# Annual Report 2012

Daiichi Sankyo Co., Ltd.





Passion for Innovation.
Compassion for Patients.™

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# **■ Consolidated Financial Highlights**

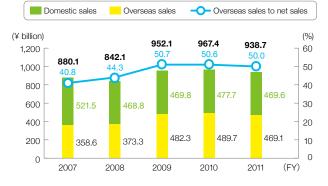
#### ▶ DAIICHI SANKYO COMPANY, LIMITED and Consolidated Subsidiaries

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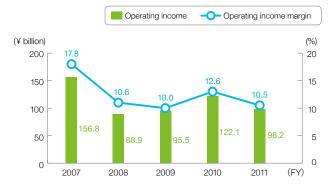
, , , , , , , , , , , , , , , , , , ,	Million					en U.S. dollars*	
	FY2007	FY2008	FY2009	FY2010	FY2011	FY2011	
Net sales	¥ 880,120	¥ 842,147	¥ 952,106	¥ 967,365	¥938,677	\$11,421	
Operating income	156,827	88,871	95,509	122,144	98,202	1,195	
Net income (loss)	97,660	(215,499)	41,852	70,121	10,383	126	
Overseas sales	358,639	373,254	482,337	489,734	469,085	5,707	
Overseas sales to net sales (%)	40.8	44.3	50.7	50.6	50.0	50.0	
R&D expenses	163,472	184,539	196,803	194,330	185,052	2,252	
R&D expenses to net sales (%)	18.6	21.9	20.7	20.1	19.7	19.7	
Depreciation and amortization expense	38,733	40,582	45,942	43,946	46,305	563	
Total assets	1,487,889	1,494,600	1,489,510	1,480,240	1,518,479	18,475	
Total net assets	1,244,513	888,617	889,508	887,703	832,749	10,132	
Return on shareholders' equity (%)	7.8	(20.5)	4.9	8.2	1.3	1.3	
Net income (loss) per share of common stock (yen and U.S. dollars)	¥135.35	¥(304.22)	¥59.45	¥99.62	¥14.75	\$0.18	
Cash dividends per share (yen and U.S. dollars)	70	80	60	60	60	0.73	

<sup>\*</sup> The U.S. dollar amounts represent translations of Japanese yen, solely for convenience, at the rate of ¥82.19=US\$1.00, the approximate exchange rate prevailing on March 31, 2012. The exchange rate for March 31, 2012 is the telegraphic transfer middle rate of Tokyo Foreign Exchange Market.

#### Net Sales / Overseas Sales to Net Sales



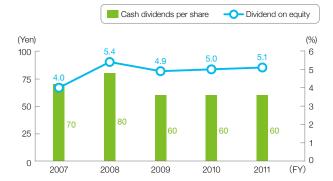
#### Operating Income / Operating Income Margin



#### R&D Expenses / R&D Expenses to Net Sales



## Cash Dividends per Share / Dividend on Equity





I would like to take this opportunity to thank our shareholders and investors for the confidence that they have placed in the executive officers of Daiichi Sankyo.

As developed countries adopt policies aimed at holding down healthcare costs and pharmaceutical markets become increasingly diverse, the Daiichi Sankyo Group has prepared itself for this changing business environment by transforming ourselves into an organization that seeks a wider variety of growth opportunities, the most significant of these lies in fostering new, innovative pharmaceutical products and bringing them to market.

In terms of mid to long range planning, we are focused on the three areas of 1) strengthening Daiichi Sankyo's innovative pharmaceuticals business, 2) putting Ranbaxy Laboratories Ltd. ("Ranbaxy") back on the road to growth, and 3) evolving the Hybrid Business Model.

We recognize that the most significant growth opportunity lies in our innovative pharmaceuticals business.

With regard to the sales of our key product, the antihypertensive agent olmesartan has suffered in the U.S. from the appearance of generic versions of one of the drug's competitors due to patent expiration, but we expect continued growth for olmesartan in Japan and the EU.

As for the launch and fostering of new products, we have accelerated our global market penetration efforts for the antiplatelet agent Effient/Efient, which we view as one of our next generation key products, during the two year period encompassing fiscal year 2010 and fiscal year 2011. Now that the TRILOGY ACS study, which was conducted with the aim of obtaining additional indications for Effient/Efient, is complete, we can look forward to expanding Effient/Efient's its uses and maximizing its product value. We also began marketing new drugs in Japan, including *Memary*, a treatment for Alzheimer's Disease (AD), and Nexium, the proton pump inhibitor, and are geared towards maximizing product value and sales of these new drugs as early as possible.

On the R&D side, late stage development has been making impressive progress, while our pipeline has been robust, particularly in the field of oncology, where there are substantial unmet medical needs.

