1,411,433
Gross profit	199,909	207,515	193,023	2,221,211
Selling, general and administrative expenses	95,121	86,569	80,067	1,056,900
Research and development expenses	53,225	54,243	54,609	591,389
Operating income	51,563	66,703	58,347	572,922
Other income (expenses):				
Interest and dividend income	2,034	1,444	1,982	22,600
Interest expense (Note 20)	(135)	(177)	(269)	(1,500)
Other (Note 9)	9,644	(1,542)	2,896	107,156
	11,543	(275)	4,609	128,256
Income before income taxes and minority interests	63,106	66,428	62,956	701,178
Income taxes (Note 10)	(22,276)	(24,537)	(22,874)	(247,511)
Minority interests	(1,565)	(1,830)	(1,664)	(17,389)
Net income (Note 22)	¥ 39,265	¥ 40,061	¥ 38,418	\$ 436,278

See accompanying notes to consolidated financial statements.

## Consolidated Financial Statements:

## Consolidated Statements of Changes in Net Assets

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries / Years ended December 31, 2008, 2007 and 2006

	Thousands	Millions of yen										
		Shareholders' equity (Note 8)					Valuation, translation adjustments and others					
	Number of shares issued (Note 18)	Common stock	Additional paid-in capital	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Net unrealized holding gain on securities	Translation adjustments	Total valuation, translation adjustments and others	Stock subscription rights	Minority interests in consolidated subsidiaries	Total net assets
Balance at December 31, 2005	558,656	¥72,444	¥92,296	¥206,834	¥(7,612)	¥363,962	¥3,782	¥562	¥4,344	¥ —	¥1,693	¥369,999
Conversion of convertible bonds (Note 19)	388	148	148			296						296
Exercise of stock subscription rights (Note 19)	449	301	300			601						601
Bonuses to directors				(222)		(222)						(222)
Purchases of treasury stock					(29)	(29)						(29)
Disposition of treasury stock			3		51	54						54
Net income				38,418		38,418						38,418
Cash dividends paid				(18,821)		(18,821)						(18,821)
Net changes in items other than shareholders' equity							(546)	1,541	995		313	1,308
Balance at December 31, 2006	559,493	72,893	92,747	226,209	(7,590)	384,259	3,236	2,103	5,339	—	2,006	391,604
Conversion of convertible bonds (Note 19)	143	55	54			109						109
Purchases of treasury stock					(27,615)	(27,615)						(27,615)
Disposition of treasury stock			(5)	(26)	97	66						66
Net income				40,061		40,061						40,061
Cash dividends paid				(18,146)		(18,146)						(18,146)
Net changes in items other than shareholders' equity							(478)	(159)	(637)	140	216	(281)
Balance at December 31, 2007	559,636	72,948	92,796	248,098	(35,108)	378,734	2,758	1,944	4,702	140	2,222	385,798
Conversion of convertible bonds (Note 19)	50	19	19			38						38
Purchases of treasury stock					(87)	(87)						(87)
Disposition of treasury stock				(9)	27	18						18
Net income				39,265		39,265						39,265
Cash dividends paid				(16,345)		(16,345)						(16,345)
Net changes in items other than shareholders' equity							(1,403)	(9,833)	(11,236)	186	(570)	(11,620)
Balance at December 31, 2008	559,686	¥72,967	¥92,815	¥271,009	¥(35,168)	¥401,623	¥1,355	¥(7,889)	¥(6,534)	¥326	¥1,652	¥397,067

(Thousands of U.S. dollars) (Note 4)

	(Thousands of U.S. dollars) (Note 4)										
	Shareholders' equity (Note 8)					Valuation, translation adjustments and others					
	Common stock	Additional paid-in capital	Retained earnings	Treasury stock, at cost	Total shareholders' equity	Net unrealized holding gain on securities	Translation adjustments	Total valuation, translation adjustments and others	Stock subscription rights	Minority interests in consolidated subsidiaries	Total net assets
Balance at December 31, 2007	\$810,533	\$1,031,067	\$2,756,644	\$(390,089)	\$4,208,155	\$30,644	\$21,600	\$52,244	\$1,556	\$24,689	\$4,286,644
Conversion of convertible bonds (Note 19)	211	211			422						422
Purchases of treasury stock				(966)	(966)						(966)
Disposition of treasury stock			(100)	300	200						200
Net income			436,278		436,278						436,278
Cash dividends paid			(181,611)		(181,611)						(181,611)
Net changes in items other than shareholders' equity						(15,588)	(109,256)	(124,844)	2,066	(6,333)	(129,111)
Balance at December 31, 2008	\$810,744	\$1,031,278	\$3,011,211	\$(390,755)	\$4,462,478	15,056	\$(87,656)	\$(72,600)	\$3,622	\$18,356	\$4,411,856

See accompanying notes to consolidated financial statements.

## Consolidated Financial Statements:

## Consolidated Statements of Cash Flows

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries / Year ended December 31,

	Millions of yen			Thousands of U.S. dollars (Note 4)
	2008	2007	2006	2008
<b>Cash flows from operating activities</b>				
Income before income taxes and minority interests	¥ 63,106	¥ 66,428	¥ 62,956	\$ 701,178
Adjustments to reconcile income before income taxes and minority interests to net cash provided by operating activities:				
Depreciation and amortization	20,080	14,914	13,815	223,111
Loss on impairment of fixed assets	748	32	107	8,311
Decrease in reserve for employees' retirement benefits	(510)	(1,535)	(1,952)	(5,667)
Interest and dividend income	(2,034)	(1,444)	(1,982)	(22,600)
Interest expense	135	177	269	1,500
Loss on disposal of fixed assets	357	327	509	3,967
Loss (gain) on sales of fixed assets	(411)	35	47	(4,567)
Loss (gain) on sales and revaluation of investment securities	20	21	(2,231)	222
Decrease (increase) in notes and accounts receivable	(2,504)	(1,257)	13,290	(27,822)
Decrease (increase) in inventories	(25,562)	6,174	(13,838)	(284,022)
Increase (decrease) in notes and accounts payable	12,291	(10,709)	6,989	136,567
Increase (decrease) in accrued consumption taxes	(2,036)	1,128	(1,704)	(22,622)
Others	4,236	5,639	(3,155)	47,066
Subtotal	67,916	79,930	73,120	754,622
Interest and dividends received	1,586	1,366	1,944	17,622
Interest paid	(134)	(176)	(265)	(1,489)
Income taxes paid	(30,091)	(20,755)	(34,260)	(334,344)
Net cash provided by operating activities	39,277	60,365	40,539	436,411
<b>Cash flows from investing activities</b>				
Purchases of time deposits	(138)	—	—	(1,533)
Purchases of marketable securities	(187,595)	(225,852)	(185,882)	(2,084,389)
Proceeds from sales of marketable securities	202,000	242,900	175,491	2,244,445
Purchases of investment securities	(4,005)	(3,504)	(1,018)	(44,500)
Proceeds from sales of investment securities	379	1,336	2,741	4,211
Purchases of fixed assets	(25,223)	(22,597)	(21,323)	(280,256)
Proceeds from sales of fixed assets	429	191	608	4,767
Net decrease in short-term loans	—	2	—	—
Net decrease in long-term loans	31	14	12	344
Net cash used in investing activities	(14,122)	(7,510)	(29,371)	(156,911)
<b>Cash flows from financing activities</b>				
Net decrease in long-term debt	(305)	(0)	(0)	(3,389)
Net decrease (increase) in treasury stock	(69)	(27,517)	24	(767)
Cash dividends paid	(16,335)	(18,137)	(18,821)	(181,500)
Cash dividends paid to minority interests	(1,652)	(1,519)	—	(18,355)
Net cash used in financing activities	(18,361)	(47,173)	(18,797)	(204,011)
<b>Effect of exchange rate changes on cash and cash equivalents</b>	(9,865)	(292)	1,581	(109,611)
<b>Net increase (decrease) in cash and cash equivalents</b>	(3,071)	5,390	(6,048)	(34,122)
<b>Cash and cash equivalents at beginning of year</b>	73,723	68,333	74,381	819,144
<b>Cash and cash equivalents at end of year (Note 19)</b>	¥ 70,652	¥ 73,723	¥ 68,333	\$ 785,022

See accompanying notes to consolidated financial statements.



## Consolidated Financial Statements:

## Notes to Consolidated Financial Statements

Chugai Pharmaceutical Co., Ltd. and Consolidated Subsidiaries

## 1. Basis of Presentation of Financial Statements

Chugai Pharmaceutical Co., Ltd. (the “Company”) and its domestic consolidated subsidiaries maintain their books of account in accordance with accounting principles generally accepted in Japan, and its overseas consolidated subsidiaries maintain their books of account in conformity with those of their respective countries of domicile.

The accompanying consolidated financial statements of the Company and consolidated subsidiaries are prepared on the basis of accounting principles generally accepted in Japan, which are differ-

ent in certain respects as to the application and disclosure requirements of International Financial Reporting Standards, and have been compiled from the consolidated financial statements prepared by the Company as required by the Financial Instruments and Exchange Law of Japan. Certain modifications of, and reclassifications in, the presentation of the accompanying consolidated financial statements have been made to facilitate understanding by readers outside Japan.

## 2. Significant Accounting Policies

## (a) Basis of consolidation and accounting for investments in unconsolidated subsidiaries and affiliates

The accompanying consolidated financial statements include the accounts of the Company and significant companies which it controls directly or indirectly. All significant intercompany accounts and transactions have been eliminated in consolidation.

Investments in companies which are neither consolidated nor accounted for by the equity method are carried at cost or less. Where there has been a permanent decline in the value of such investments, the Company has written them down.

## (b) Foreign currency translation

The revenue and expense accounts of the overseas consolidated subsidiaries are translated into Japanese yen at the average exchange rate in effect for the year. Their balance sheet accounts, except for the components of net assets excluding minority interests in consolidated subsidiaries, are translated into Japanese yen at the rates of exchange in effect at the balance sheet date. The components of net assets excluding minority interests in consolidated subsidiaries are translated at their historical rates. Translation differences are presented as translation adjustments and minority interests in consolidated subsidiaries in net assets.

## (c) Cash and cash equivalents

Cash and cash equivalents consist principally of cash in banks and highly liquid investments with maturities of three months or less when purchased.

## (d) Inventories

Inventories other than work in process are stated at cost determined principally by the average cost method. Work in process is stated at cost determined principally by the first-in, first-out method.

## (e) Depreciation and amortization

Depreciation of property, plant and equipment is calculated primarily by the declining-balance method at rates based on the estimated useful lives of the respective assets.

Amortization of intangible assets is calculated primarily by the straight-line method. Amortization of software for internal use is calculated based on the usable period (five years).

## (f) Leases

Non-cancelable leases are primarily accounted for as operating leases (whether such leases are classified as operating or finance leases) except that leases which stipulate the transfer of ownership of leased assets to the lessee are accounted for as finance leases.

## (g) Securities

Securities other than equity securities issued by subsidiaries and affiliates are classified into three categories: trading, held-to-maturity and other securities. Trading securities are carried at fair value and held-to-maturity securities are carried at amortized cost. Marketable securities classified as other securities are carried at fair value with any changes in unrealized holding gain or loss, net of the applicable income taxes, included directly in net assets. Non-marketable securities classified as other securities are carried at cost. If the value of marketable securities classified as other securities declines significantly, such securities are written down to their respective fair value thus establishing a new cost basis, and the amount of each write-down is charged to income as an impairment loss unless the fair value is deemed to be recoverable.

## (h) Retirement benefits

The reserve for employees' retirement benefits is stated at the amount required to cover the liability as of the balance sheet date and is based on the Company's estimate of its liability for retirement benefits and its pension fund assets as of the balance sheet date.

The retirement benefit obligation is attributed to each period by the straight-line method over the estimated years of service of the eligible employees. Certain domestic consolidated subsidiaries adopt the simplified method in their calculation of the retirement benefit obligations.

Prior service cost is being amortized as incurred by the declining-balance method over a period (10 years) which is shorter than the average remaining years of service of the active participants in the plans.

Actuarial gain or loss is amortized in the year following the year in which the gain or loss is recognized by the declining-balance method over a period (10 years) which is shorter than the average remaining years of service of the active participants in the plans.

Directors and corporate auditors are not covered by the retirement benefit plans referred to above. However, the liability for their retirement benefits is calculated based on management's estimate of the amounts which would be payable if these corporate officers resigned their offices as of the balance sheet date. Amounts payable to directors and corporate auditors upon retirement are subject to the approval of the shareholders.

## (i) Research and development expenses

Research and development expenses are charged to income when

incurred.

**(j) Income taxes**

Deferred tax assets and liabilities are determined based on the differences between financial reporting and the tax bases of the assets and liabilities and are measured using the statutory tax rates which will be in effect when the differences are expected to be realized.

