

(Securities Code 4506)

## Quest for Further Innovation



Sumitomo Dainippon Pharma Co., Ltd.

http://www.ds-pharma.com

## Overview Mission

#### Sumitomo Dainippon Pharma's Missions

#### **Corporate Mission**

To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide

#### Management Mission

- •To contribute to healthcare and people's well-being based upon the principles of patient-oriented management and innovative research
- •To continuously strive to maximize corporate value through constant business development and to fulfill shareholder expectations
- •To create an environment in which employees can fulfill their potential and increase their creativity
- •To maintain the trust of society and to contribute to the realization of a better global environment

#### Corporate History

Sumitomo Dainippon Pharma Co., Ltd. was established in October 2005 through the merger of Dainippon Pharmaceutical Co., Ltd. and Sumitomo Pharmaceuticals Co., Ltd. with the aim of broadly contributing to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide.

Dainippon Pharmaceutical has its origins in Osaka Pharmaceuticals Co., Ltd., which was established in 1897 in Doshomachi, Osaka, by 21 prominent leaders in the pharmaceutical industry. In the following year, 1898, the company acquired Dainippon Pharmaceutical Company, which had been established under the supervision of the government in 1883 as Japan's first pharmaceutical manufacturer. The company inherited its new acquisition's name and trademark, becoming Dainippon Pharmaceutical Co., Ltd.

Sumitomo Pharmaceuticals was established in February 1984, from the Research, Development, and Manufacturing divisions of Sumitomo Chemical Co., Ltd.'s pharmaceuticals business, as well as the Pharmaceuticals Sales division of Inabata & Co., Ltd.

The spirit of these two companies has been passed on to Sumitomo Dainippon Pharma. While striving to be a cutting-edge pharmaceutical company with a strong market presence, we will continue to provide innovative and useful pharmaceuticals to people not only in Japan, but also around the world.





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### Editorial Policy Applicable Period

This report is based on the results for fiscal 2013 (April 1, 2013 to March 31, 2014). Some of the activities described were conducted in fiscal 2014.

#### **Organizational Scope**

The report covers the 16 companies in the Sumitomo Dainippon Pharma Group (Sumitomo Dainippon Pharma Co., Ltd., its 15 consolidated subsidiaries). However, environmental performance data in the report are totals for major facilities in Japan only (plants, research laboratories, distribution centers, Osaka Head Office, Tokyo Head Office, branches).

#### **Disclaimer Regarding Forward-Looking Statements**

The forward-looking statements in this annual report are based on management's assumptions and beliefs in light of information available up to the date of publication, and involve both known and unknown risks and uncertainties. Actual financial results may dif fer materially from those presented in this document, being dependent on a number of factors. Information concerning pharmaceuticals (including compounds under development) contained within this material is not intended as advertising or medical advice



# Our New Vision and the Roadmap to Success

In our quest for innovation, we have outlined five new basic strategies and set out a new vision: "Aspire to be a globally active R&D-based company" and "Contribute to medical care through leading-edge technologies."

To attain the business goals and realize the corporate vision outlined in the third Mid-term Business Plan (the 3rd MTBP,FY2013-2017), the Sumitomo Dainippon Pharma Group is moving forward, promoting new business development and innovation in line with six strategies covering its products, therapeutic areas, regions, R&D, investment and financial position while working to strengthen its business foundation and promote CSR management.



#### **Basic Strategies of the 3rd MTBP**

- Establish a robust revenue base in Japan
- Further expand overseas business and maximize earnings
- Expand global pipeline
- Continuously pursue operational efficiency and CSR
- Build an active corporate culture and develop talent

2012~

Made a full-scale entry into the oncology research area

**New Vision: Quest for Further** Innovation

1. Aspire to be a globally active R&D-based company

2. Contribute to medical care through leading-edge technologies

2013~

Made real progress toward commercializing regenerative medicine and cell therapy

- Jointly developed cell therapies using iPS cells with Healios K.K. (2013)
- Established Sighregen K.K., a joint venture company for regenerative medicine and cell therapy business (2014)
- Opened the Kobe Regenerative & Cellular Medicine Center as a research and manufacturing base (2014)
- Acquired Boston Biomedical, Inc. and its anti-cancer drugs BBI608 and BBI503 (2012)
- Moved to independently develop cancer peptide vaccines WT4689 and WT2725 (2013)