As for our Indian subsidiary, Ranbaxy, we will consolidate its position as the India's top pharmaceutical company, since the Indian market accounts for the largest share of its sales. In addition, we will develop and enhance our business in emerging countries by getting the maximum leverage from the Ranbaxy corporate brand. We will also be working to launch drugs ahead of our competitors in both developed and emerging countries, such as first-to-file (FTF) products in the U.S. as well as high value generics in various markets.

Now that definite progress has been made in the negotiations with the Food and Drug Administration (FDA) / U.S. Department of Justice (DOJ), which had been a major issue over the past few years, we will step up the evolution of our Hybrid Business Model. Specifically, along with strengthening the operations of our two business axes - Daiichi Sankyo's innovative pharmaceuticals business and the Ranbaxy's generic business - we will seek to optimize the role that we play in each geographic area of the world by tailoring our activities to local market characteristics. Furthermore, by combining assets possessed by the two companies, including technology and know-how, we will be able to create unprecedented new value and generate further cost synergies, thereby accelerating our efforts to boost overall profitability.

I am confident that by 1) strengthening Daiichi Sankyo's innovative pharmaceuticals business, 2) putting Ranbaxy back on the road to growth, and 3) evolving the Hybrid Business Model, we will be able to excel in terms of growth and profitability while meeting increasingly diverse healthcare needs.

I look forward to the continued understanding and support of our shareholders and investors as the Daiichi Sankyo Group tackles these challenges.

July 2012

Joji Nakayama

Representative Director, President and CEO

# Message from the President

#### Fiscal year 2011 Business Results

In fiscal year 2011, consolidated net sales declined 3.0% (28.7 billion yen) over the previous year to 938.7 billion yen.

Net sales in Japan declined 6.2 billion yen year on year. Sales of new products such as the antihypertensive agent Rezaltas, the Alzheimer's Disease (AD) treatment Memary, and the proton pump inhibitor Nexium, grew, as did sales of the anti-inflammatory analgesic Loxonin Tape. However, this was not enough to offset the decline in sales of approximately 24.0 billion yen caused by the return of domestic marketing rights to licensers\*. Furthermore, the antihypertensive agents Olmetec and Calblock were affected by the shrinking, single-agent ARB\*\* and CCB\*\*\* markets, resulting in a decline in sales over the previous year. Taking all of these factors together, our overall sales in Japan declined.

In businesses outside of Japan, sales increased 9.5 billion yen over the previous year after adjusting for foreign currency effects.

Sales at Daiichi Sankyo, Inc. (DSI), one of our U.S. subsidiaries, grew 7.3 billion yen over the previous fiscal year. Despite being affected by competing generic products, sales were up in the olmesartan franchise led by the mainstay, antihypertensive agent Benicar. In addition, the antihyperlipidemic agent and treatment for type 2 diabetes Welchol also achieved an increase in sales. Furthermore, alliance revenue from the antiplatelet agent Effient also increased.

Another U.S. subsidiary, Luitpold Pharmaceuticals, Inc. (LPI), experienced a 5.4 billion yen decline in sales. Sales of its mainstay product, the anemia treatment Venofer, were negatively affected by competing products, and LPI itself was affected by a warning issued by the Food and Drug Administration (FDA) in the early part of the fiscal year 2011 concerning its plant in Shirley, New York.

Daiichi Sankyo Europe GmbH (DSE), a European subsidiary, experienced a 6.5 billion yen increase in sales thanks to the extension of the olmesartan franchise and alliance revenue from Efient.

Ranbaxy experienced a significant 23.8 billion yen increase in sales thanks to sales of AD treatment donepezil during the 180day first-to-file (FTF) exclusivity period in the U.S., and the launch of another FTF product, the hypercholesterolemia treatment atorvastatin, at the end of 2011.

However, the strong yen had the negative effect of reducing revenue in dollars, euros, and rupees by the equivalent of 39.0 billion yen, and this roughly offset the increased revenue at foreign subsidiaries. Furthermore, other factors, including a reduction in exports of the synthetic antibacterial agent levofloxacin linked to patent expirations in Europe and the U.S., had a negative impact of about 18.0 billion yen on sales.

Operating income declined 19.6% (23.9 billion yen) over the previous year to 98.2 billion yen.

In Japan, operating income declined 2.0 billion yen over the previous year, reflecting the impact on gross profit of the decline in net sales together with an increase in SG&A expenses mainly linked to the launches of new products.

Overseas, operating income decreased 3.0 billion yen. Although DSI and DSE increased sales and reduced expenses, overall operating income was affected by lower sales at LPI and a changing portfolio mix at Ranbaxy. Approximately 19.0 billion yen of the decline in operating income is attributable to factors such as reduction in exports of levofloxacin and the absence of the onetime payments for the anti-RANKL antibody denosumab that were booked in the previous fiscal year.

Ordinary income fell 42.2% to 76.2 billion yen, reflecting foreign exchange losses and loss on valuation of derivatives at Ranbaxy, among other factors. The Group posted net income of 10.4 billion yen, a fall of 85.2% compared with fiscal year 2010. Contributing factors included a provision of 39.9 billion yen for potential losses relating to the settlement by Ranbaxy of claims by the U.S. Department of Justice (DOJ).