**(k) Derivative financial instruments**

The Company enters into various derivative transactions in order to manage certain risk arising from adverse fluctuation in foreign

currency exchange rates and interest rates. Derivatives are carried at fair value with any changes in unrealized gain or loss charged or credited to income.

**(l) Distribution of retained earnings**

Under the Corporation Law of Japan (the “Law”), the distribution of retained earnings with respect to a given financial period is made by resolution of the shareholders at a general meeting held subsequent to the close of such financial period. The accounts for that period do not, therefore, reflect such distributions. Refer to Note 18.

### 3. Accounting Changes

(i) Effective the year ended December 31, 2006, the Company adopted an accounting standard for the presentation of net assets in the balance sheet and the related implementation guidance. In addition, effective the year ended December 31, 2006, preparation of consolidated statements of changes in net assets is required instead of consolidated statements of shareholders’ equity. In this connection, the consolidated balance sheets as of December 31, 2005 and the consolidated statement of shareholders’ equity for the year then ended have been restated to conform to the presentation and disclosure of the consolidated financial statements for the year ended December 31, 2006.

(ii) Effective January 1, 2007, the Company has adopted a new accounting standard for stock options.

As a result, both operating income, and income before income taxes and minority interests decreased by ¥139 million for the year ended December 31, 2007 from the corresponding amounts which would have been recorded under the previous method.

(iii) Until the year ended December 31, 2006, the Company recorded patents and licensing-related income as non-operating income or extraordinary income in the consolidated statements of income. Due to the recent economic success of R&D activities, it is probable that the patents and licensing-related income will increase in the future and those income has been becoming material, the Company has started to record them as revenue effective January 1, 2007.

As a result of this change, both revenue and operating income increased by ¥11,864 million for the year ended December 31, 2007 over the corresponding amounts which would have been recorded under the previous method. This change had no impact on income before income taxes and minority interests.

(iv) Effective the year ended December 31, 2007, the Company and its domestic consolidated subsidiaries have changed their method of depreciation for all tangible fixed assets aside from buildings (excluding leasehold improvements to such buildings) acquired on or after April 1, 2007 to reflect the revisions to the

Corporation Tax Law.

As a result of this change, both operating income and income before income taxes and minority interests decreased by ¥362 million for the year ended December 31, 2007 from the corresponding amounts which would have been recorded under the previous method.

(v) Effective the year ended December 31, 2007, the Company has changed its method of accounting for foreign currency translation into yen to using the annual average exchange rates in effect with respect to revenues and expenses of overseas consolidated subsidiaries. Until the year ended December 31, 2006, the Company used spot rates in the foreign currency exchange market at the balance sheet dates to translate those revenues and expenses. This change was made to properly reflect the related gains and losses that occur throughout the accounting period in the consolidated financial statements by averaging the impacts of temporary fluctuations in exchange rates.

As a result of this change, revenues, operating income and income before income taxes and minority interests increased by ¥1,249 million, ¥408 million and ¥447 million, respectively, for the year ended December 31, 2007 over the corresponding amounts which would have been recorded under the previous method.

(vi) Effective the year ended December 31, 2008, in relation to revisions to the Corporation Tax Law, for those tangible fixed assets, other than buildings (excluding building fixtures and equipment) that were purchased on or before March 31, 2007, the Company and its consolidated subsidiaries depreciate the difference between 5% of the acquisition cost and nominal value by the straight line method over a period of five years from the year following the year in which accumulated depreciation reached 95% of acquisition cost.

As a result, operating income and income before income taxes and minority interests were each ¥410 million (\$4,556 thousand) lower than they would have been in the absence of this change in the method of calculating depreciation.

#### 4. U.S. Dollar Amounts

The U.S. dollar amounts in the accompanying consolidated financial statements as of and for the year ended December 31, 2008 have been translated from Japanese yen amounts at ¥90 = U.S.\$1.00, the exchange rate prevailing on December 31, 2008.

This translation is presented for convenience only and should not be construed as a representation that Japanese yen have been, could have been, or could in the future be, converted into U.S. dollars at that or any other rate.

#### 5. Inventories

Inventories at December 31, 2008 and 2007 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2008	2007	2008
Finished products	¥ 38,760	¥ 30,180	\$ 430,667
Work in process and semifinished products	22,987	12,392	255,411
Raw materials and supplies	16,989	12,615	188,766
	¥ 78,736	¥ 55,187	\$ 874,844

#### 6. Depreciation

Depreciation of property, plant and equipment for the years ended December 31, 2008, 2007 and 2006 amounted to ¥17,493 million (\$194,367 thousand), ¥11,507 million and ¥10,539 million, respectively.

#### 7. Short-Term Bank Loans and Long-Term Debt

The Company had no short-term bank loans as of December 31, 2008 and 2007.

Long-term debt at December 31, 2008 and 2007 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2008	2007	2008
1.05% unsecured convertible bonds due 2008	¥ —	¥ 42	\$ —
0.8969% unsecured bonds with undetachable stock subscription rights due 2008	—	301	—
	—	343	—
Less current portion	—	343	—
	¥ —	¥ —	\$ —

The Company has entered into loan commitment agreements amounting to ¥40,000 million (\$444,444 thousand) with 10 banks. There were no loans payable outstanding at December 31, 2008 under these loan commitment agreements.

#### 8. Legal Reserve and Additional Paid-in Capital

The Law provides that an amount equal to 10% of the amount to be disbursed as distributions of capital surplus (other than the additional paid-in capital) and retained earnings (other than the legal reserve) be transferred to the additional paid-in capital and the legal

reserve, respectively, until the sum of the additional paid-in capital and the legal reserve equals 25% of the capital stock account. Such distributions can be made at any time by resolution of the shareholders, or by the Board of Directors if certain conditions are met.

## 9. Other Income (Expenses)

The components of “Other” in “Other income (expenses)” for the years ended December 31, 2008, 2007 and 2006 were as follows:

	Millions of yen			Thousands of U.S. dollars
	2008	2007	2006	2008
Milestone royalty payments made by Roche	¥ —	¥ —	¥ 550	\$ —
Gain on sales of fixed assets	421	—	—	4,678
Gain on sales of marketable securities	—	—	2,231	—
Gain on liquidation of an affiliate	—	294	—	—
Gain on foreign exchange	6,255	—	—	69,500
Gain on settlement of co-development costs	6,341	—	—	70,456
Subsidies received for construction of a plant	500	—	—	5,556
Retirement benefit expenses	(107)	—	—	(1,189)
Loss on derivatives	(1,341)	—	—	(14,900)
Loss on disposal of fixed assets	(357)	(327)	(509)	(3,967)
Loss on impairment of fixed assets	(748)	(32)	(107)	(8,311)
Loss on restructuring costs, net	(536)	(1,521)	(394)	(5,956)
Loss on inventories	(1,915)	(2,236)	(361)	(21,278)
Loss on sales of fixed assets	(10)	(35)	(47)	(111)
Other	1,141	2,315	1,533	12,678
	¥ 9,644	¥ (1,542)	¥ 2,896	\$ 107,156

## 10. Income Taxes

Income taxes in Japan applicable to the Company and its domestic consolidated subsidiaries consist of corporation tax, inhabitants' taxes and enterprise tax. The approximate aggregate statutory tax

rate was 40.4% for the years ended December 31, 2008, 2007 and 2006. Income taxes for the years ended December 31, 2008, 2007 and 2006 consisted of the following:

	Millions of yen			Thousands of U.S. dollars
	2008	2007	2006	2008
Income taxes:				
Current	¥ 25,966	¥ 30,387	¥ 21,514	\$ 288,511
Deferred	(3,690)	(5,850)	1,360	(41,000)
	¥ 22,276	¥ 24,537	¥ 22,874	\$ 247,511



The significant components of deferred tax assets and liabilities at December 31, 2008 and 2007 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2008	2007	2008
Deferred tax assets:			
Prepaid expenses	¥ 8,531	¥ 5,926	\$ 94,789
Depreciation	5,214	3,918	57,933
Reserve for employees' retirement benefits	4,838	4,968	53,756
Amortization of deferred charges	3,146	2,313	34,956
Supplies	2,207	3,576	24,522
Reserve for bonuses to employees	1,766	1,832	19,622
Enterprise tax payable	978	1,306	10,867
Other	10,423	10,657	115,810
Gross deferred tax assets	37,103	34,496	412,255
Valuation allowance	(1,569)	(2,538)	(17,433)
Amount offset by deferred tax liabilities	(1,501)	(2,499)	(16,678)
Deferred tax assets, net	¥ 34,033	¥ 29,459	\$ 378,144
Deferred tax liabilities:			
Unrealized gain on securities	¥ 917	¥ 1,867	\$ 10,189
Deferred gain on sales of properties for tax purposes	584	632	6,489
Other	1	4	11
Total deferred tax liabilities	1,502	2,503	16,689
Amount offset by deferred tax assets	(1,501)	(2,499)	(16,678)
Deferred tax liabilities, net	¥ 1	¥ 4	\$ 11

A reconciliation of the statutory and effective tax rates for the years ended December 31, 2008, 2007 and 2006 is summarized as follows:

	2008	2007	2006
Statutory tax rate	40.4%	40.4%	40.4%
Permanently non-deductible expenses for tax purposes such as entertainment expenses	2.8	2.3	2.2
Permanently non-taxable income such as dividend income	(0.1)	(0.0)	(0.7)
Inhabitants' per capita taxes	0.2	0.2	0.2
Different tax rates applied to overseas subsidiaries	(1.7)	(1.3)	(1.3)
Tax credit for research and development expenses	(5.0)	(6.5)	(4.4)
Change in valuation allowance	(1.5)	2.1	—
Other	0.2	(0.3)	(0.1)
Effective tax rates	35.3%	36.9%	36.3%

## 11. Retirement Benefits

### (a) Overview of retirement benefits

The Company has various retirement benefit plans such as defined contribution pension plans and certain types defined benefit pension plans comprising corporate pension fund, tax qualified pension plan and lump-sum retirement benefit plans. The Company's domestic consolidated subsidiaries participate in the lump-sum

retirement benefit plan.

Certain employees may be entitled to additional special retirement benefits (which have not been provided for) based on the conditions under which termination occurs.

The Company has a retirement benefit trust to fund the lump-sum retirement benefit plan.

### (b) Retirement benefit obligation

The following table sets forth the funded and accrued status of the plans, and the amounts recognized in the accompanying consolidated balance sheets as of December 31, 2008 and 2007 for the Company's and the consolidated subsidiaries' defined benefit plans:

	Millions of yen		Thousands of U.S. dollars
	2008	2007	2008
Retirement benefit obligation	¥ (63,061)	¥ (61,482)	\$ (700,678)
Plan assets at fair value	58,069	62,733	645,211
Funded status	(4,992)	1,251	(55,467)
Unrecognized prior service cost	(2,324)	(2,927)	(25,822)
Unrecognized actuarial (gain) loss	5,502	(648)	61,133
Net amount	(1,814)	(2,324)	(20,156)
Prepaid pension expense	270	280	3,000
Reserve for employees' retirement benefits	¥ (2,084)	¥ (2,604)	\$ (23,156)

### (c) Retirement benefit expenses

	Millions of yen			Thousands of U.S. dollars
	2008	2007	2006	2008
Service cost <sup>(*)</sup>	¥ 2,600	¥ 2,587	¥ 2,219	\$ 28,889
Interest cost	1,372	1,345	1,183	15,244
Expected return on pension plan assets	(1,377)	(1,380)	(1,110)	(15,300)
Amortization of actuarial gain	(134)	(537)	(732)	(1,489)
Amortization of prior service cost	(603)	(759)	(956)	(6,700)
Contribution payments to a defined contribution pension plan	754	741	628	8,378
Additional retirement benefits paid	—	658	—	—
Effect of application of the benchmark method for calculation of retirement benefit obligation <sup>(*)</sup>	107	—	—	1,189
Total	¥ 2,719	¥ 2,655	¥ 1,232	\$ 30,211

(\*) Retirement benefit expenses of consolidated subsidiaries which adopted the simplified method are included in this amount.

(\*) During the year ended December 31, 2008, certain domestic consolidated subsidiary changed its calculation method of retirement benefit obligations from the simplified method to the benchmark method. In this connection, unrecognized obligations at the beginning of the fiscal year in amount of ¥107 million (\$1,189 thousand) were fully charged to income.