**Psychiatry & Neurology Area** 

#### Accelerating the Global Development of LATUDA®

• Made a full-scale entry into the North American market with LATUDA®, which the Company successfully developed in-house as a global strategic product (2011)

- Obtained approval for the indication for bipolar depression in addition to schizophrenia in the North American market (2013)
- Obtained approvals in Europe and Australia. The marketing authorization application (MAA) is under review in Taiwan and Phase III clinical studies are under way in Japan and China (2014)
- Expanded the development pipeline in the Psychiatry & Neurology area

#### **Mid-term Business Plans**

#### First Phase, FY2007 to FY2009: Solid Fundamentals

•Focus resources on four strategic products •Early maximization of new products

Overseas •Establish US marketing organization

- •Expand US/EU clinical development organization
- •Start-up US business in our own sales organization

R&D

•Strengthen new drug discovery activities and inlicensing activities

#### Second Phase, FY2010 to FY2012: Take Off

•Transform domestic business foundation

Overseas •Expand North American business through our own sales organization

R&D •Expand new product pipeline

#### Third Phase, FY2013 to FY2017: Sustained Growth

•Establish strong domestic business foundation

Overseas •Strengthen profitability in North America

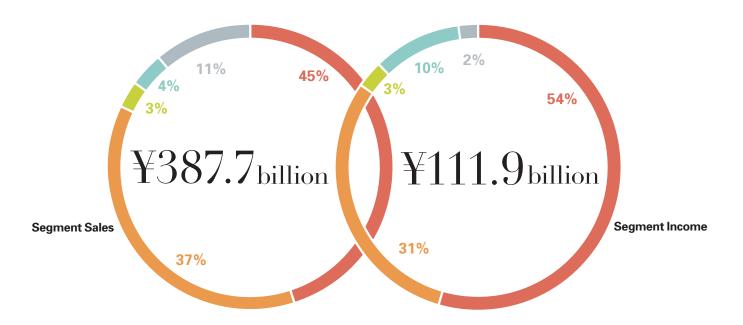
•Expansion into Europe and Asia

R&D Expand global pipeline

Develop leading-edge science fields

# Performance

Segment Sales and Segment Income for Fiscal 2013



#### Japan

Segment sales: ¥171.9 billion Segment income: ¥60.8 billion

In addition to sales of the Company's four strategic products, which comprise the therapeutic agents for hypertension AIMIX® and AVAPRO®, the atypical antipsychotic LONASEN®, and the therapeutic agent for Parkinson's disease TRERIEF®, sales of the biguanide oral hypoglycemic METGLUCO® grew drastically. However, this growth did not fully cover decreases in sales of other existing products partly attributable to the expiration of the patents duration and a decrease in commissioned manufacturing. Consequently, segment sales declined 1.5% from the previous fiscal year to ¥171,898 million. As selling, general and administrative (SG&A) expenses, excluding research and development costs, improved thanks to reduction efforts, segment income edged up 0.3 % year on year to ¥60,827 million.

#### North America

Segment sales: ¥145.3 billion Segment income: ¥33.9 billion Segment sales rose to ¥145,271 million, up 25.4% from the previous fiscal year, supported by a further increase in sales of the atypical antipsychotic LATUDA® and the weakened yen, which compensated for a considerable fall in sales of XOPENEX®, a short-acting beta agonist, due to the expiration of its period of exclusivity. SG&A expenses, excluding research and development costs, improved, reflecting a reduction in personnel costs due to business structure improvement and the completion of partial patent depreciation on a local currency basis. Because of the weakened yen, however, SG&A expenses were up in terms of yen. Nevertheless, the impact of sales growth outstripped these factors, leading to a 125.2% surge in segment income to ¥33,877 million.