#### Overview of FY2011 Results and FY2012 Forecast

JPY Bn

Overview of Income Statement					Ranbaxy Group****				
		FY2010 FY20	FY2011	FY2011 FY2012	012			2012(Jan-Dec)	
		Results	Results	Forecast	YoY	(Jan-Dec) Results	(Jan-Dec) Results	Forecast	YoY
Net Sales		967.4	938.7	980.0	413	173.1	176.6	179.0	2.4
Cost of Sales		281.7	268.6	297.0	284	79.8	81.7		
SG&A Expenses		563.5	571.9	583.0	111	65.6	74.4		
	R&D Expenses	194.3	185.1	193.0	79	12.0	9.3		
	Other Expenses	369.2	386.8	390.0	32	53.5	65.1		
Operating Income		122.1	98.2	100.0	18	27.7	20.4		
Ordinary Income		131.8	76.2	100.0	238	40.0	-3.4		
Net Income		70.1	10.4	50.0	396	23.3	-33.7		

\*\*\*\* Figures of Ranbaxy are pre-adjusted before consolidation

<sup>\*</sup> Due to the expiration of contract period, we have returned domestic marketing rights for *Panaldine* (antiplatelet agent), *Mobic* (non-steroidal anti-inflammatory analgesic) and *Kremezin* (treatment for chronic renal failure) to their licensers.

<sup>\*\*</sup>Angiotensin II receptor blockers (ARBs)

<sup>\*\*\*</sup> Calcium channel blockers (CCBs)

#### Fiscal year 2012 Business Outlook

We are forecasting a 4.4% increase in sales in fiscal year 2012 to 980.0 billion yen and 1.8% increase in operating income to 100.0 billion yen.

The innovative pharmaceuticals business in Japan should be the driving force behind both sales and operating income.

Although our business in Japan will be affected by NHI price revisions, we are aiming for an increase in sales of nearly 40.0 billion yen or more thanks to Memary and Nexium, products that debuted in fiscal year 2011, and the anti-RANKL antibody Ranmark that we launched in April 2012, as well as the extension of our mainstay products, Olmetec, Rezaltas, and Calblock. We are targeting a 24.0 billion yen gain in operating income. Although expenses will increase as a result of a beefed-up marketing efforts aimed at quickly maximizing new product sales, we expect the accompanying increase in revenue to make a substantial contribution to boosting profits.

We see operating income from businesses outside of Japan decreasing 12.0 billion yen from a year earlier. Although Effient/ Efient in the U.S. and Europe and Ranbaxy's atorvastatin, which was launched in the U.S. in 2011, will continue to contribute, this will be counterbalanced by the decline in sales of olmesartan due to the introduction of competing generic products and the LPI mainstay, Venofer.

#### **Second Mid-Term Business Plan** (fiscal year 2010 to 2012): Results to Date

Since unveiling our Second Mid-Term Business Plan in March 2010, we have been working to strengthen and expand our business platform in order to realize growth over the medium and longer term. This effort has produced three major results:

- 1. We have strengthened our product portfolio in the innovative pharmaceuticals business. This is especially true in the Japanese market, where we have introduced numerous new products such as Rezaltas, Memary, Nexium and Ranmark. We are also actively working to increase Effient/Efient's global market penetration.
- 2. We have steadily advanced and strengthened the R&D pipeline. We have moved forward on trials aimed at obtaining additional indications for Effient/Efient and on two largescale clinical trials for edoxaban. Additionally, we have designated the oncology field as a prioritized research area for the future, and we have taken steps to augment our pipeline, including the acquisition of Plexxikon Inc. in 2011. We are working to put the outside know-how that we have acquired to work and optimize the entire group's R&D organization.
- 3. We have expanded our business domain so that we can meet increasingly diverse healthcare needs.

In Japan, we entered the generic drug market by establishing Daiichi Sankyo Espha Co., Ltd., intending to leverage Daiichi Sankyo's expertise and brand power. We have also entered the vaccine business in a fully committed way by establishing Kitasato Daiichi Sankyo Vaccine Co., Ltd. and Japan Vaccine Co., Ltd.

The Daiichi Sankyo Group has built a unique business platform that encompasses an innovative pharmaceuticals business, an established pharmaceuticals business (generic drugs and off-patent, long-listed drugs), vaccines, and OTC drugs.





# **Changing Business Environment and Management Issues**

The business environment has changed significantly in the past two years.

Fiscal year 2012 will mark the final year of our Second Mid-Term Business Plan, and there will be a 170.0 billion yen discrepancy with the original projected sales figure of 1.15 trillion yen. While 85.0 billion yen, or roughly half of this discrepancy, can be attributed to the yen's strength, there are also four major changes that have had an impact.