### (d) The assumptions utilized in accounting for the retirement benefit plans are summarized as follows:

	2008	2007	2006
(1) Discount rates	2.25%	2.25%	2.25%
(2) Expected rates of return on plan assets	0.7% - 2.5%	0.7% - 2.5%	0.69% - 2.0%

## 12. Leases

The Company holds certain machinery, equipment and software under finance leases which do not transfer ownership of the leased assets to the lessee. These leases are not capitalized, but are accounted for as operating leases. If the leases had been capitalized,

the acquisition costs, accumulated depreciation/amortization and net book value of such leased assets at December 31, 2008 and 2007 would have been as follows:

2008	Millions of yen				Thousands of U.S. dollars			
	Machinery	Equipment	Software	Total	Machinery	Equipment	Software	Total
Acquisition costs	¥ —	¥ 1,944	¥ 3	¥ 1,947	\$ —	\$ 21,600	\$ 33	\$ 21,633
Accumulated depreciation/amortization	—	839	1	840	—	9,322	11	9,333
Net book value	¥ —	¥ 1,105	¥ 2	¥ 1,107	\$ —	\$ 12,278	\$ 22	\$ 12,300

2007	Millions of yen			
	Machinery	Equipment	Software	Total
Acquisition costs	¥ 137	¥ 1,977	¥ 3	¥ 2,117
Accumulated depreciation/amortization	97	1,142	0	1,239
Net book value	¥ 40	¥ 835	¥ 3	¥ 878

Rental expenses, primarily for office space and equipment, amounted to ¥4,358 million (\$48,422 thousand), ¥4,092 million and ¥3,912 million for the years ended December 31, 2008, 2007, and 2006, respectively.

Lease payments relating to finance leases accounted for as operating leases included in the above amounts totaled ¥387 million (\$4,300

thousand), ¥453 million and ¥530 million for the years ended December 31, 2008, 2007 and 2006, respectively, which are equal to the depreciation/amortization expense of the leased assets computed by the straight-line method over the respective lease terms. Future minimum lease payments subsequent to December 31, 2008 for finance leases accounted for as operating leases are summarized as follows:

	Millions of yen	Thousands of U.S. dollars
2009	¥ 393	\$ 4,367
2010 and thereafter	714	7,933
	¥ 1,107	\$ 12,300

## 13. Securities

Securities consisted of marketable securities and non-marketable securities classified as other securities. The acquisition cost, carrying value and unrealized gain (loss) on marketable securities at December 31, 2008 and 2007 are summarized by type of security as follows:

### (a) Other securities with determinable market value

2008	Millions of yen			Thousands of U.S. dollars		
	Acquisition cost	Carrying value	Unrealized gain (loss)	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:						
Stocks	¥ 2,780	¥ 5,761	¥ 2,981	\$ 30,889	\$ 64,011	\$ 33,122
Bonds	2,000	2,000	0	22,222	22,222	0
Other	25,000	25,000	0	277,778	277,778	0
Subtotal	29,780	32,761	2,981	330,889	364,011	33,122
Securities whose carrying value does not exceed their acquisition cost:						
Bonds	30,400	29,690	(710)	337,778	329,889	(7,889)
Other	6,000	6,000	(0)	66,667	66,667	(0)
Subtotal	36,400	35,690	(710)	404,445	396,556	(7,889)
Total	¥ 66,180	¥ 68,451	¥ 2,271	\$ 735,334	\$ 760,567	\$ 25,233

2007	Millions of yen		
	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities whose carrying value exceeds their acquisition cost:			
Stocks	¥ 2,775	¥ 7,534	¥ 4,759
Bonds	2,000	2,005	5
Other	33,000	33,026	26
Subtotal	37,775	42,565	4,790
Securities whose carrying value does not exceed their acquisition cost:			
Bonds	38,684	38,520	(164)
Subtotal	38,684	38,520	(164)
Total	¥ 76,459	¥ 81,085	¥ 4,626

**(b) Sales of securities classified as other securities**

Sales proceeds from, and aggregate gain and loss on, sales of securities classified as other securities for the years ended December 31, 2008, 2007 and 2006 are summarized as follows:

	Millions of yen			Thousands of U.S. dollars
	2008	2007	2006	2008
Sales proceeds	¥ —	¥ 972	¥ 2,741	\$ —
Aggregate gain	—	2	2,231	—
Aggregate loss	—	(20)	—	—

**(c) Securities without determinable market value**

	Millions of yen		Thousands of U.S. dollars
	2008	2007	2008
Other securities:			
Unlisted securities, except for those traded on the OTC market and other	¥ 422	¥ 1,066	\$ 4,689

**(d) The redemption schedule for other securities with maturity dates is summarized as follows:**

2008	Millions of yen		Thousands of U.S. dollars	
	Due in one year or less	Due after one year through five years	Due in one year or less	Due after one year through five years
Other securities with maturity dates:				
Corporate bonds	¥ 12,721	¥ 7,975	\$ 141,344	\$ 88,611
Other bonds	10,994	—	122,156	—
Other	31,000	—	344,444	—
Total	¥ 54,715	¥ 7,975	\$ 607,944	\$ 88,611

2007	Millions of yen	
	Due in one year or less	Due after one year through five years
Other securities with maturity dates:		
Corporate bonds	¥ 11,997	¥ 8,558
Other bonds	19,970	—
Other	33,025	—
Total	¥ 64,992	¥ 8,558



## 14. Derivatives

The Company utilizes derivative financial instruments such as forward foreign exchange contracts, currency swaps and interest-rate swaps for the purpose of hedging its foreign currency and interest rate risks, but does not enter into such transactions for speculative trading purposes.

The Company is exposed to certain market risk arising from the forward foreign exchange contracts and swap agreements referred to above. The Company is also exposed to the risk of credit loss in the event of non-performance by its counterparties to these derivatives positions; however, the Company does not anticipate non-

performance by any of its counterparties, all of whom are financial institutions with high credit ratings.

The Company enters into these derivatives transactions in accordance with the policies and strategies established by management. Routine operations involving derivatives transactions are subject to strict oversight by management.

The contract amounts of the derivatives in the table below are nominal amounts or notional principal amounts and thus do not fully reflect the potential risk associated with these open derivatives positions.

### (a) Currency-related transactions

2008	Millions of yen			Thousands of U.S. dollars		
	Notional amounts	Estimated fair value	Unrealized gain	Notional amounts	Estimated fair value	Unrealized gain
Currency swap:						
Swiss francs	¥ 2,468	¥ 2,588	¥ 120	\$ 27,422	\$ 28,756	\$ 1,333
Total	¥ 2,468	¥ 2,588	¥ 120	\$ 27,422	\$ 28,756	\$ 1,333

There were no open derivatives positions of currency-related transactions at December 31, 2007.

### (b) Interest rate-related transactions

There were no open derivatives positions of interest rate-related transactions at December 31, 2008 or 2007.

## 15. Segment Information

The Company and its consolidated subsidiaries are engaged principally in the manufacture and sales of pharmaceutical products in Japan and overseas.

### Business segments

For the years ended December 31, 2008, 2007 and 2006, as the Company and its consolidated subsidiaries operated solely in the pharmaceutical business segment, the disclosure of business segment information has been omitted.

### Geographical segments

As revenues and total assets of the overseas consolidated subsidiaries constituted less than 10% of the consolidated totals for the years ended December 31, 2008, 2007 and 2006, the disclosure of geographical segment information has been omitted.

### Overseas sales

Overseas sales for the years ended December 31, 2008 and 2007 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2008	2007	2008
Overseas sales	¥ 33,804	¥ 36,444	\$ 375,600
Total consolidated revenues	¥ 326,938	¥ 344,808	\$ 3,632,644
Overseas sales as a percentage of total consolidated revenues	10.3%	10.6%	10.3%

As overseas sales was less than 10% of total consolidated revenues for the year ended December 31, 2006, the disclosure of overseas sales information has been omitted.

## 16. Loss on Impairment of Fixed Assets

The Company and its domestic consolidated subsidiaries determined that substantially the entire business constitutes a single cash generating unit since the Company and its consolidated subsidiaries are engaged principally in the manufacture and sales of pharmaceutical products. However, the Company and its domestic consolidated subsidiaries determine whether an asset is impaired on an individual asset basis if the asset is considered idle or to be disposed of.

Loss on impairment of idle assets and assets to be disposed of, which was recognized by reducing the book value of such assets

to their respective net realizable value, for the years ended December 31, 2008, 2007 and 2006 amounted to ¥748 million (\$8,311 thousand), ¥32 million and ¥107 million, respectively. Loss on impairment of idle assets and assets to be disposed of for the year ended December 31, 2008 mainly consisted of losses on land in the aggregate amount of ¥178 million (\$1,978 thousand), buildings and structures in the aggregate amount of ¥447 million (\$4,967 thousand), and others in the aggregate amount of ¥123 million (\$1,366 thousand).

## 17. Contingent Liabilities

The Company was contingently liable as guarantor of loan obligations for its employees of ¥500 million (\$5,556 thousand) and ¥582 million in the aggregate at December 31, 2008 and 2007, respectively.

## 18. Supplementary Information for Consolidated Statements of Changes in Net Assets

### (a) Type and number of outstanding shares

2008 Type of shares	Number of shares			
	Balance at beginning of year	Increase in shares during the year	Decrease in shares during the year	Balance at end of year
Issued stock:				
Common stock (*1)	559,636,061	49,828	—	559,685,889
Total	559,636,061	49,828	—	559,685,889
Treasury stock:				
Common stock (*2,3)	14,831,246	52,309	11,359	14,872,196
Total	14,831,246	52,309	11,359	14,872,196

(\*1) The number of outstanding shares of common stock increased by 49,828 shares due to the conversion of convertible bonds.

(\*2) Treasury stock increased by 52,309 shares due to the repurchase of fractional shares of less than one unit.

(\*3) Treasury stock decreased by 11,359 due to the exercise of stock options resulting in a decrease of 3,600 shares and the sale of 7,759 fractional shares of less than one unit.

2007 Type of shares	Number of shares			
	Balance at beginning of year	Increase in shares during the year	Decrease in shares during the year	Balance at end of year
Issued stock:				
Common stock (*1)	559,493,113	142,948	—	559,636,061
Total	559,493,113	142,948	—	559,636,061
Treasury stock:				
Common stock (*2,3)	5,363,173	9,512,367	44,294	14,831,246
Total	5,363,173	9,512,367	44,294	14,831,246

(\*1) The number of outstanding shares of common stock increased by 142,948 shares due to the conversion of convertible bonds.

(\*2) Treasury stock increased by 9,512,367 shares due to the repurchase of 9,500,000 shares of common stock and the repurchase of 12,367 fractional shares of less than one unit.

(\*3) Treasury stock decreased by 44,294 due to the exercise of stock options resulting in a decrease of 43,400 shares and the sale of 894 fractional shares of less than one unit.

### (b) Dividends

#### (1) Dividends paid to shareholders

Date of approval	Resolution approved by	Type of shares	Amount (Millions of yen)	Amount (Thousands of U.S. dollars)	Amount per share (Yen)	Amount per share (U.S. dollars)	Shareholders' cut-off date	Effective date
March 27, 2008	Annual general meeting of shareholders	Common stock	¥ 8,172	\$ 90,800	¥ 15	\$ 0.17	December 31, 2007	March 28, 2008
July 31, 2008	Board of directors	Common stock	¥ 8,173	\$ 90,811	¥ 15	\$ 0.17	June 30, 2008	September 9, 2008

Date of approval	Resolution approved by	Type of shares	Amount (Millions of yen)	Amount per share (Yen)	Shareholders' cut-off date	Effective date
March 23, 2007	Annual general meeting of shareholders	Common stock	¥ 9,974	¥ 18	December 31, 2006	March 26, 2007
July 31, 2007	Board of directors	Common stock	¥ 8,172	¥ 15	June 30, 2007	September 7, 2007

(2) Dividends with a shareholders' cut-off date during the current fiscal year but an effective date subsequent to the current fiscal year

Date of approval	Resolution approved by	Type of shares	Amount (Millions of Yen)	Amount (Thousands of U.S. dollars)	Paid from	Amount per share (Yen)	Amount per share (U.S. dollars)	Shareholders' cut-off date	Effective date
March 25, 2009	Annual general meeting of shareholders	Common stock	¥ 10,351	\$ 115,011	Retained earnings	¥ 19	\$ 0.21	December 31, 2008	March 26, 2009

Date of approval	Resolution approved by	Type of shares	Amount (Millions of Yen)	Paid from	Amount per share (Yen)	Shareholders' cut-off date	Effective date
March 27, 2008	Annual general meeting of shareholders	Common stock	¥ 8,172	Retained earnings	¥ 15	December 31, 2007	March 28, 2008

## 19. Supplementary Cash Flow Information

(a) Cash and cash equivalents at December 31, 2008 and 2007 classified by account on the balance sheets were as follows:

	Millions of yen		Thousands of U.S. dollars
	2008	2007	2008
Cash on hand and at bank	¥ 70,768	¥ 73,168	\$ 786,311
Short-term securities with maturity of within three months	—	555	—
Time deposits over three months	(116)	—	(1,289)
Cash and cash equivalents	¥ 70,652	¥ 73,723	\$ 785,022

(b) Significant non-cash transactions were as follows:

Convertible bonds and stock subscription rights

	Millions of yen			Thousands of U.S. dollars
	2008	2007	2006	2008
Decrease in convertible bonds resulting from conversion	¥ 38	¥ 109	¥ 296	\$ 422
Decrease in bonds with stock subscription rights resulting from exercise	¥ —	¥ —	¥ 601	\$ —

## 20. Related Party Transactions

The Company is substantively a 61.5%-owned consolidated subsidiary of Roche Pharmholding B.V. (the "parent company"). The parent company is indirectly owned by Roche Holding Ltd. ("Roche Holding"). The Company principally purchases raw materials from F. Hoffmann-La Roche Ltd. ("Roche"), a consoli-

dated subsidiary of Roche Holding.