#### China

Segment sales: ¥11.9 billion Segment income: ¥3.2 billion Sales of MEROPEN®, a carbapenem antibiotic, continued to increase and ALMARL®, a therapeutic agent for hypertension, angina pectoris and arrhythmia, also recorded successful results. In addition, benefiting from the weakened yen, segment sales grew 56.1% from the previous fiscal year to ¥11,928 million and segment income jumped 73.8% to ¥3,182 million.

#### Other Regions

Segment sales: ¥16.7 billion Segment income: ¥11.4 billion Although the export of MEROPEN® to major countries overseas decreased due to patent expiration, industrial property revenue was generated because of the approval of LATUDA® in Europe. Consequently, segment sales were ¥16,713 million, an 80.3 % increase from the previous fiscal year, and segment income rocketed 161.6% to ¥11,359 million.

#### Other Businesses

Segment sales: ¥41.9 billion Segment income: ¥2.7 billion Sales of food ingredients, food additives, chemical product materials, veterinary drugs, diagnostic agents and other businesses are conducted by the Sumitomo Dainippon Pharma Group, including DSP Gokyo Food & Chemical Co., Ltd., DS Pharma Animal Health Co., Ltd. and DS Pharma Biomedical Co., Ltd. Segment sales rose 3.4% year on year to ¥41,883 million and segment income decreased 10.8% to ¥2,673 million.

#### Financial/Non-financial Highlights

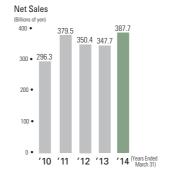
Net sales	Fiscal 2012 (¥ billion)	Fiscal 2013 (¥ billion)	(change) 11.5%	Fiscal 2017 (¥ billion)
	<b>U17.7</b>	007.7	11.0/0	100.0
Sales of pharmaceuticals	307.2	345.8	12.6%	400.0
Operating income	25.0	42.1	68.3%	80.0
EBITDA	60.3	68.1	12.9%	110.0
R&D costs	59.8	69.8	16.6%	80.0
Exchange rate (yen/\$)	79.8	100.2		80.0
ROE	3.0	5.4		(%)
CO <sub>2</sub> Emissions	(Thousand tons/Year)	(Thousand tons/Year)  76.1	△5.2%	(Thousand tons/Year)
Waste generated	(Tons/Year)	6,085	△41.0%	(Tons/Year)
Waste Recycled	(Tons/Year) 7,628	4,839	△36.6%	(Tons/Year)

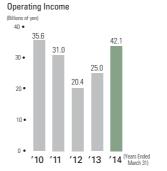
### Eleven-Year Summary of Selected Financial Data

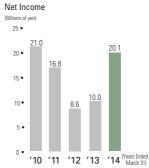
Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31