The first change is the global economic downturn and the stunted growth experienced by pharmaceutical markets in developing countries. As stated above, our global business has been negatively impacted by currency market fluctuations, especially the strong yen. Furthermore, policies geared towards restraining healthcare costs in developing countries have resulted in low growth in pharmaceutical markets.

The second change is the weak growth in sales of olmesartan, a mainstay product, due to a changing market environment. In the U.S. market in particular, the entry of competing generic products in 2010 has had a greater than expected effect. We expect the entry of new competing generic products to have a further impact in fiscal year 2012.

The third change is the altered growth scenario for *Effient/Efient*, a next-generation key product, as it had taken longer than we initially expected to establish its growth path.

The fourth change, prolonged negotiations between Ranbaxy and FDA/DOJ, has had an effect on Ranbaxy's financial results, culminating in less than expected contributions to sales and earnings in the U.S. As a result, we are slightly behind schedule in generating the synergies that we hope to achieve from our Hybrid Business Model.



## Issues to be Tackled over the Medium to Long Term

In light of these changes in the business environment, we have compiled a list of the issues that we must systematically tackle in fiscal year 2012 and the mid to long term, and implemented measures to enhance our operations this year. Moreover, we will incorporate further concrete measures to achieve mid to long term growth and profitability in our next mid-term business plan.

To date, we have focused on aggressively on laying the groundwork for growth in our various businesses, but we are now focused on the urgent need to improve profitability.

Among other things, we must again strengthen the innovative pharmaceuticals business, which is Daiichi Sankyo's core business. In order to do this, the critical issues will be how to maintain and grow the mainstay products that represent the current source of sales and profits and what we should do to quickly develop next-generation key products, as well as to increase profitability.

It will also be crucial that we stimulate R&D activities and improve productivity to create a more robust pipeline of new compounds that will be successfully approved.

We will be taking measures to enhance our portfolio, including bolstering our drug discovery infrastructure and pursuing strategic early-stage development projects geared towards achieving proof-of-concept\* in order to ensure solid growth over the mid to long term.

Another important issue will be getting the Ranbaxy business back on track for growth and evolving the Hybrid Business Model.

Consolidating its position as India's top pharmaceutical company, Ranbaxy aims to achieve reliable growth in India, which accounts for the largest share of its sales. Another important issue is developing and enhancing our business in emerging countries by getting the maximum leverage from the Ranbaxy corporate brand.

We will also be working to launch drugs ahead of our competitors in both developed and emerging countries, such as FTF products in the U.S. as well as high value generics in various markets.

Now that definite progress has been made in the negotiations with the FDA and DOJ that had been a major issue over the past few years, we will step up the evolution of our Hybrid Business Model. Specifically, along with strengthening our operations along two business axes – the innovative pharmaceuticals business and the Ranbaxy generic business – we will seek to optimize the role that we play in each geographic area of the world by tailoring our activities to local market characteristics. Furthermore, by combining assets possessed by the two companies, including technology and know-how, we will be able to create unprecedented new value and generate further cost synergies, thereby accelerating our efforts to boost overall profitability.

<sup>\*</sup> Confirmation in human clinical trials of a development concept predicted from pre clinical trials.



## What is the current status of the olmesartan franchise and its prospects for the future?

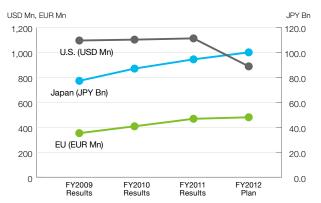
Since its release, the olmesartan franchise had been steadily selling and was actually growing until fiscal year 2010. However, the entry of generic products as a result of a rival product's patent expiring in the U.S. in 2010 has had a greater than expected impact. We believe it will also be impossible to avoid the effects of new competing generic products due to be released by other companies in fiscal year 2012.

Based on these factors, we expect fiscal year 2012 sales of the olmesartan franchise, which includes products such as Benicar and Benicar HCT, to decline by 20.2%, or 888 million dollars on a local currency basis, compared to fiscal year 2011, which saw sales of 1,112 million dollars (a 0.9% increase over the fiscal year 2010).

Meanwhile, we believe that there is still ample room for the olmesartan franchise to grow in Japan and Europe.

Since the olmesartan franchise is the most important global product group contributing to profit maximization, we will continue to work hard to maintain and increase global sales of olmesartan.

#### Sales of Olmesartan (Local Currency Basis)



	FY2009 Results	FY2010 Results	FY2011 Results	FY2012 Plan
Japan (JPY Bn)	77.2	87.0	94.4	100.0
U.S. (USD Mn)	1,095	1,102	1,112	888
EU (EUR Mn)	353	408	468	480

Breakdown for Olmesartan

Japan: Olmetec, Rezaltas U.S.: Benicar, Benicar HCT, Azor, Tribenzor Europe: Olmetec, Olmetec Plus, Sevikar, Sevikar HCT

# What is the current status of Effient/Efient and its prospects for

Effient/Efient's sales growth immediately after its launch in 2009 was lower than expected.