Significant balances at December 31, 2008 and 2007 and transactions for the years ended December 31, 2008, 2007 and 2006 with related parties are summarized as follows:

	Millions of yen		Thousands of U.S. dollars
	2008	2007	2008
Balances:			
Parent company:			
Bonds with stock subscription rights	¥ —	¥ 301	\$ —
Other payables	¥ —	¥ 0	\$ —
Roche:			
Trade payables	¥ 21,452	¥ 10,608	\$ 238,356

	Millions of yen			Thousands of U.S. dollars
	2008	2007	2006	2008
Transactions:				
Parent company:				
Interest expense on bonds	¥ 2	¥ 3	¥ 3	\$ 22
Roche:				
Purchases of raw materials	¥ 69,695	¥ 54,279	¥ 70,394	\$ 774,389

## 21. Stock Option Plans

At December 31, 2008 and 2007, the Company had the following stock option plans approved by its shareholders in accordance with the Law:

2008	2007 plan	2006 plan	2005 plan	2004 plan	2003 plan
Date of approval by shareholders	April 9, 2007	April 3, 2006	April 1, 2005	April 5, 2004	August 5, 2003
Grantees	6 directors and 110 employees of the Company and 3 directors and 4 employees of a subsidiary	6 directors and 111 employees of the Company	6 directors and 24 employees of the Company	6 directors and 19 employees of the Company and 1 director of a subsidiary	5 directors and 23 employees of the Company and 1 director of a subsidiary
Type of stock	Common stock	Common stock	Common stock	Common stock	Common stock
Number of shares granted	355,000	344,000	252,000	232,000	231,000
Exercise price (yen)	¥ 3,039	¥ 2,245	¥ 1,649	¥ 1,675	¥ 1,454
Exercise price (U.S. dollars)	\$ 33.77	\$ 24.94	\$ 18.32	\$ 18.61	\$ 16.16
Exercisable period	April 1, 2009 - March 23, 2017	April 1, 2008 - March 23, 2016	April 1, 2007 - March 23, 2015	April 1, 2006 - March 25, 2014	July 1, 2005 - June 25, 2013
	2007 plan	2006 plan	2005 plan	2004 plan	2003 plan
<b>Non-vested</b> (number of shares)					
Outstanding at the beginning of the year	355,000	344,000	—	—	—
Granted during the year	—	—	—	—	—
Forfeited during the year	—	—	—	—	—
Vested during the year	—	344,000	—	—	—
Outstanding at the end of the year	355,000	—	—	—	—
<b>Vested</b> (number of shares)					
Outstanding at the beginning of the year	—	—	252,000	218,000	131,200
Vested during the year	—	344,000	—	—	—
Exercised during the year	—	—	—	—	3,600
Forfeited during the year	—	—	—	—	—
Outstanding at the end of the year	—	344,000	252,000	218,000	127,600
Weighted-average market price (yen)	¥ —	¥ —	¥ —	¥ —	¥ 1,665
Weighted-average market price (U.S. dollars)	\$ —	\$ —	\$ —	\$ —	\$ 18.50



2007	2007 plan	2006 plan	2005 plan	2004 plan	2003 plan
Date of approval by shareholders	April 9, 2007	April 3, 2006	April 1, 2005	April 5, 2004	August 5, 2003
Grantees	6 directors and 110 employees of the Company and 3 directors and 4 employees of a subsidiary	6 directors and 111 employees of the Company	6 directors and 24 employees of the Company	6 directors and 19 employees of the Company and 1 director of a subsidiary	5 directors and 23 employees of the Company and 1 director of a subsidiary
Type of stock	Common stock	Common stock	Common stock	Common stock	Common stock
Number of shares granted	355,000	344,000	252,000	232,000	231,000
Exercise price (yen)	¥ 3,039	¥ 2,245	¥ 1,649	¥ 1,675	¥ 1,454
Exercisable period	April 1, 2009 - March 23, 2017	April 1, 2008 - March 23, 2016	April 1, 2007 - March 23, 2015	April 1, 2006 - March 25, 2014	July 1, 2005 - June 25, 2013
	2007 plan	2006 plan	2005 plan	2004 plan	2003 plan
<b>Non-vested</b> (number of shares)					
Outstanding at the beginning of the year	—	344,000	252,000	—	—
Granted during the year	355,000	—	—	—	—
Forfeited during the year	—	—	—	—	—
Vested during the year	—	—	252,000	—	—
Outstanding at the end of the year	355,000	344,000	—	—	—
<b>Vested</b> (number of shares)					
Outstanding at the beginning of the year	—	—	—	225,000	167,600
Vested during the year	—	—	252,000	—	—
Exercised during the year	—	—	—	7,000	36,400
Forfeited during the year	—	—	—	—	—
Outstanding at the end of the year	—	—	252,000	218,000	131,200
Weighted-average market price (yen)	¥ —	¥ —	¥ —	¥ 2,971	¥ 2,511

## 22. Amounts Per Share

	Yen			U.S. dollars
	2008	2007	2006	2008
Net income:				
Basic	¥ 72.07	¥ 73.23	¥ 69.35	\$ 0.80
Diluted	¥ 72.04	¥ 73.16	¥ 69.26	\$ 0.80
	Yen		U.S. dollars	
	2008	2007	2008	
Net assets	¥ 725.18	¥ 703.80	\$ 8.06	

Basic net income per share is computed based on the net income available for distribution to shareholders of common stock and the weighted-average number of shares of common stock outstanding during each year. Diluted net income per share is computed based on the net income available for distribution to the shareholders and the weighted-average number of shares of common stock outstanding during each year after giving effect to the dilutive potential of shares of common stock to be issued upon the conversion of convertible bonds, and the exercise of stock subscription rights and stock

options. The potential dilutive impact of 202,440 shares, 544,350 shares and 822,687 shares of common stock has been included in the computation of the weighted-average number of shares for the years ended December 31, 2008, 2007 and 2006, respectively.

Net assets per share are computed based on the net assets available for distribution to the shareholders of common stock (i.e., net assets excluding minority interests and stock subscription rights) and the number of shares of common stock outstanding at each balance sheet date.

Consolidated Financial Statements:

## Independent Auditors' Report



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### Report of Independent Auditors

The Board of Directors  
Chugai Pharmaceutical Co., Ltd.

We have audited the accompanying consolidated balance sheets of Chugai Pharmaceutical Co., Ltd. and consolidated subsidiaries as of December 31, 2007 and 2008, and the related consolidated statements of income, changes in net assets, and cash flows for each of the three years in the period ended December 31, 2008, all expressed in yen. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Chugai Pharmaceutical Co., Ltd. and consolidated subsidiaries at December 31, 2007 and 2008, and the consolidated results of their operations and their cash flows for each of the three years in the period ended December 31, 2008 in conformity with accounting principles generally accepted in Japan.

#### *Supplemental Information*

As disclosed in Note 3(iii), effective January 1, 2007, the Company has changed its classification of patents and licensing-related income in the consolidated statements of income.

The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended December 31, 2008 are presented solely for convenience. Our audit also included the translation of yen amounts into U.S. dollar amounts and, in our opinion, such translation has been made on the basis described in Note 4.

*Ernst & Young ShinNihon LLC*

March 25, 2009

A member firm of Ernst & Young Global Limited

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# Development Pipeline (As of February 4, 2009)

Development Code (*Additional Indication)	Indication	Status Phase I	Phase II	Phase III	Filed	Approved
Oncology						
R340*	Colorectal cancer				'08/2	
	Gastric cancer					
R435*	Non-small cell lung cancer				'08/11	
	Colon cancer (adjuvant)			(Global study)		
	Gastric cancer			(Global study)		
	Breast cancer (adjuvant)			(Global study)		
	Breast cancer					
	R597*	Gastric cancer			(Global study)	
EPOCH*	Chemotherapy-induced anemia					
R1415*	Pancreatic cancer					
R744	Chemotherapy-induced anemia					
MRA*	Multiple myeloma		(Overseas)			
R1273	Breast cancer, etc.					
TP300	Colorectal cancer, etc.	(Overseas)				
CIF(R7167)	Solid tumors	(Overseas)				
GC33	Liver cancer	(Overseas)				
R7159 (GA101)	Non-Hodgkin's lymphoma					
CKI27 (R7304)	Solid tumors	(Overseas)				
R1507	Solid tumors					
Renal Diseases						
R744	Renal anemia					
Bone and Joint						
MRA*	Rheumatoid arthritis				'09/1 (Overseas / EU)	
					'07/11 (Overseas / US)	
	Systemic onset juvenile idiopathic arthritis (sJIA)			(Overseas)		
	Rheumatoid arthritis (new formulation: subcutaneous injection)		(I / II)			
R1594	Rheumatoid arthritis			(Global study)		
ED-71	Osteoporosis					
R484	Osteoporosis			(II / III)		
Transplant, Immunology and Infectious diseases						
R964*	Compensated liver cirrhosis caused by hepatitis C virus			(II / III)		
R442*	Compensated liver cirrhosis caused by hepatitis C virus			(II / III)		
	Chronic hepatitis B			(II / III)		
MRA*	Crohn's disease					
	Castleman's disease	(Overseas)				
	Systemic lupus erythematosus (SLE)	(Overseas)				
NA808	Chronic hepatitis C	(Japan)				
		(Overseas)				
Other diseases						
EPOCH*	Predeposit of autologous blood transfusion				'02/3	
R1678	Schizophrenia		(Global study)			
GM-611	Diabetic gastroparesis		(Japan)			
			(Overseas)			
	Irritable bowel syndrome (IBS)		(Overseas)			
R1583 (ITM-077)	Type II diabetes					
CSG452 (R7201)	Type II diabetes					
R1579	Type II diabetes					

Generic Name / Product Name	Origin (Collaborator)	Mode of Action
capecitabine / Xeloda	Roche	Antimetabolite, 5-FU derivative (Oral)
bevacizumab / Avastin	Roche / Genentech	Anti-VEGF (Vascular Endothelial Growth Factor) humanized monoclonal antibody (Injection)
trastuzumab / Herceptin	Roche / Genentech	Anti-HER2 humanized monoclonal antibody (Injection)
epoetin beta / Epogin	In-house	Recombinant human erythropoietin (Injection)
erlotinib / Tarceva	Roche / Genentech / OSI	EGFR tyrosine kinase inhibitor (Oral)
(Overseas name: Mircera)	Roche	Continuous erythropoietin receptor activator (Injection)
tocilizumab / Actemra	In-house (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody (Injection)
pertuzumab	Roche / Genentech	HER dimerization inhibitory humanized monoclonal antibody (Injection)
—	In-house	Topoisomerase I inhibitor (Injection)
—	In-house (Roche)	(Oral)
—	In-house	Humanized anti-Glypican-3 monoclonal antibody (Injection)
—	Roche / GlycArt	Humanized anti-CD20 monoclonal antibody (Injection)
—	In-house (Roche)	(Oral)
—	Roche	Human anti-IGF-1R monoclonal antibody (Injection)
(Overseas name: Mircera)	Roche	Continuous erythropoietin receptor activator (Injection)
tocilizumab / Actemra, RoActemra	In-house (Roche)	Humanized anti-human IL-6 receptor monoclonal antibody (Injection)
tocilizumab / Actemra	In-house (Roche)	
tocilizumab / Actemra	In-house (Roche)	
ocrelizumab	Roche / Genentech	Humanized anti-CD20 monoclonal antibody (Injection)
eldecalcitol	In-house (Taisho Pharmaceutical)	Activated Vitamin D <sub>3</sub> derivative (Oral)
ibandronate sodium hydrate (Overseas name: Bonviva, Boniva)	Roche (Taisho Pharmaceutical)	Bisphosphonate (Injection) Bisphosphonate (Oral)
ribavirin / Copegus	Roche	Anti-viral agent in combination with Pegasys (Oral)
peginterferon alfa-2a / Pegasys	Roche	Peginterferon alfa-2a agent (recombinant) (Injection)
tocilizumab / Actemra	In-house	Humanized anti-human IL-6 receptor monoclonal antibody (Injection)
tocilizumab / Actemra	In-house (Roche)	
—	In-house	(Injection)
epoetin beta / Epogin	In-house	Recombinant human erythropoietin (Injection)
—	Roche	GLYT1 inhibitor (Oral)
mitomycin	In-house	Motilin agonist, Recovery of gastrointestinal motility (Oral)
taspeglutide	Roche / Ipsen (Teijin)	GLP-1 analogue (Injection)
—	In-house (Roche)	(Oral)
—	Roche	DPP-IV inhibitor (Oral)



## Basic Information

### Basic Information on the Pharmaceutical Industry

#### Overview of Domestic Pharmaceutical Market and NHI Drug Price Revisions

##### Trends in the National Medical Insurance System

Without medical system reforms, Japan's national medical expenses will increase at an annual rate of approximately 3% to 4% going forward. In FY2006, national medical expenses totaled ¥33,127.6 billion, a ¥1.3 billion decrease from the previous year. The rapid aging of Japan's society presents the serious challenge of how to efficiently manage the marked increase in medical costs for the elderly.