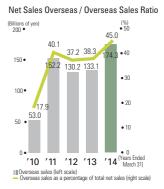
Years Ended March 31											Millions of yen	Percent change	Thousands of U.S. dollars
	2004	2005	2006	2007	2008	2009	2010	2011	2012	2013	2014	2014/2013	2014
RESULTS OF OPERATIONS:													
Net sales	¥171,672	¥175,088	¥245,784	¥261,213	¥263,993	¥264,037	¥296,262	¥379,513	¥350,396	¥347,724	¥ 387,693	11.5%	\$3,764,010
Overseas sales revenue	3,630	3,820	9,696	22,032	24,521	22,051	53,015	152,226	130,243	133,125	174,286	30.9%	1,692,097
Ratio of overseas sales revenue	2.1%	2.2%	3.9%	8.4%	9.3%	8.4%	17.9%	40.1%	37.2%	38.3%	45.0%		
Cost of sales	110,013	111,099	130,437	99,346	99,385	103,741	112,263	110,030	98,857	101,686	104,100	2.4%	1,010,680
Selling, general and administrative expenses	51,546	52,404	86,461	116,312	124,794	129,130	148,374	238,531	231,137	220,994	241,450	9.3%	2,344,175
Operating income	10,113	11,585	28,886	45,555	39,814	31,166	35,625	30,952	20,402	25,044	42,143	68.3%	409,155
Income before income taxes	13,836	11,686	25,687	38,415	41,457	32,168	31,423	25,050	16,328	18,158	34,709	91.1%	336,981
Net income	7,968	6,924	15,377	22,605	25,592	19,988	20,958	16,796	8,630	10,044	20,061	99.7%	194,767
Comprehensive income (loss)	_	_	_	_	_	_	27,148	(12,066)	2,396	37,174	45,165	21.5%	438,495
FINANCIAL POSITION:													
Current assets	118,562	131,176	249,733	234,313	251,063	263,540	287,555	333,000	334,251	333,439	359,612	7.8%	3,491,379
Net property, plant and equipment	34,473	32,611	68,336	65,241	70,280	69,105	74,084	69,794	66,697	69,862	72,689	4.0%	705,718
Total assets	193,238	201,431	392,966	382,535	399,791	391,295	626,743	589,868	559,410	607,219	659,033	8.5%	6,398,379
Current liabilities	45,927	49,196	80,071	56,039	67,915	53,350	265,000	157,204	105,966	124,831	131,208	5.1%	1,273,864
Long-term liabilities	16,258	16,802	24,262	20,484	13,598	13,449	18,260	108,681	134,217	133,140	129,285	(2.9%)	1,255,195
Net assets	130,268	135,433	288,633	306,012	318,278	324,496	343,483	323,983	319,227	349,248	398,540	14.1%	3,869,320
OTHER STATISTICS:													
Research and development costs	15,929	17,444	29,636	40,870	47,266	52,819	51,371	68,160	56,891	59,844	69,804	16.6%	677,709
Capital expenditures	4,294	3,064	6,616	9,543	15,491	10,569	6,471	8,663	8,742	12,384	23,421	58.6%	190,738
Depreciation and amortization	5,821	5,233	8,901	12,008	11,870	11,455	18,650	44,628	40,232	35,085	26,777	(23.7%)	259,971
EBITDA	16,040	16,446	36,179	54,875	48,802	41,970	56,448	77,971	59,880	60,333	68,101	12.9%	661,175
PER SHARE OF COMMON STOCK:													
Basic net income	¥ 48.05	¥ 41.76	¥ 54.57	¥ 56.86	¥ 64.39	¥ 50.30	¥ 52.75	¥ 42.27	¥ 21.72	¥ 25.28	¥ 50.49	99.7%	\$ 0.49
Net assets	784.24	815.76	723.63	767.52	800.63	816.49	864.51	815.44	803.47	879.03	1,003.11	14.1%	9.74
Cash dividends applicable to the year	10.00	10.00	12.00	14.00	18.00	18.00	18.00	18.00	18.00	18.00	18.00	0.0%	0.17
FINANCIAL INDICATORS:													
Operating margin	5.9%	6.6%	11.8%	17.4%	15.1%	11.8%	12.0%	8.2%	5.8%	7.2%	10.9%		
ROE	6.5%	5.2%	7.3%	7.6%	8.2%	6.2%	6.3%	5.0%	2.7%	3.0%	5.4%		
ROA	4.2%	3.5%	5.2%	5.8%	6.5%	5.1%	4.1%	2.8%	1.5%	1.7%	3.2%		
Equity ratio	67.1%	66.8%	73.2%	79.8%	79.6%	82.9%	54.8%	54.9%	57.1%	57.5%	60.5%		