However, Effient/Efient was subsequently recommended for use in the guidelines of major American and European academic communities, and in the fall of 2010 we reviewed its promotion strategy direction, putting emphasis on expanding prescriptions from specialized hospitals and medical specialists.

These efforts have yielded results and we are now on a solid growth path.

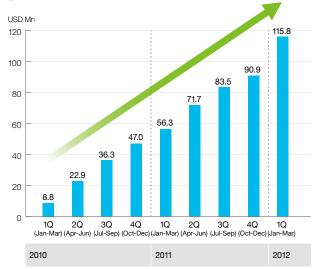
Sales grew smoothly especially in the past year, and globally they have exceeded 100 million dollars on quarterly basis. We will continue working to maintain and expand this momentum.

Although presently acute coronary syndrome undergoing percutaneous coronary intervention (ACS-PCI) is the only approved indication for Effient/Efient, a clinical trial for an additional indication of acute coronary syndrome, medically managed without revascularization (ACS-MM), has been completed and we plan to file for approval in major countries in Europe and the U.S. by the end of 2012.

By receiving approval for additional indications, it will be possible to enter even larger markets. Consequently, the path to maximizing Effient/Efient's product value has become more viable, and we want to build momentum to further promote sales growth.

In Japan, three Phase 3 focusing on patients with acute coronary syndromes who have undergone percutaneous coronary intervention (PCI), elective PCI patients, and ischemic cerebrovascular disease patients studies are underway. We are hopeful that the product will become one of the major products in this market.

#### Effient/Efient Global Sales



\* Source: financial announcements of Lilly

#### How is development of the early phase portfolio progressing?

One important issue we face in order for the Daiichi Sankyo Group to become a true Global Pharma Innovator is to establish a portfolio of first in class drugs, leading to the creation of corporate value.

Our R&D portfolio is well balanced with products at each stage of development, and each phase includes products with the potential to be first in their class.

In addition, our biotechnology group that includes our subsidiaries Asubio Pharmaceuticals Co., Ltd., U3 Pharma GmbH, and Plexxikon Inc., is generating a good range of compounds, and we anticipate that our Indian research center RCI\* will also contribute to this in the near future.

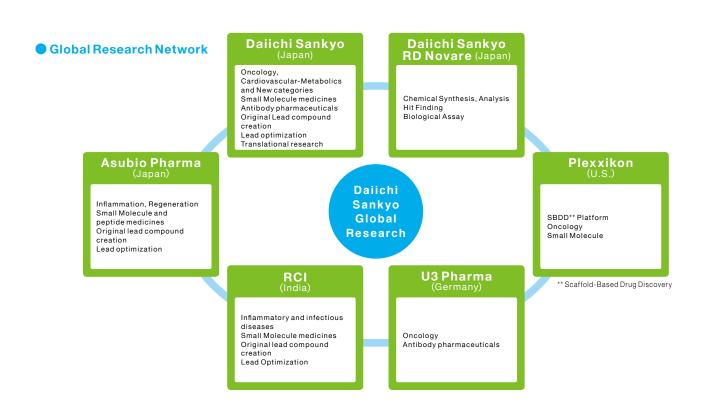
Moreover, we are expanding our pipeline in the oncology field, including compounds at the pre clinical stage.

We will further improve our pipeline by strengthening our drug discovery capability and proceeding with strategic early stage development projects with a view to obtaining proof-of-concept, thus creating an even more solid platform for medium to long term growth.

\* Daiichi Sankyo Life Science Research Centre in India







# What is the current situation regarding late-stage development

The development of prasugrel (CS-747), edoxaban (DU-176b), and tivantinib (ARQ 197) is proceeding steadily, and these three products are expected to contribute to global health and increase our corporate value.

#### 1. Prasugrel (CS-747)

Regarding the antiplatelet agent prasugrel (brand name in current marketed countries, Effient/Efient), we plan to file for an additional indication in ACS medically managed without revascularization (ACS-MM), which is expected to represent an even larger commercial market in major countries in Europe and the U.S. within fiscal year 2012.

In Japan, three Phase 3 studies focusing on patients with acute coronary syndromes who have undergone percutaneous coronary intervention (PCI), elective PCI patients, and ischemic cerebrovascular disease patients are underway. As for the Phase 3 study for ACS-PCI, we expect to get top line results in the second half of fiscal year 2012.

#### 2. Edoxaban (DU-176b)

Edoxaban is a novel, once-daily oral anticoagulant that specifically, reversibly and directly inhibits factor Xa, an important factor in the coagulation cascade. Edoxaban was put on the market in Japan in July 2011 under the brand name Lixiana as the first factor Xa

inhibitor licensed for the prevention of venous thromboembolism (VTE) in patients undergoing total knee, total hip arthroplasty and hip fracture surgery.