##### National Health Insurance (NHI) Drug Price Revision

The Ministry of Health, Labour and Welfare (MHLW) generally reviews drug reimbursement prices every two years and sets standard prices (reimbursement prices) so that pharmaceuticals prescribed under the health insurance system are at a level approximating their actual

market price. It does this by investigating the prices and volumes of all prescription drug transactions during a given period. In FY2008, drug reimbursement prices declined by 1.2% overall on a medical cost basis, or 5.2% on a reimbursement price basis.

##### Changes to Promote Use of Generic Drugs<sup>\*1</sup>

MHLW is instituting changes to prescription rules in line with an Action Program announced in October 2007 to promote the safe use of generic drugs. Until now, physicians have ticked the "Can be substituted" box on the prescription form if they had determined that a generic drug was acceptable. However, from April 2008 the prescription form changed so that they need to tick a box only if they do not agree to substitution by a generic drug. The Japanese government aims to trim medical expenditure by raising the generic drug share of prescription drug volume from the current level of approximately 18.7% (as of 2007) to 30% by 2012.

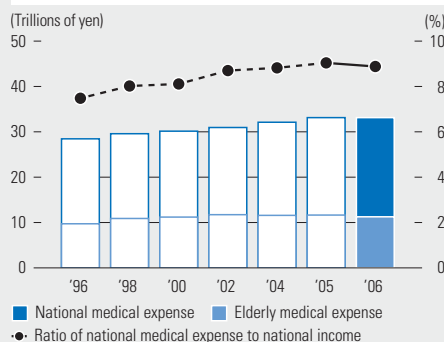
##### Advanced Elderly Healthcare System

Under reforms to Japan's healthcare system implemented in 2006, a new healthcare insurance system has been instituted for all elderly persons aged 75 or over<sup>\*2</sup>. A greater burden is expected to fall on the current working population for healthcare for the elderly amid Japan's aging and low-birthrate society. The new system differs substantially from the existing elderly healthcare system in terms of funding, since approximately 10% of the new system's budget will be covered by insurance premiums borne equally by elderly people. In addition, separate reforms are in progress for the system covering medical treatment fees.

<sup>\*1</sup> The term "generic drug" refers to a drug manufactured by another pharmaceutical company after the expiry of the patent protection for the drug. It has the same active ingredients and efficacy as the original formulation. Because companies do not incur development costs, a generic drug can be 20% to 70% cheaper than the original drug.

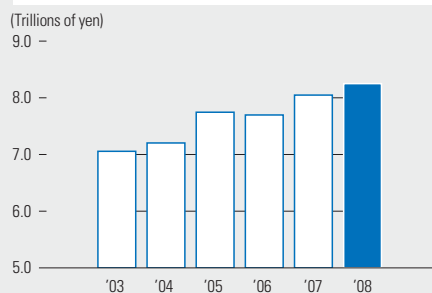
<sup>\*2</sup> 65 or over with certain disabilities.

**Trends in National Medical Insurance System and Elderly Medical Expense**



Source: Overview of National Medical Expense by Ministry of Health, Labour and Welfare.  
Note: National income is based on the actual results of the System of National Accounts (announced in June 2008 by the Cabinet office).

**Prescription Drug Market**



Source: IMS Pharmaceutical Market Statistics (Reimbursement price basis), Dec. 2003-2008 MAT, Reproduction without consent is prohibited.

**Impact of National Health Insurance Price Revision**

NHI Price Reduction Rate (%)	2004	2006	2008
Industry Average	4.2	6.7	5.2
Chugai	4.3	7.2	7.2

Source: Company data

## Oncology Field

### Overview of Diseases and Treatment Methods

#### Leading Cause of Death in Japan

Cancer has been the single most common cause of death in Japan since 1981. In 2007, approximately 336,000 people died of cancer, 30.4% of all deaths in that year and the highest figure recorded since government surveys began in 1899.

#### Establishment of the Basic Act for Anti-Cancer Measures and Changes in the Healthcare Environment

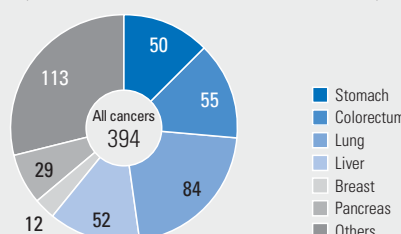
In June 2006, the Diet enacted the Basic Act for Anti-Cancer Measures, which stipulates the obligation of national and local governments to promote measures to fight cancer. The basic principle of the law is to develop optimal cancer treatment systems in every corner of the country so that patients can receive optimal treatment in accordance to their wishes (“the availability of optimal treatment” for cancer patients). The law includes provisions for (1) improvement of cancer prevention and treatment technologies, (2) development of oncologists and “hub” institutions specialized in cancer, and (3) enhanced provision of information to patients.

#### The Changing Cancer Treatment Environment from the Patient's Perspective

Measures introduced as part of the patient-centered cancer treatment policy are bringing about major changes in the Japanese cancer treatment environment. The Basic Act for Anticancer Measures requires the national government to formulate a basic plan and policies to fight cancer after listening to the opinions of patients, their families, and experts. As a result of these patient-centered policies, great progress is being made in the training of oncologists and other healthcare professionals such as nurses and pharmacists working with oncologists. Advances have also been seen in efforts such as establishing networks among local medical institutions by designating inter-regional hub cancer centers. Japan's first medical oncologists were certified in 2006 and as of April 2008 there were 205 such specialists. Today, there is a growing multidisciplinary approach involving oncologists and other healthcare professionals such as nurses, pharmacists, and nutritionists. The “drug lag”

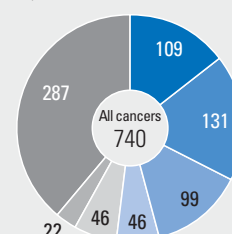
**Cancer Mortality (estimates for 2010)**

(Thousands of cases)



**Cancer Incidence (estimates for 2010)**

(Thousands of cases)



Source: Cancer White Paper-Incidence/Death/Prognosis-2004 (Shinohara Shuppan Shinsha).

problem—the inability of Japanese patients to gain access to global standard or state-of-the-art treatments—has also been addressed through the establishment of the Investigational Committee for Usage of Unapproved Drugs. Other significant changes reflecting the adoption of a patient-centered approach to treatment in Japan include the establishment of treatment guidelines.

#### Solving the Drug Lag Problem

In January 2005, the Japanese Ministry of Health, Labour and Welfare established the Investigational Committee for Usage of Unapproved Drugs as one means of helping solve the drug lag problem. The Committee is charged with investigating the clinical necessity and the appropriateness of usage of drugs already approved in Europe and the United States but not yet in Japan. This is to promote the clinical trials of those drugs in Japan facilitating access by patients.

The Ministry has also reinforced several functions of the Pharmaceutical and Medical Devices Agency, an independent administrative institution responsible for reviewing of drugs and medical devices for approval. These include increasing the number of staff involved in the reviewing process, introducing a project management system under which a dedicated staff is appointed to oversee the progress, providing guidelines on global clinical studies, clarifying reviewing criteria, and offering an improved consultancy function. By 2011, the aim is to shorten the period from new drug development through approval by two-and-a-half years, and to shorten the reviewing process to one year.

#### Changes in Treatment Methods

Cancer treatment is increasingly being based on a multidisciplinary approach that combines surgery, radiation therapy, and anti-cancer agents. In particular, the field of anti-cancer agents is evolving, and highly innovative medications such as molecular targeted drugs have been introduced. This has brought about a dramatic improvement in treatment outcomes in colorectal, lung and breast cancer, malignant lymphoma, and other forms of cancer. As the adverse reaction profiles of these drugs differ from those of conventional anti-cancer agents, it is now recognized that there is a need for cancer drug therapy specialists with a thorough knowledge of drug mechanisms of action, pharmacokinetics, and the effects of co-administration with other drugs. Furthermore, in recent years, there has been a rapid increase in the number of cancer patients receiving drug treatment on an out-patient basis, which allows them to maintain their normal lifestyles. To ensure the medical safety of chemotherapy for these patients, a multidisciplinary approach involving close collaboration between oncologists and other healthcare professionals has become essential.

### Overview of Products and Development Projects

#### Neutrogin

Neutrogin is a recombinant human granulocyte-stimulating factor (G-CSF) developed by Chugai. G-CSF is a hematopoietic factor that specifically promotes the differentiation and growth of cells of the granulocytic series (especially neutrophils) in bone marrow. Neutrogin has the effect of reducing the period

when the neutrophil count is low and promoting recovery in various types of neutropenia. Neutrogin is used to treat neutropenia that occurs as a side effect of anti-cancer agents, mobilize peripheral blood progenitor cells, promote neutrophilia after hematopoietic cell transplantation, and treat neutropenia associated with myelodysplastic syndrome, aplastic anemia, HIV infection, and immunosuppressive therapy following kidney transplantation. Overseas, Neutrogin is sold under the name Granocyte.

#### Herceptin

Herceptin is a targeted monoclonal antibody that works across all stages of human epidermal growth factor receptor type 2 (HER2)-positive breast cancer. The product specifically activates the immune system and suppresses the HER2 protein that contributes to tumor cell growth.

In Japan, the product is indicated for the treatment of patients with metastatic breast cancer with HER2 over-expression and now also for postoperative adjuvant therapy of patients with early HER2-positive breast cancer.

#### Rituxan

Rituxan is a targeted monoclonal antibody for the treatment of CD20-positive, B-cell non-Hodgkin's lymphoma. It works by binding to a specific protein (the CD20 antigen) found on the surface of normal and malignant B cells, activating the immune system to eliminate the marked cells. These are then replaced by healthy B cells from the bone marrow. The efficacy of Rituxan has been confirmed in many overseas and domestic clinical trials, and it is now the standard therapy for non-Hodgkin's lymphoma. As a result, it has gained wide recognition internationally. In Japan,

Rituxan is marketed jointly by Chugai and Zenyaku Kogyo Co., Ltd. Outside Japan and North America, Rituxan is sold under the brand-name MabThera by the Roche Group.

#### Avastin

The humanized anti-VEGF (vascular endothelial growth factor) monoclonal antibody Avastin is the first anti-angiogenesis agent in the world to receive approval. Avastin inhibits angiogenesis — the growth of the network of blood vessels that supply nutrients and oxygen to cancerous tissues.

Avastin is marketed globally by Roche Group companies. We plan to investigate the efficacy of combinations of Avastin and Chugai's other anti-cancer agents. We expect Avastin to play a key role in improving Chugai's presence in oncology in Japan.

In Japan, Avastin is currently approved for the treatment of advanced and recurrent colorectal cancer.

#### Kytril

Kytril is a selective inhibitor of the 5-HT<sub>3</sub> (serotonin) receptors found in afferent vagal nerve endings distributed mainly along the gastrointestinal tract. It is widely prescribed as an antiemetic agent to alleviate nausea and vomiting caused by the adverse reactions due to anti-cancer agents.

#### Xeloda

Xeloda was developed at the Kamakura Research Laboratories of the former Nippon Roche to improve the efficacy and safety of Furtulon. After Xeloda is absorbed by the body, it is gradually metabolized by certain enzymes present in high concentrations in the

liver and tumors and is eventually converted into 5-FU within tumors. It is an innovative drug with high target specificity. Xeloda is the standard treatment for metastatic breast cancer and colorectal cancer in more than 100 countries around the world. In Japan, Xeloda is currently used to treat inoperable or recurrent breast cancer and as a postoperative adjuvant chemotherapy for colon cancer.