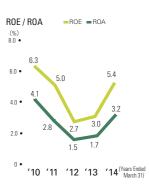
- Notes 1. The U.S. dollar amounts in this report represent translations of Japanese yen included solely for the reader's convenience at the rate of ¥103 = US\$1.00, the approximate rate of exchange at March 31, 2014.
  - 2. Dainippon Pharmaceutical Co., Ltd. merged with Sumitomo Pharmaceuticals Co., Ltd. on October 1, 2005 and changed its name to Dainippon Sumitomo Pharma Co., Ltd. On June 19, 2014, the company name was changed to Sumitomo Dainippon Pharma Co., Ltd. in preparation for global development.
  - 3. Sumitomo Dainippon Pharma Co., Ltd. and its consolidated subsidiaries adopted the new accounting standards for presentation of net assets in the balance sheet from years ended March 31, 2007. In accordance with the adoption of the new accounting standards, net assets in the financial position till years ended March 31, 2006
  - 4. Sumitomo Dainippon Pharma Co., Ltd. acquired Sepracor Inc. (now Sunovion Pharmaceutical Inc.) in October 2009. Consolidated results for 2010 include the results of this company for 2.5 months (October 15 - December 31, 2009).
  - 5. Sumitomo Dainippon Pharma Co., Ltd. and consolidated subsidiaries adopted the new accounting standard for presentation of comprehensive income and the revised accounting standard for consolidated financial statements in accordance with the adoption of the new accounting standards, comprehensive income (loss) has been presented in the results of operations from 2010 to 2013.
  - $6. \ \ EBITDA = Income \ before \ income \ tax \ and \ minority \ interests + interest \ expense interest \ income \ + \ depreciation \ and$ amortization + amortization of goodwill - extraordinary income (loss).











# Focus

Sumitomo Dainippon Pharma. has identified psychiatry & neurology and oncology as focus therapeutic areas for research and development. We are also engaged in developing new fields encompassing disease fields where no approved drugs exist as well as regenerative medicine / cell therapy field.

Focus Therapeutic Areas and Explore New Fields



# Focus Therapeutic Areas

Psychiatry & Neurology
Oncology

## Explore new fields

Disease fields where no approved drugs exist Regenerative Medicine/Cell Therapy fields Psychiatry & neurology and oncology are our focus therapeutic areas for research and development. By fiscal 2017, during the third Mid-term Business Plan, we aim to have initiated clinical research on eight compounds in oncology and ten compounds outside oncology, including in psychiatry & neurology.

#### Psychiatry & Neurology

In psychiatry & neurology, we are promoting research and development that addresses such disorders as schizophrenia, depression, Alzheimer's disease, neuropathic pain, developmental disorders and neurodegenerative disorders,

with an emphasis on alleviating symptoms where treatments are unsatisfactory and finding new ways to help patients for whom the efficacy of existing treatments is insufficient.

#### Oncology

In oncology, we are focusing efforts on discovering innovative new drugs. In 2012, we acquired the U.S. biotechnology company Boston Biomedical, Inc. Through this acquisition, we gained a revolutionary development pipeline and superi-

or drug discovery and development capabilities. With this global research network, we aim to lead the world in cancer stem cell research and sustainably create groundbreaking products.

## Explore New Fields: Disease fields where no approved drugs exist and Regenerative Medicine/Cell Therapy fields

In regenerative medicine/cell therapy fields, we established the Regenerative & Cellular Medicine Office in September 2013 to vigorously promote the commercialization of cell therapy and regenerative medicine using induced pluripotent stem (iPS) cells and other cutting edge technologies. In addition to human iPS cells, we are bringing to bear the most advanced scientific developments in our push to develop

treatments for disease fields where no approved drugs exist. In the area of disease fields where no approved drugs exist, we are currently developing EPI-743 for the prospective indication Leigh syndrome. It was granted orphan designation for Leigh syndrome, which is diagnosed in around 200 patients in Japan.

<sup>\*</sup>Leigh syndrome: A lethal, progressive, neurodegenerative mitochondrial disease that develops in early childhood. It induces cell death through DNA mutations, leading to various clinical symptoms, including irregular respiration, nystagmus, ataxia, and optic neuropathy.

# Overview Products

#### Strategic Products in Japan









#### AIMIX® (Therapeutic agent for hypertension, Launch: December 2012)

AIMIX® Combination Tablets LD/HD have a 24-hour-lasting antihypertensive effect and are a combination product of irbesartan (brand name: AVAPRO®), a long-acting angiotensin II receptor antagonist (ARB) and amlodipine besilate (brand name: AMLODIN®), a calcium antagonist with a strong, sustained hypotensive effect.

AIMIX® Combination Tablets HD is the first combination product in Japan including 10mg of amlodipine.