The Phase 3 study, ENGAGE AF-TIMI 48, which aims to secure the additional indication for stroke prevention in atrial fibrillation (AF) patients, is due to complete by the end of fiscal year 2012. We will intently focus on early completion of a regulatory filing for stroke prevention in AF patients, who are believed to form a large group in clinical terms.

In addition, the "last patient-last visit (LPLV)" of the Phase 3 study, HOKUSAI VTE, focusing on the prevention of recurrent venous thromboembolism (VTE) in patients with conditions such as deep vein thrombosis (DVT) or pulmonary embolism (PE) will be completed in the second half of fiscal year 2012.

#### 3. Tivantinib (ARQ 197)

Tivantinib is an orally available, selective MET inhibitor, and we are currently conducting a Phase 3 study for non-small cell lung cancer (MARQUEE) in Europe and the U.S. etc., for which enrollment was completed in May, 2012.

In Phase 2 study of hepatocellular carcinoma patients, tivantinib significantly improved progression free survival and overall survival in patients with MET-high tumors (presented at the American Society of Clinical Oncology, ASCO, in June 2012.) We believe this is a major achievement in the progression of the drug's development.

#### Major R&D Pipeline (as of May, 2012)

Therapeutic area	Phase 1	Phase 2	Phase 3	Application
Cardiovascular- Metabolics	■ CS-3150 (Anti-hypertensive) ■ DS-7309 (Anti-diabetes) ■ DS-7250 (Anti-diabetes)	■ CS-747 (US) (Prasugrel / Sickle cell disease / anti-platelet agent)	■ DU-176b (Global) (Edoxaban / AF / oral factor Xa inhibitor) ■ DU-176b (Global) (Edoxaban / VTE / oral factor Xa inhibitor) ■ CS-747 (Global) (Prasugrel / ACS-MM / anti-platelet agent) ■ CS-747 (JP) (Prasugrel / PCI / anti-platelet agent) ■ CS-747 (JP) (Prasugrel / isohemic stroke / anti-platelet agent)	
Oncology	■ U3-1565 (Anti-HB-EGF antibody) ■ DS-2248 (Hsp90 inhibitor) ■ DS-7423 (PiSK/mTOR inhibitor) ■ ARQ 092 (AKT inhibitor) ■ DS-3078 (mTOR inhibitor)	■ U3-1287 (Anti-HER3 antibody) ■ CS-1008 (Tigatuzumab / anti-DR5 antibody) ■ CS-7017 (Efatutazone / PPAR9 agonist) ■ DE-766 (Nimotuzumab / anti-EGFR antibody) ■ PLX3397(Fms/kti/Fl3-TD inhibitor) ■ PLX4032 (Vemurafenib / BRAF inhibitor)	ARQ 197 (Global*) (Tivantinib / NSCLC / Met inhibitor)      AMG 162 (JP) (Denosumab / breast cancer adjuvant / Anti-RANKL antibody)	
Others	■ CS-8958 (Laninamivir / anti-influenza / Outlicensing with Biota) ■ CS-4771 (Anti-isspsis) ■ DS-8587 (Broad spectrum antibacterial agent) ■ PLX5622 (Rheumatoid arthritis) ■ CS-0777 (Immuno-modulator) ■ SUN13837 (Spinal cord injury)	AMG 162 (JP) (Denosumab / rheumatoid arthritis / anti-RANKL antibody)      SUN13834 (US) (Atopic Dermatitis / Chymase inhibitor)      DS-5565 (Global) (Chronic pain / a26 ligand)	CS-8958 (JP) (Laninamivir / anti-influenza, prophylactic / Neuraminidase inhibitor) DD-723-8 (JP) (Perflubutane / Contrast enhanced ultrasonography for prostate tumor/ ultrasound contrast agent)	■ DD-723-B (JP) (Perflubutane / Contrast enhanced ultrasonography for breast tumor / ultrasound contrast agent) ■ AMG 162 (JP) (Denosumab / osteoporosis / Anti-RANKL antibody)

The most advanced stages are described here in oncology area

<sup>\*</sup> Study on-going outside Japan

# What is the current status and future prospects for Ranbaxy's business development?

Ranbaxy is an innovation driven generics company focused on science and technology, and one of its key features is its capacity for R&D. Thanks to a highly knowledgeable and skilled R&D workforce, India's highest level of R&D funding, and dedicated facilities for generic research, Ranbaxy has already submitted one of the highest number of applications for approval among pharmaceutical companies worldwide.

In addition, Ranbaxy has established an attractive portfolio of ANDAs\* and FTF pipeline in the U.S.

There are two points to note concerning Ranbaxy's future business strategy.

The first is to increase growth investment in emerging nations, including India where Ranbaxy is based, to secure sustainable profit growth. We will consolidate Ranbaxy's position as India's top pharmaceutical company, and developing and enhancing our business in emerging countries by getting the maximum leverage from the Ranbaxy's corporate brand will be important issues.

The second is to acquire business opportunities with high commercial potential in developed markets by means of high value products to which we have exclusive rights, such as FTF products in the U.S. market. We will diligently continue to market important FTF products.