#### Tarceva

Tarceva is a targeted, small-molecule drug that inhibits the activation of human epidermal growth factor receptor (EGFR) by blocking the enzyme tyrosine kinase. EGFR plays a key role in the growth, progression and metastasis of cancer. The product is marketed overseas by Roche, Genentech and OSI Pharmaceuticals. It is approved in Europe and the United States for the second-line treatment of advanced non-small cell lung cancer and the first-line treatment of metastatic pancreatic cancer. In Japan, Tarceva is currently approved for the second-line or later treatment of non-small cell lung cancer.

#### Femara

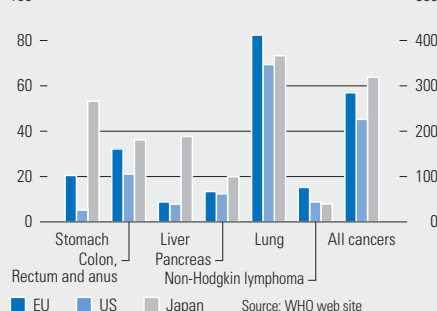
We commenced joint marketing of Femara, an aromatase inhibitor, with Novartis Pharma K.K., Femara's manufacturer and distributor, in May 2006. Femara is one of the standard drugs used in endocrine therapies for breast cancer and it has already been approved in over 100 countries around the world as a breast cancer treatment for postmenopausal women.

Although it is the third agent to come into the domestic market as a third generation aromatase inhibitor, we will aim to differentiate Femara from competitor products using the strong evidence in its favor: (1) Femara is the first aromatase inhibitor shown in large-scale clinical trials to be useful as an extended adjuvant therapy (adjuvant therapy after five years of standard tamoxifen therapy after surgery for breast cancer); (2) large-scale clinical trials overseas have confirmed that Femara reduces the risk of cancer recurrence as an initial adjuvant therapy commencing immediately after surgery; and (3) large-scale clinical trials have confirmed that Femara is more effective than tamoxifen in treating advanced and recurrent breast cancer.

### Cancer Mortality Rate (2005)

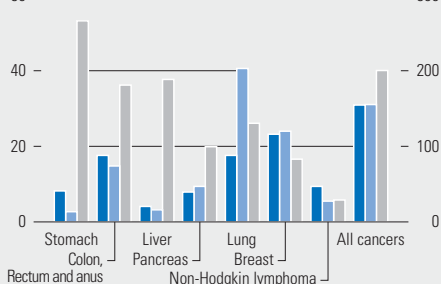
#### <Male>

per 100,000 population  
(By cancer type)



#### <Female>

per 100,000 population  
(By cancer type)



**TP300**

TP300 is a topoisomerase\* I inhibitor which prevents the growth of cancer cells by obstructing the activity of an enzyme called topoisomerase I, which contributes to the replication of DNA. With existing topoisomerase I inhibitors, concentrations in the blood following administration vary from patient to patient; these agents can also cause severe diarrhea as a adverse reaction. TP300 is designed to overcome these disadvantages, and we expect that it will demonstrate a high level of safety and efficacy.

\* Topoisomerase inhibitors designed as anti-cancer agents suppress the functioning of topoisomerase I or II in order to inhibit the synthesis of deoxyribonucleic acid (DNA). Topoisomerase is an enzyme that has the function of assisting the replication of the genetic code by unknotting the double helical configuration of DNA, by temporarily loosening the binding of the DNA to manifest the genetic code. Topoisomerase I cuts one strand of DNA and Topoisomerase II cuts two strands.

**CIF (R7167) / CKI27 (R7304)**

CIF and CKI27 are targeted small-molecule agents developed by Chugai. Chugai has licensed them to Roche, and we are working on their development overseas.

**GC33**

GC33, a humanized antibody from Chugai research, targets glypican-3 proteins which are specifically expressed in liver cancer. The project involves joint research between Chugai and Tokyo University, as well as clinical proteomics work by PharmaLogicals Research, a joint venture in which Chugai participates. Phase I overseas clinical trials started in October 2008.

**R1273**

R1273 is a monoclonal antibody licensed from Roche. This is the first in a new class of targeted agents known as HER dimerization inhibitors, and is being developed for breast cancer.

**R7159 (GA101)**

R7159 is a humanized monoclonal antibody licensed from Roche. Chugai has started phase I domestic clinical trials in October 2008 for the intended indications of non-Hodgkin's lymphoma.

**R1507**

R1507 is a human anti-insulin like growth factor (IGF-1R) monoclonal antibody licensed from Roche. Chugai has started phase I domestic clinical trials in January 2009.

## Renal Diseases Field

### Overview of Diseases and Treatment Methods

**Chronic Kidney Disease**

Chronic kidney disease is defined as the continuation for three months or more of "manifestations showing the existence of renal disease, such as positive proteinuria" or "presence of kidney damage (a glomerular filtration rate of less than 60 ml/min)." Recently, reports containing ample evidence of the major risk posed by chronic kidney disease in end stage renal failure and cardiovascular disease have prompted efforts to address this disease around the world.

In Japan, too, measures are being put in place to deal with the problem. For example, the Japanese Society of Nephrology issued "Chronic Kidney Disease Guidelines" in July 2007. The Ministry of Health, Labour and Welfare has initiated strategic research through The Kidney Foundation, Japan with the objective of achieving a 15% reduction in five years of the number of dialysis patients compared with current forecasts.

**Chronic Renal Failure and Renal Anemia**

Chronic renal failure is a disease in which renal function is significantly reduced due to a variety of causes, including diabetes-related renal dis-

ease, chronic glomerulonephritis, nephrosclerosis, and polycystic kidney disease. In recent years, the rise in the number of diabetes patients has led to a corresponding increase in chronic renal failure in patients with underlying diabetes-related renal disease; this has become the primary reason for dialysis use.

For dialysis patients and end-stage renal failure patients, the treatment of serious complications of advanced renal dysfunction, such as renal anemia, secondary hyperparathyroidism, and abnormal calcium and phosphorus metabolism, is a major issue. Of these complications, renal anemia is one of the most frequent, occurring not only in dialysis patients but also in pre-dialysis patients. Renal anemia, in turn, is thought to be responsible for a wide range of further complications suffered by renal failure patients, including deterioration in heart, brain, and hemostatic functions.

**Treatment Methods and Changes in the Medical Environment****Erythropoietin**

Erythropoietin is a hemopoietic factor produced mainly in the kidneys which speeds up erythrocyte production by acting on normoblastic progenitor cells found in bone marrow. Erythropoietin (EPO) is effective in

treating renal anemia caused primarily by the decline in erythropoietin production due to chronic renal failure. In addition, by correcting and controlling anemia, the drug is also thought to help improve the secondary complications listed above. Large-scale studies have shown that correction of anemia with erythropoietin helps reduce the length of hospital stays and improves both quality of life and life expectancy. It is estimated that EPO preparations are currently used by approximately 80% of dialysis patients and the majority of pre-dialysis renal failure patients with serum creatinine levels of 2mg/dL or more. Chugai's Epogin is thus an essential drug for the treatment of renal anemia.

**A Flat-sum Reimbursement System for Erythropoietin Preparations**

The number of patients receiving dialysis treatment in Japan is increasing each year by about 4%, reaching 275,000 people in 2007, partly due to increased use of dialysis in patients with diabetes-related renal disease. Expenses for erythropoietin (about ¥140 billion\*), essential for dialysis treatment, accounted for 8.8% of all dialysis-related expenses in 2005.

Consequently, the government decided in its 2006 revisions of medical fees that the administration of erythropoietin in dialysis

treatment would be comprehensively incorporated as a flat-sum reimbursement within the medical fee points\*<sup>2</sup> for “artificial kidney” (dialysis treatment). The government changed the previous mechanism under which the number of fee points awarded depended on the amount of erythropoietin used. The new mechanism provides an integrated fee structure by adding the average amount of erythropoietin used per dialysis session to the medical fee points for one session.

\*<sup>1</sup> IMS data. Erythropoietin market in 2005.

The scope of the market is defined by Chugai.

\*<sup>2</sup> Formerly, the average amount of erythropoietin used per patient was approximately 4,500 international units per week, on the basis of three dialysis sessions per week. The new system adds points equivalent to 1,500 international units, to the artificial kidney medical fee points and provides an integrated fee structure.

## Overview of Products and Development Project

### Epogin

Erythropoietin is a hemopoietic factor produced mainly in the kidneys which speeds up erythrocyte production by acting on normoblastic progenitor cells found in bone marrow. The full utilization of Chugai’s unique gene recombinant technology enabled the creation of Epogin, a human erythropoietin formulation that uses epoetin beta as its main active ingredient. Erythropoietin is effective in

improving renal anemia primarily caused by the decline in erythropoietin production due to chronic renal failure. It also contributes to the improvement of a wide range of complications arising from anemia.

### R744 (overseas product name: Mircera)

R744 is a new anemia treatment with a very long serum half-life, enabling stable and sustained control of haemoglobin. R744 stimulates erythropoiesis by a different interaction with the erythropoietin receptor on progenitor cells in the bone marrow.

The serum half-life of R744 is virtually the same, whether administered subcutaneously or via intravenous injection, and the drug demonstrates effectiveness in relieving the symptoms of anemia when administered at four-week intervals. Consequently, it may reduce the cost of hospital visits for chronic kidney disease patients not on dialysis and may contribute to better treatment compliance. Furthermore, as a dialysis-related treatment, R744 is expected to reduce medical costs such as drug administration costs and medical waste by dramatically reducing administration frequency. The product thus has the potential to expand the options for the treatment of renal anemia.

### Renagel

Renagel is used to treat hyperphosphatemia.

Because depressed renal functions impair the ability of dialysis patients to eliminate phosphorous excretions, phosphorous intake is controlled by phosphorous-eliminating dialysis and strictly controlled diets. However, these methods are not 100% effective in correcting oversupplies of phosphorous, so a phosphate binder is required to eliminate the excess phosphorous amounts. Renagel differs from conventional calcium carbonates used to treat this condition, and there is almost no possibility of hypercalcemia occurring with Renagel use, as it is a new type of treatment, free of aluminum and calcium. Therefore, synergies with Chugai’s other products can be expected. For instance, it becomes easier to use vitamin D3 derivatives, in particular Oxarol, an agent for the treatment of secondary hyperparathyroidism.

### Oxarol

Synthesized by Chugai, Oxarol is the first intravenous activated vitamin D3 derivative agent in Japan. It treats secondary hyperparathyroidism—a result of prolonged dialysis—by acting directly on the parathyroid gland to control PTH synthesis and secretion, and by acting to improve osteitis fibrosa and excess remodeling. Even in cases where previous oral vitamin D3 derivatives had no positive effect, Oxarol is producing nice results.

## Bone and Joint Diseases Field

### Osteoporosis

Osteoporosis is considered to be a serious disease as fractures, especially compression fractures of the spine and femoral neck, caused by the disease can decrease quality of life, leave patients bedridden, and increase mortality risks.

It is estimated that over 12 million people suffer from osteoporosis throughout Japan, with one in every two women aged 65 or over said to suffer from the disease. However, the treatment rate stands at around only 30% of the estimated number of sufferers due to a lack of readily noticeable symptoms. Consequently, the appearance of a new drug acts to expand the osteoporosis treatment market by exposing more patients.

#### Treatment Methods

In the past, drug treatment of osteoporosis mainly involved activated vitamin D3 derivatives, bisphosphonates, and calcitonin preparations. Since 2005, however, there has been an increase in the use of Evista, a selective estrogen receptor modulator (SERM).

#### Regulatory Trends

National guidelines for osteoporosis treatment underwent major revision in October 2006 for the first time in about four years, with the aim of improving quality of life of the elderly and containing medical costs. Among the main points of the new guidelines are: (1) emphasis on the prevention of fractures; (2) a new focus on “bone quality” as a measure of bone strength; and (3) establishment of criteria for

the initiation of drug treatment that are separate from the criteria for diagnosis. The Ministry of Health, Labour and Welfare also seeks to promote diagnosis by urging local governments to provide periodical bone density testing for women from the age of 40.

#### Overview of Products and Development Projects

##### Evista

Evista, a new category of osteoporosis treatment called SERM, uses the estrogen-like effect only for blocking the reduction of bone mass, while reducing the occurrence of gynecological adverse reactions that are associated with existing estrogen drugs. In Japan, Evista has been jointly marketed by Chugai and Eli Lilly Japan since May 2004.



Based on large-scale overseas clinical trials conducted by Eli Lilly & Co., Evista has been established as an evidence-based medicine. The drug reduces vertebral fractures and has low risk of causing breast cancer. New treatment guidelines implemented in October 2006 designated Evista as a grade-A recommended agent.

#### Alfarol

Alfarol, an activated vitamin D3 derivative, is positioned as the base drug for osteoporosis treatment. Alfarol inhibits the decline of bone mass by adjusting calcium and bone metabolism, and therefore is effective in preventing vertebrate fractures. The latest treatment guidelines also indicate the drug's effect on prevention of falls, focusing attention to this feature that other osteoporosis treatment do not have.