#### **AVAPRO**<sup>®</sup> (Therapeutic agent for hypertension, Launch: July 2008)

AVAPRO® is a long-acting ARB with a long half-life in blood and a 24-hour-lasting blood pressure-lowering effect, having high antihypertensive effect for mild to severe hypertension. Abundant data for efficacy and safety available from the U.S. and Europe where this drug is on the market under the brand name of AVAPRO or APROVEL.

#### LONASEN® (Atypical antipsychotic, Launch: April 2008)

LONASEN® blocks dopamine-2 receptors and serotonin-2A receptors. In clinical studies, this drug showed efficacy for not only positive symptoms of schizophrenia (such as hallucinations or delusions), but also negative symptoms (such as flat affect or hypobulia). The incidence of adverse reactions such as extrapyramidal symptoms hyperprolactinemia and weight gain in the clinical studies was lower than the incidence reported for other drugs in this therapeutic area.

#### TRERIEF®

#### (Therapeutic agent for Parkinson's disease, Launch: March 2009)

TRERIEF® is a once daily treatment of Parkinson's disease patients who are not sufficiently treated by other anti-Parkinson's disease drugs which shows improvement in movement ability, daily fluctuation and activities of daily living.

It has also been shown that this drug has few of the side-effects that are often a problem in treating Parkinson's disease, including psychiatric symptoms and dyskinesia.

#### Main Products in North America

#### LATUDA® (Atypical antipsychotic, Launch: February 2011)

LATUDA® is an atypical antipsychotic indicated for adult patients with schizophrenia and bipolar depression. LATUDA® has an affinity for dopamine D2, serotonin 5-HT2A and serotonin 5-HT7 receptors where it has antagonist effects. In addition, LATUDA® is a partial agonist at the serotonin 5-HT1A receptor and has no appreciable affinity for histamine or muscarinic receptors. LATUDA® was approved as the first atypical antipsychotic indicated for the treatment of bipolar depression as monotherapy and as an adjunctive therapy to lithium or valproate by the U.S. FDA in June 2013.



#### **BROVANA®** (Long-acting ß-agonist,Launch: April 2007)

BROVANA® is a long-acting  $\mbox{\ensuremath{\mathbb{G}}}$ -agonist developed in-house. It is an inhalation solution bronchodilator indicated for the maintenance treatment of Chronic Obstructive Pulmonary Disease (COPD).



#### APTIOM® (Antiepileptic,Launch: April 2014)

APTIOM® is an antiepileptic for use as an adjunctive therapy in adults with partial-onset seizures. APTIOM®, a voltage-gated sodium channel blocker, is taken once daily and can be taken whole or crushed, with or without food. APTIOM® is not classified as a controlled substance by the FDA.



### Overview

# Highlights 2013

June 29, 2013

LATUDA® Approved for Bipolar Depression in the United States

LATUDA®, already on sale in the United States as a treatment for schizophrenia in adults, became the first atypical antipsychotic approved by the U.S. FDA for the treatment of bipolar depression in adults as a monotherapy and an adjunctive therapy with either lithium or valproate.

#### **January 31, 2014**

Sumitomo Dainippon Pharma Deepens Cooperation with Edison Pharmaceuticals

In March 2013, we entered into an agreement with Edison Pharmaceuticals, Inc. granting us exclusive research, development and commercial rights in Japan for EPI-743 and EPI-589, therapeutic agents under development for mitochondrial disease.

In January 2014, the agreement was amended to grant the company exclusive development and commercial rights for EPI-589 in North America for agreed-upon indications in adults. In addition, the two companies signed a joint research agreement for the discovery of novel candidate pharmaceutical compounds targeting cellular energy metabolism.

#### March 6, 2014

Established Sighregen, a Joint Venture Company to Advance the Regenerative Medicine and Cell Therapy Business

Healios K.K. and Sumitomo Dainippon Pharma are continuing to carry out joint development in Japan of iPS cell-derived retinal pigment epithelial (RPE) cells for the treatment of agerelated macular degeneration and other eye diseases. The companies established the joint venture company Sighregen K.K. in Kobe City to engage in the manufacture and sales promotion of any jointly developed iPS cell-derived RPE cell products commercialized in the future.