Ranbaxy's capacity for maximizing FTF opportunities and value

were again demonstrated at the end of 2011 with the launch of atorvastatin as an FTF product.

In its fourth week on the market, it took a higher share than the authorized generic product, and in its sixth week, it also overtook the innovator's product to take the top market share.

We will also be working to launch high value generics ahead of our competitors in both developed and emerging countries.

The consent decree signed with the FDA which came into effect in January 2012 was an important factor in moving our Ranbaxy business strategy forward.

Ranbaxy is steadily implementing the corrective measures stipulated in the consent decree and is developing an in-house framework to ensure cGMP\*\* compliance and data integrity. It is also continuing close negotiations with the DOJ to reach a settlement and resolve outstanding issues as soon as possible (as of June 2012).

Exports of atorvastatin to the U.S. market from Ranbaxy's facility at Mohali, India, started in March, 2012. This marks the first time exports from Indian factories to the U.S. have restarted since the FDA issued a ban on imports from two of Ranbaxy's Indian plants in September, 2008.

- \* ANDA(Abbreviated New Drug Application)
  An abbreviated new drug application (ANDA) is a simplified procedure for submitting an application for a generic drug to the FDA by submitting data indicating its biochemical equivalence to the reference brand-name drug.
- \*\* Current good manufacturing practice: Current standard for pharmaceutical manufacturing and quality management.



## What are the future prospects for your Hybrid Business?

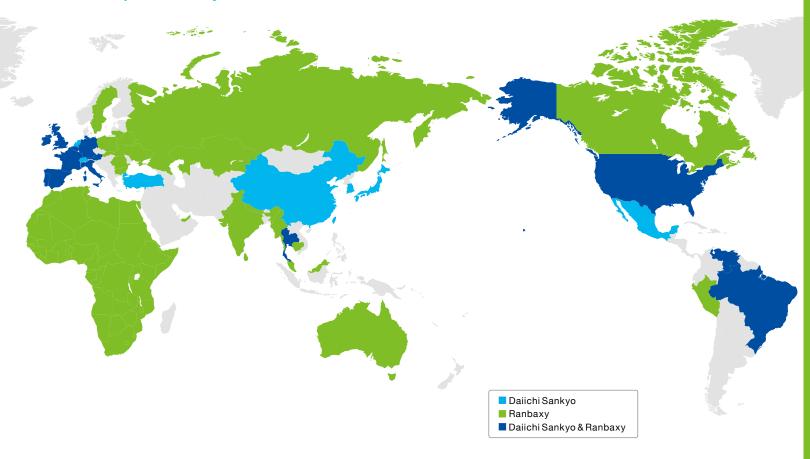
Negotiations with U.S. authorities, which had been a major management issue since Ranbaxy became part of the Daiichi Sankyo Group, have reached a point of closure and we regard stepping up the evolution of our Hybrid Business Model as an important issue that should be dealt with promptly.

Specifically, along with strengthening our operations along two business axes - Daiichi Sankyo's innovative pharmaceuticals business and Ranbaxy's generic business - we will seek to optimize the role that we play in each geographic area of the world by tailoring our activities to local market characteristics.

Furthermore, by combining assets possessed by the two

companies, including technology and know-how, we will be able to create unprecedented new value and generate further cost synergies, thereby accelerating our efforts to boost the Group's overall profitability and increase profits.

#### Development of the Hybrid Business Model in the Global Market



## What are the significant risks for your business and how will you

We recognize that the current strategic mission of the Daiichi Sankyo Group is to achieve mid to long term growth and profitability, and to restore the company's corporate value.

At present, building a solid quality management system at Ranbaxy is one of our highest priority business issues and something which must be implemented for effective risk management.

Regarding regulatory issues with the FDA, Ranbaxy signed a consent decree on January 26, 2012 which will remain in legal force for a period of five years.

The consent decree commits Ranbaxy to institute a range of corrective measures in relation to its systems for quality assurance, quality control, data integrity, cGMP compliance and production auditing.

Ranbaxy's CEO & Managing Director, Arun Sawhney has taken executive responsibility for the establishment of a program to institute these measures, while the Ranbaxy board of directors will monitor their progress.

Ranbaxy has been working to improve its cGMP compliance systems even before the Application Integrity Policy (AIP)\* was invoked in February 2009. After the AIP invocation, Ranbaxy accelerated its efforts, including an overhaul of the management team. Since the signing of the consent decree, Ranbaxy has been taking additional steps to further upgrade its data integrity systems. The implementation by Ranbaxy of the program of corrective measures specified in the consent decree is a required task to ensure progress in the development of the Hybrid Business Model encompassing the Group's innovative and generic drug operations.

Ranbaxy recorded a provison of 500 million dollars in 2011, which we believe will be sufficient to cover any potential losses relating to the settlement with the DOJ. As a result of this, Daiichi Sankyo recorded a provision of 39.9 billion yen in fiscal year 2011.