#### ED-71

ED-71 is a vitamin D3 preparation, that was born out of our many years of research in vitamin D. Currently, we are developing it as a promising drug to replace Alfarol. Clinical trials have confirmed that ED-71 has the same safety level as the existing D3 derivatives and that it also has significantly greater effect in preventing fractures. In May 2008, we concluded a co-development and co-marketing agreement with Taisho Pharmaceutical Co., Ltd. We are planning to file for application in 2009.

#### R484 (overseas product name: Bonviva/Boniva)

R484 is a bisphosphonate that requires less frequent administration than existing medicines of the same class. It is available overseas in two dosage forms: a tablet that needs to be taken only once a month, and an injection that is given once every three months. These more convenient treatment schedules are expected to help patients continue their medication, an important issue in osteoporosis. In order to expedite development and maximize sales of R484, Chugai concluded a co-development and co-marketing agreement with Taisho Pharmaceutical Co., Ltd. in September 2006.

## Rheumatoid Arthritis, Osteoarthritis

Rheumatoid arthritis (RA) is a systemic disease characterized by inflammation of joints leading to dysfunction, pain and deformity. A lack of appropriate treatment tends to result in deterior-

ation of a patient's condition over time. It is estimated that there are about 600,000 to 700,000 patients in Japan suffering from RA, of whom some 350,000 are currently receiving drug treatment. The number of patients is increasing as the average age of the population rises. Systemic onset juvenile idiopathic arthritis (sJIA), the form of RA suffered by children below 16 years of age, accompanies growth disorders. It is considered even more difficult to treat than adult forms of the disease, as few suitable drugs are available.

The most common joint disease is osteoarthritis. Degeneration of the cartilage in the joints and surrounding areas causes joint pain, stiffness, and loss of function. The disease is more common in older people and occurs in more than 80% of people over 60 years of age.

#### Treatment Methods and Market Conditions

Rheumatoid arthritis has been conventionally treated with anti-rheumatic drugs and anti-inflammatory analgesics, but biologic agents (anti-TNF-agents) targeting cytokines, proteins involved in the process of inflammation, have recently entered the market and expanded the range of treatment choices. Research in recent years implies that the administration of biologic agents at the early onset stage is effective in inhibiting bone and joint damage. The global market for these agents is expected to exceed US\$6 billion by 2008, and in Japan, also, it is expected that the number of patients treated with biologics will grow, now standing at around 35,000.

Systemic onset juvenile idiopathic arthritis (sJIA) is a serious and potentially fatal disease. While it is rare, with only a few hundred patients in Japan, no effective treatment is available. Current therapy relies on steroid drugs, which can cause growth impairment and other adverse reactions. Accordingly, the approval and launch of Actemra in April 2008 is expected to provide a significant step forward in therapy.

The main drug therapies for osteoarthritis include non-steroidal anti-inflammatory analgesics, steroids, and hyaluronic acid preparations. However, the level of satisfaction with these therapies is not high and more useful drugs are needed.

#### Regulatory Trends

In October 2005, the Ministry of Health,

Labour and Welfare released the Report of the Rheumatism and Allergy Countermeasure Committee. The report calls for the following measures to prevent rheumatism from becoming severe: (1) promotion of early diagnosis and the development of highly effective treatment methods; (2) establishment of medical service systems to provide appropriate care; and (3) improvement of the patient environment, including consultation opportunities and access to information.

The 2001-2010 period has been designated as the Bone and Joint Decade, and academic societies and other players are aggressively approaching research, diagnosis and treatment of osteoarthritis.

#### Overview of Products and Development Project

##### Suvenyl

Suvenyl, a drug that improves joint function through injection into the joint cavity, is a high molecular weight hyaluronate sodium drug that alleviates knee joint pains caused by knee osteoarthritis and rheumatoid arthritis. Recently, the superior performance of Suvenyl over low molecular weight hyaluronic acid, due to its physical and chemical properties being close to that of natural hyaluronic acid, has begun to widen the understanding among clinicians of the value of high molecular weight.

##### Actemra

Actemra, the first antibody drug created in Japan, blocks the activity of interleukin-6 (IL-6), a type of cytokine. The high expectations placed by doctors in this new medication are shared by patients for whom conventional treatments for rheumatoid arthritis, including existing biologic agents, have failed to be effective.

In April 2008, we obtained the domestic approval and launched for additional indication of rheumatoid arthritis, polyarticular-course juvenile idiopathic arthritis, and systemic-onset juvenile idiopathic arthritis. Overseas, Actemra was approved in the European Union in January 2009 (European product name: RoActemra). In the United States, we have received the Complete Response Letter (CRL) from the U.S. Food and Drug Administration (FDA) in September 2008, and we are currently preparing the requested additional materials for submission with Roche.

**R1594**

R1594 is a second-generation humanized anti-CD20 monoclonal antibody that binds to a particular protein (the CD20 antigen) on the surface of human B cell lymphocytes, activat-

ing the immune system to eliminate the marked cells. R1594 is expected to be effective in treating diseases that involve B cells and is currently being studied for a variety of autoimmune diseases by Roche Group com-

panies. Japan is participating in an ongoing global phase III study of R1594 for rheumatoid arthritis.

## Others Field

### Chronic Hepatitis C

Chronic hepatitis C is a liver disease caused by persistent infection by the hepatitis C virus (HCV). In Japan, this disease has been designated a “21st century national health issue,” as there are approximately two million HCV carriers. Early detection and treatment of the hepatitis C virus is particularly important because approximately 70% of those infected develop chronic hepatitis, which gradually progresses to liver cirrhosis and then liver cancer.

#### Treatment Methods and Market Conditions

There are two methods of treating chronic hepatitis C: antiviral therapy to eradicate HCV from the body, and liver-support therapy to improve liver function and prevent the hepatitis from worsening.

Interferon therapy is the main antiviral treatment. However, the limited efficacy of conventional interferon drugs has led to an increase in the use of liver-support therapy in Japan, where 80% of chronic hepatitis C patients do not receive interferon treatment. Since 2001, the introduction of interferon-ribavirin combination therapy and of peginterferon\*<sup>1</sup> has increased the treatment options available for patients with hepatitis C. Overseas, combined peginterferon and ribavirin is now the standard treatment.

\*<sup>1</sup> Interferon conjugated with polyethylene glycol, which makes the medication longer-acting.

#### Regulatory Trends

The government has been focusing its effort to double the number of hepatitis patients treated with interferon in the next seven years since April 2008. It has been cooperating with local governments to implement a seven-year program for the treatment of hepatitis, which is

the comprehensive measures tackling hepatitis. In order to diagnose potential patients who are unaware of their infection due to a lack of symptoms, public healthcare centers have been offering free testing since 2008 to people aged 20 or older. Also, regional hospitals in each prefecture will be designated as hub centers for hepatitis C treatment in order to provide patients with a framework for treatment and consultation. Additionally, a new policy will be implemented to ease the financial burden of hepatitis patients, with the upper limit of co-payments set at 10,000 yen, 30,000 yen and 50,000 yen, based on a patient's income level.

#### Overview of Products and

##### Development Projects

##### Pegasys/Copegus

Pegasys (generic name: peginterferon alfa-2a) enables sustained therapeutic concentrations to be achieved with once-weekly\*<sup>2</sup> administration, with fewer adverse reactions than standard interferon preparations. The guidelines for chronic hepatitis C treatment published by the Ministry of Health, Labour and Welfare recommend Pegasys as monotherapy for patients with a low viral load or those who cannot use ribavirin.

Copegus (generic name: ribavirin) is a chronic hepatitis C treatment that synergistically strengthens the antiviral effect when used in combination with interferon. In January 2007, Chugai obtained approval for Copegus and launched it in March in combination with Pegasys for the treatment of patients with chronic hepatitis C serogroup 1\*<sup>3</sup> infection and high viral load, or those who have either not responded to, or have relapsed following, interferon monotherapy. This approval makes Chugai the only pharmaceutical company in

Japan that can offer peginterferon for both monotherapy and combination therapy. The Company plans to use this advantage to maximize the value of the two products by seeking to expand its market share in the treatment of chronic hepatitis C and further expanding the range of indications. Pegasys is establishing its position as monotherapy for patients who are unable to use ribavirin.

\*<sup>2</sup> Conventional interferon must be injected three or more times per week.

\*<sup>3</sup> Genotypes I (1a) and II (1b), with which approximately 70% of HCV patients in Japan are infected.

Note: See the “Copegus-Expanded Options in HCV Treatment” figure on p.28.

##### NA808

NA808 is a small-molecule compound that is expected to prove effective as a treatment for chronic hepatitis C. The drug acts on the body, not the virus, to inhibit the growth of the virus.

### Influenza

Influenza is an acute infectious disease characterized by the rapid onset of high fever (38 degrees centigrade or more) and severe systemic symptoms. It is highly infectious, and epidemics can develop quickly. In some cases, secondary infections can lead to very serious illness. Influenza is classified into types A, B, and C based on differences in the antigenicity of the underlying virus. Types A and B can infect humans and cause major outbreaks. There are three anti-influenza drugs currently on the market: they treat only type A, or treat both types (A and B). Either type requires administration to begin within two days of symptoms appearing.

## Overview of Product

### Tamiflu

Tamiflu is the only oral anti-influenza agent that is effective against both type A and type B infections. It inhibits viral replication by binding to and blocking the action of neuraminidase, an enzyme essential for the multiplication of the influenza virus. Launched in capsule form in February 2001 and dry syrup form in July 2002, dosages are available for patients one years of age and older. In July 2004 approval was granted for limited prophylactic use. Abnormal behavior has occurred in some influenza patients who have also taken Tamiflu. Although no causal relationship with Tamiflu has been established, the authorities introduced restrictions on the use of Tamiflu in teenage patients from March 2007 as a precaution. The interim report of an epidemiological survey published by a working group at the Ministry of Health, Labour and Welfare in July 2008 showed that so far there have been no findings that point to a causal association between Tamiflu and the abnormal behavior of patients taking the drug. The Ministry's Subcommittee on the Safety of Drugs later said that further investigations were needed and decided to continue the restriction on the use of Tamiflu in teenage patients during the 2008-2009 influenza season.

## Angina Pectoris

Hardening of the coronary artery or coronary spasms can cause constriction of the artery and lead to ischemia, a condition where the heart does not receive sufficient blood flow. Clinical symptoms of angina pectoris include chest pain and pressure that accompany temporary ischemia. Nitric acid is used to treat angina pectoris, enlarging the coronary artery and increasing blood flow to the ischemia affected areas. In addition, beta blocker agents are used for exertional angina pectoris treatment and calcium blockers are used for coronary spasm related angina pectoris.

## Overview of Product

### Sigmat

Anti-anginal agent Sigmat is a drug that over-

comes the flaws of nitric acid compounds such as nitroglycerin and is effective in treating various types of angina pectoris. In December 2007, additional approval was obtained for acute heart failure.

## Castleman's Disease

Castleman's disease is a lymphoproliferative disease characterized by symptoms such as systemic lymphadenopathy, fever, and general fatigue, as well as various abnormal laboratory test values including anemia, hyper gamma globulinemia, and hypoalbuminemia. It has been confirmed that these manifestations result from the excessive production of interleukin-6 (IL-6), one of the proteins that causes inflammation. Castleman's disease is very rare, affecting approximately 1,500 people in Japan.

## Overview of Product

### Actemra

Actemra, a humanized anti-human IL-6 receptor monoclonal antibody produced using genetical recombination technology, is the first antibody drug created in Japan. With a mechanism of action that inhibits the receptor for IL-6, a type of cytokine, the drug improves Castleman's disease symptoms. Patients who are eligible for Actemra treatment are those who cannot be treated by surgery and show resistance to traditional therapies, and the number of patients is estimated at 160.

## Diabetes

The number of patients suffering from diabetes is increasing worldwide. In Japan, the 2002 Diabetes Survey Report issued by the Ministry of Health, Labour and Welfare put the total number of "persons strongly suspected of having diabetes" and "persons for which having diabetes cannot be denied" at approximately 16.2 million. Patients with type 2 diabetes have higher than normal blood sugar levels due to difficulty in controlling blood sugar caused by a diminished insulin secretory function or lower insulin sensitivity. Treatment using various kinds of oral diabetic drugs becomes necessary as the disease progresses, and further deteriora-

tion requires insulin replacement therapy.

## Overview of Development Projects

### R1583 (ITM-077)

R1583 is a new compound that mimics GLP-1 (glucagon-like peptide 1), a hormone that stimulates the secretion of insulin. As GLP-1 stimulates insulin secretion only when blood sugar levels are too high, there is little risk of the drug causing low blood sugar. R1583 is formulated using technology from Ipsen that enables maintenance of stable therapeutic concentrations for extended periods, and is expected to allow less frequent administration compared to existing medications. R1583 is being co-developed in Japan with Teijin Pharma Limited.