# March 31, 2014 Obtained European Marketing Authorization for LATUDA®

In March 2014, the European Commission granted Marketing Authorization for LATUDA® to our European partner Takeda Pharmaceutical Company Limited. LATUDA® will be marketed in the United Kingdom by Sunovion Pharmaceutical's European subsidiary Sunovion Pharmaceuticals Europe by Takeda's European subsidiary.

## April 7, 2014 APTIOM® launched in U.S.

APTIOM® (eslicarbazepine acetate), a antiepileptic drug indicated for use as an adjunctive treatment for partial-onset seizures in patients aged 18 years and older, was approved by the U.S. FDA in November 2013 and was launched in the U.S. in April 2014.

 $\overset{\scriptscriptstyle{2013}}{ ext{Mar.}}$ 

Apr.

May

Jun.

Jul.

Aug.

Sep.

Nov. Dec.

Jan.

2014

Feb. Mar.

Apr.

#### March 11, 2013

Opened "SUKOYAKA," a Self-Directed Study Space for Junior High and High School Students in Areas Affected by the Great East Japan Earthquake

In cooperation with the non-profit organization Children's Welfare Laboratory, we opened "SUKOYAKA," a self-directed study space for junior high and high school students, in Tome City, Miyagi Prefecture. Minami-Sanrikucho in Miyagi Prefecture was devastated in the Great East Japan Earthquake, and Tome City has accepted evacuees from there and other areas in the prefecture struck by the disaster. The new facility offers two self-study rooms and study materials for the children in this area. There is

also a cafe adjacent to the facility where light meals are offered free of charge. "SUKOYAKA" supports stability and prosperity in the region. Committed to supporting children's education as one facet of its recovery support efforts, we will continue to ensure this facility is able to contribute to the welfare of children in this region.



April 1, 2013

Fiscal 2013 Grant

Recipients and the Winners of Research Prizes and Research Service Prizes

The Japan Epilepsy Research Foundation again awarded Grant Recipients and recognized the Winners of its Research Prizes and Research Service Prizes. In 1987, Sumitomo Dainippon Pharma donated the funding that began the Japan Epilepsy Research Foundation to encourage the advance of research regarding the causes, conditions, diagnosis and treatment of epilepsy.

October 7, 2013

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Revamped Our Japanese Website "SUKOYAKA Compass"

As part of its activities to support educating the next generation, we established the website "SUKOYAKA Compass(http://www.ds-pharma.co.jp/sukoya-ka/)." A Japanese-language site, SUKOYAKA Compass provides such content as explanations about medications and information about our efforts to give back to the community. The website was revamped in fiscal 2013 and updated with new content.

**November 15, 2013** 

"Shinno Festival Marché," a Market to Support Areas Recovering from the Earthquake

Every year since 2011, we have held the "Shinno Festival Marché" (marché is the French word for market) as an event at Osaka's annual Shinno Festival to support the restoration of areas affected by the Great East Japan Earthquake. In the "Shinno Festival Marché," we sell specialty food and alcohol from the area of northeastern Japan where the Earthquake hit in addition to food and sundry items produced by welfare vocational aid centers. The event was launched as an initiative to help support the people affected by the earthquake by providing a venue where goods from the area can be sold. Also on sale at the festival in 2013 were baked goods from the Heart Bread Project, which donates a portion of its proceeds to areas recovering from the earthquake.

February 14, 2014
Supporting the
Reconstruction Support
Intern Project

The Reconstruction Support Intern Project is run by Fukko University and the Reconstruction Office of the Miyagi Prefecture Reconstruction Agency. The project provides undergraduate and graduate students with the opportunity to work at companies affected by the earthquake. The participants then return home to share their experiences, what they felt and learned while working in the affected areas and at the companies recovering from the earthquake. We offer economic assistance in the form of underwriting the lodging and transportation fees of the student participants.

## Interview with the President



For the Sumitomo Dainippon Pharma Group, fiscal 2013 (ended March 2014) was very important because it marked the first year of the third Mid-term Business Plan, which is designed to ensure "Sustained Growth in the Quest for Further Innovation." In accordance with the plan, we are actively working to establish a strong business foundation in Japan, strengthen profitability in North America and expand into Europe and Asia and expand our global pipeline and develop leading-edge science fields.