Another important business task that we are working on is risk response development related to the occurrence of natural disasters.

Following the Great East Japan Earthquake and in preparation for future natural disasters, the Group has formulated a new Business Continuity Plan (BCP) to support swift restoration of operations in an emergency to ensure reliable supply of high quality pharmaceuticals so that the country's healthcare system can continue to function effectively.

Based on the recovery period needed after the Great East Japan Earthquake and the probability of further earthquakes, the new BCP revises the prioritization of actions from the perspectives of ensuring the continuity of operations, especially for mainstay products, and the rapid restoration of any supplies of medicines for emergency use or where no alternatives exist, both of which are product categories with high social significance.

The supply chain risks associated with the time required to restore supplies in an emergency were also evaluated, and preventative measures, as well as contingency measures to support restoration of supply or switch to substitute products, have been examined. In addition, the entire Group has revisited risk management practices based on the revised BCP, and other divisions within the Group are updating and improving their own BCPs.

\*AIP (Application Integrity Policy)

If the FDA questions the credibility or reliability of data used in filing for drug approval, this measure is invoked on facilities where the data in question was







# What is your CSR philosophy, and what are your major CSR

The globalization of corporate activities and their growing impact on the environment and society have increased demand for companies to exercise social responsibility. A sustainable and responsible approach to business, including appropriate management of finance and ESG factors\*, is becoming a key part of modern corporate management.

The globalization of Daiichi Sankyo's own business prompted us, in fiscal year 2011, to revise the Daiichi Sankyo Group Corporate Conduct Charter, which sets out the basic principles of all Group company activities. We also made a commitment to pursue our business in a responsible manner, both within and outside the Group, by signing the United Nations Global Compact. Basing ourselves on the Daiichi Sankyo Group Corporate Conduct Charter, we will pursue our quest to improve corporate quality, not only in terms of our products and services but also with regard to the people who work for our Group companies and every aspect of corporate management and governance.

Daiichi Sankyo is also doing its part, as a front-runner in the pharmaceutical industry, to resolve international health issues and has begun providing mobile healthcare services in India, Cameroon and Tanzania. The project emphasizes partnership, bringing together the problem-solving capabilities of the Daiichi Sankyo Group, the expertise of NPOs and NGOs and the resources of governments and local communities. It has made steady progress in improving the health of local people while also enhancing Daiichi Sankyo's presence.

The Daiichi Sankyo Group conducts business as a pharmaceutical manufacturer that contributes to the welfare of society on a broad scale. We will continue to pursue these initiatives with a medium to long-term perspective to win recognition from our stakeholders around the world.

\* ESG factors: the environmental, social and corporate governance factors used in measuring the sustainability and ethical impact of corporate activities



# Company Information / Stock Information

#### **Corporate Profile**

Company Name DAIICHI SANKYO COMPANY, LIMITED

Established September 28, 2005

Headquarters 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo

103-8426, Japan

**URL** http://www.daiichisankyo.com

**Business** Research and development, manufacturing, import,

sales and marketing of pharmaceutical products

Paid-in Capital ¥50,000 million

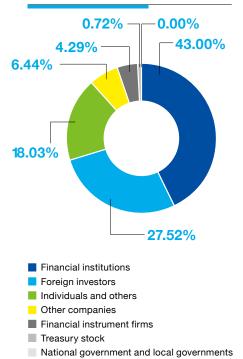
31,929 (consolidated) **Employees** 



Number of shares authorized 2,800,000,000 Number of shares issued 709,011,343 Number of shareholders 114,396



#### **Distribution of shareholders**



#### **Major Shareholders**

Name	Number of Shares Held (Thousands of Shares)	Ratio (%)
The Master Trust Bank of Japan, Ltd. (trust account)	46,249	6.52
Japan Trustee Services Bank, Ltd. (trust account)	45,975	6.48
Nippon Life Insurance Company	37,659	5.31
SSBT OD05 OMNIBUS ACCOUNT-TREATY CLIENTS	17,876	2.52
Sumitomo Mitsui Banking Corporation	13,413	1.89
JP Morgan Chase Bank 385147	13,001	1.83
Employee stock ownership of Daiichi Sankyo Group	9,215	1.29
Deutsche Securities Inc.	9,076	1.28
Deutsche Bank Trust Company Americas ADR Dept Account	8,903	1.25
Mizuho Corporate Bank, Ltd.	8,591	1.21
Total	209,964	29.61

## Other Detailed Information

Please go to the below referenced web link within "Annual Report" webpage of our corporate website for below mentioned information.

- Financial Results
- Research & Development Pipeline (Development Stage)
- Corporate Social Responsibility Report
- Corporate governance
- Board of Members



## http://www.daiichisankyo.com/ir/archive/ar/index.html

TOP > INVESTOR RELATIONS > Archive > Annual report





3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan http://www.daiichisankyo.com