### CSG452 (R7201)

An oral preparation that reduces blood sugar level, CSG453 is expected to be effective in the treatment for type 2 diabetes. Chugai licensed the drug to Roche in January 2007, and started phase I domestic clinical trials in September 2007.

### R1579

R1579 is a dipeptidyl peptidase-IV (DPP-IV) inhibitor licensed from Roche. Chugai started phase I domestic clinical trials for the treatment of type 2 diabetes in June 2008.

## Schizophrenia

It is estimated that about 1% of the population suffers from schizophrenia, a disease characterized by persistent disturbances of thought, communication, perceptions, emotions and behavior. Patients become detached from reality and may experience delusions, hallucinations, or uncontrollable thoughts.

## Overview of Development Project

### R1678

R1678, a small-molecule compound licensed from Roche, is expected to be effective in treating schizophrenia. Chugai joined global phase II clinical trials in May 2008.

# Network (As of March 25, 2009)

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Yokohama, Nagoya, Osaka,  
Kyoto, Hiroshima, Takamatsu, Fukuoka

## Plants

Ukima (Tokyo), Fujieda (Shizuoka),  
Utsunomiya (Tochigi),  
Kamakura (Kanagawa)

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Kamakura (Kanagawa), Ukima (Tokyo)

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Medical Culture Inc.  
  
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Chugai Pharma Manufacturing Co., Ltd.  
  
Chugai Clinical Research Center Co., Ltd.

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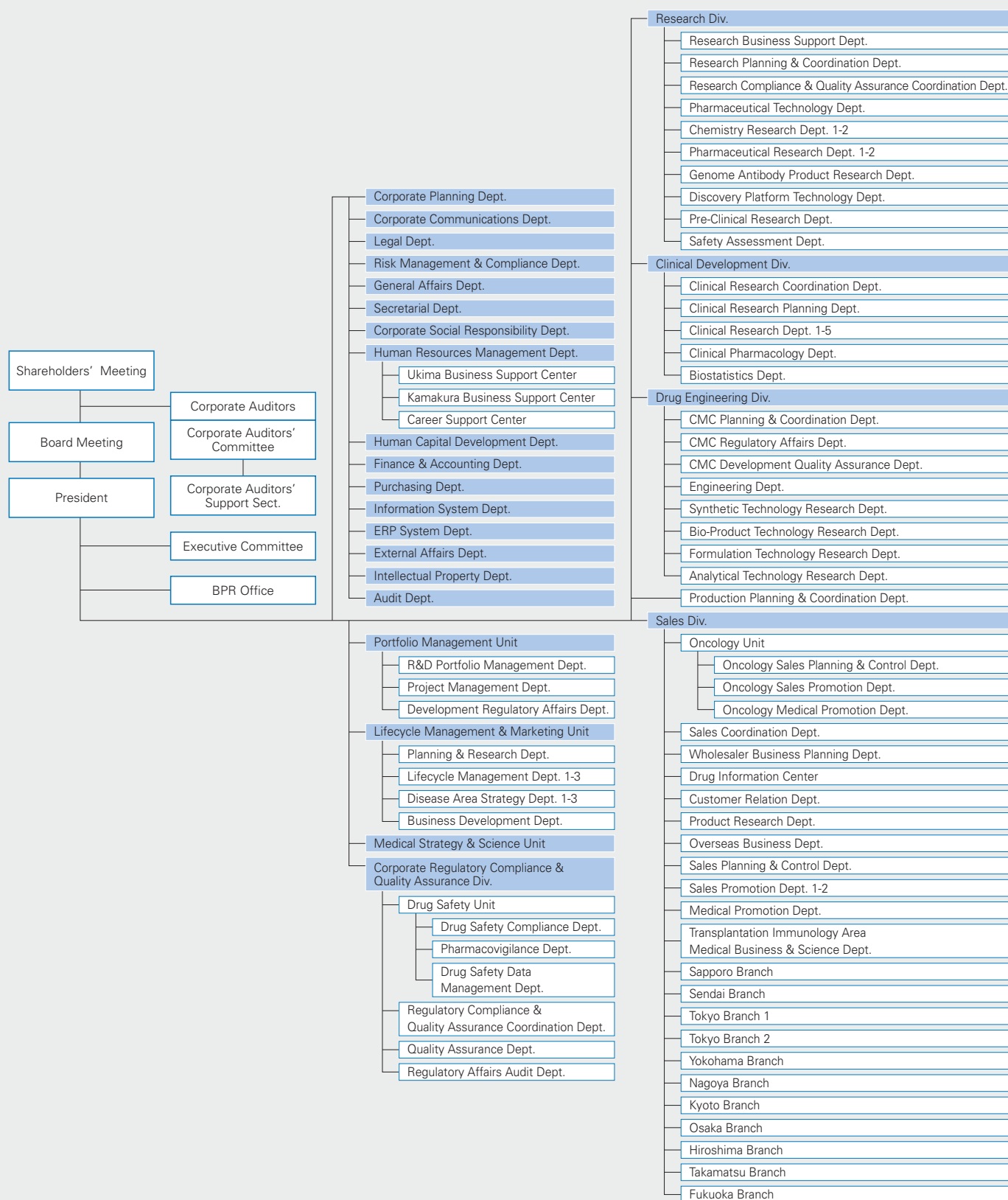
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## Chugai's Global Network





# Organization (As of March 25, 2009)



# Corporate Data

## Chugai Pharmaceutical Co., Ltd. (As of December 31, 2008)

### Year of Foundation

1925

### Year of Establishment

1943

### Address

1-1 Nihonbashi-Muromachi 2-Chome, Chuo-ku, Tokyo, 103-8324 Japan

### Stated Capital

¥72,966,825,723

### Number of Employees

6,383

### Number of Shares Issued of Common Stock

559,685,889

### Number of Shareholders

44,372

### Stock Listing

Tokyo

### Fiscal Year-End

December 31

### General Meeting of Shareholders

March

### Transfer Agent

Mitsubishi UFJ Trust and Banking Corporation

### Public Notices

Public Notices are to be made electronically on Chugai Website (<http://www.chugai-pharm.co.jp/ir>). In case electronic communications are unavailable, Public Notice will be made in the newspaper, Nihon Keizai Shimbun.

#### For further information, please contact:

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E-mail: [ir@chugai-pharm.co.jp](mailto:ir@chugai-pharm.co.jp)

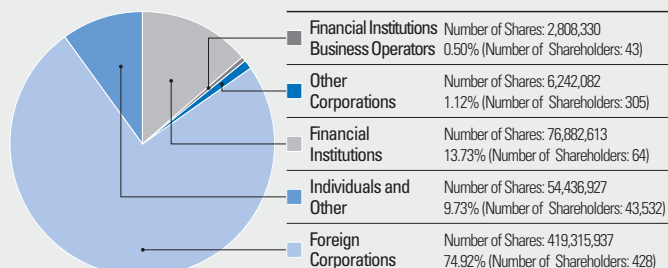
Chugai Pharmaceutical Co., Ltd. provides information on its Website:

URL: <http://www.chugai-pharm.co.jp/english>

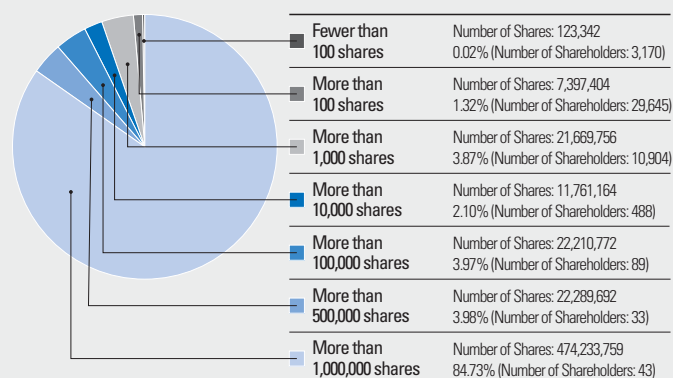
# Shareholders Information (As of December 31, 2008)

## Classification of Shareholders

### By Shareholder



### By Number of Shares Held



## Major Shareholders\*

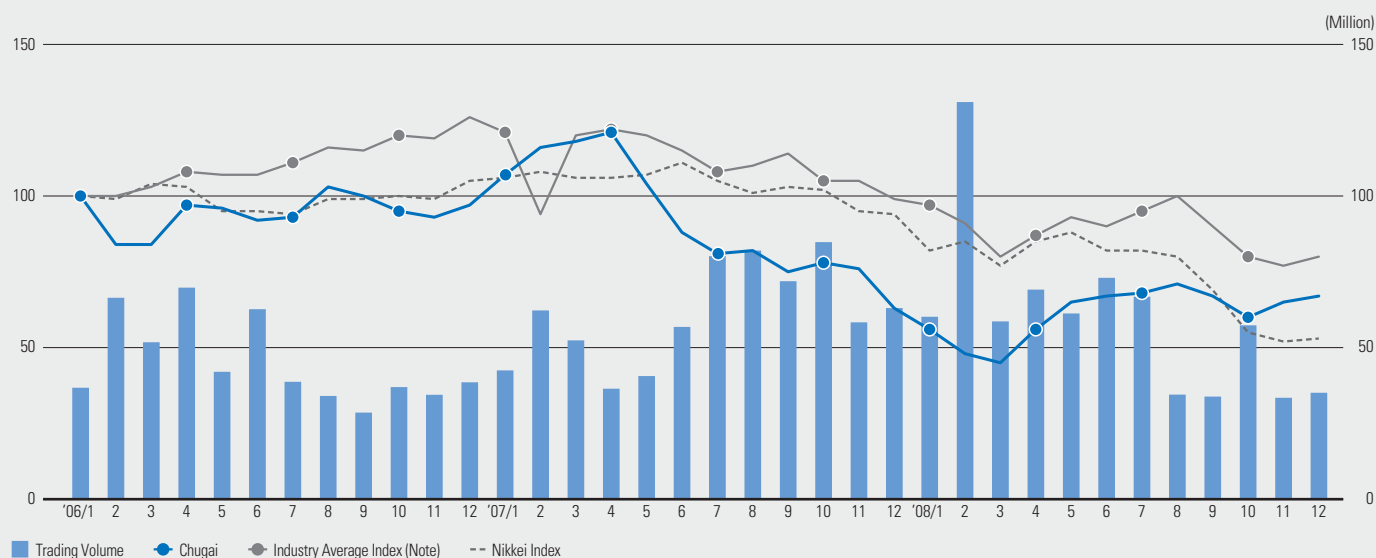
Name	Number of Shares Held (Thousands)	Percentage of Ownership Voting (%)
Roche Pharmholding B.V.	335,223	61.55
The Master Trust Bank of Japan, Ltd. (trust account)	16,776	3.08
Japan Trustee Services Bank, Ltd. (trust account)	14,067	2.58
Japan Trustee Services Bank, Ltd. (trust account 4G)	12,626	2.31
The Chase Manhattan Bank, N.A. London Secs Lending Omnibus Account	5,721	1.05
Tokio Marine & Nichido Fire Insurance Co., Ltd.	5,309	0.97
Morgan Whitefriars Equity Derivatives	5,155	0.94
Citibank Hong Kong PBG Clients H.K.	3,457	0.63
Trust&Custody Services Bank, Ltd. (securities investment trust account)	3,388	0.62
Japan Trustee Services Bank, Ltd. (trust account 4)	3,279	0.60

\* 14,872,196 shares of treasury stock held by the Company are not included in the above breakdown of major shareholders.

## Stock Price Information

	Stock Price	
	High	Low
From January 1, 2008 to December 31, 2008		
First Quarter	¥ 1,746	¥ 1,027
Second Quarter	1,759	1,138
Third Quarter	1,820	1,473
Fourth Quarter	1,824	1,221

## Share Performance of Chugai



Share price on January 4, 2006 (¥2,530) = 100

Industry average index is calculated as below (because of the merger and delisting):

2007.10-: A total of eight companies (Takeda, Daiichi-Sankyo, Astellas, Shionogi, Eisai, Mitsubishi-Tanabe, Dainippon-Sumitomo, Chugai)

2005.10-: A total of eight companies (Takeda, Daiichi-Sankyo, Astellas, Shionogi, Eisai, Tanabe, Dainippon-Sumitomo, Chugai)

A photograph of a laboratory setting. In the foreground, a glass chemical apparatus is visible, featuring a vertical column with blue liquid and a round-bottom flask containing clear liquid. In the background, three scientists in white lab coats and safety glasses are working, though they are out of focus. The overall tone is professional and scientific.

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 A member of the Roche group

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