3rd MTBP **Third Phase** First Phase **Second Phase New Vision** FY2013 to FY201 FY2010 to FY2012 FY2007 to FY2009 **Solid Fundamentals** Take Off **Sustained Growth** Strengthening and maintaining Creation and transformation toward a new stage of globalization Quest for further innovation globalization Aspire to be a globally active R&D-based Focus resources on four Transform domestic Establish strong domestic strategic products company business foundation business foundation Early maximization of new Contribute to medical Oversea Expansion into Europe nd Asia Expand global pipeline Strengthen new drug liscovery activities and 1-licensing activities •Develop leading-edge science fields R&D Expand new product pipeline

President and Chief Executive Officer

Fiscal 2013, the first vear of the third Midterm Business Plan, saw increases in both sales and profit. What were the factors behind these results?

This dual increase was due largely to the significant growth of the atypical antipsychotic LATUDA® in the United States, enlarged by the positive effects of the weaker yen. I should add that our overseas sales ratio increased substantially to 45.0%.

Consolidated net sales in fiscal 2013 increased 11.5% year on year to ¥387.7 billion. Operating income grew 68.3% to ¥42.1 billion and net income rose 99.7% to ¥20.1 billion.

In Japan, sales were down mainly owing to decreased sales of the gastroprokinetic GASMOTIN® following the expiration of its patent life. In the United States, however, the atypical antipsychotic LATUDA®, with its additional indication, became a growth driver and a big contributor to the Company's increased sales, while sales of the short-acting  $\beta$ -agonist XOPENEX® decreased owing to the end of the period of exclusivity. LATUDA® received approval for the additional indication of bipolar depression in June 2013 and we ramped up our marketing activities to raise awareness of this new indication, resulting in rapid market penetration and expanded sales. And, as the yen weakened against the U.S. dollar, the net sales in the North America segment resulted in a large increase after converting into yen.

As for the factors behind the increase in profit, there is, of course, the increase in income, but thorough cost reductions also helped us achieve this positive result. SG&A expenses decreased particularly in the North America Segment on a local currency basis, due mainly to a decline in personnel expenses from business restructuring and the termination of patent rights amortization for XOPENEX®.

I am convinced that the financial success of increased sales and profit we achieved in the first year of the third Mid-term Business Plan amid the fiercely competitive environment, have put us on track for the remaining years of the plan.



Millions of Yen 387.7 41.9 Other Business 347.7 16.7 Other Regions 11.9 China 9.3 North America Japan 145.3 115.8-200 174.5-- 171.9 FY2012 FY2013

Net Sales by Segment

Please tell me about some of the strategic achievements during **fiscal 2013.** 

In addition to positive financial business results, we achieved several qualitative results, including major advances in new drug development and the strengthening of our business management structure.

As for advances in research and development, you could say this has been a year wherein the future outlook for products under development has been set. For example, Sumitomo Dainippon Pharma is currently conducting Phase II clinical study in Japan of DSP-1747, which is expected to be a treatment for nonalcoholic steatohepatitis. The results obtained for this developmental product in an interim analysis of Phase II clinical study in the U.S. study were so encouraging that the administration of the test drug in the U.S. study was terminated ahead of schedule, and preparations for the next step are ongoing. SB623, a therapy for stroke recovery for which Sumitomo Dainippon Pharma obtained rights for joint development and exclusive marketing in North America from SanBio, Inc., had its safety confirmed and its improvement effect recognized in 18 patients of Phase I/IIa clinical study in the United States. In addition, we are making steady progress in the Phase IIb/III clinical study for EPI-743, which has been in-licensed from Edison Pharmaceuticals, Inc., as a treatment for Leigh syndrome, a mitochondrial disease. Overseas, Edison Pharmaceuticals is moving ahead with clinical studies focusing on the various ailments arising from lower mitochondrial function. In the regenerative medicine & cellular medicine area, we established the joint venture Sighregen K.K. with our joint development partner Healios K.K. as the first step toward building a business structure to handle the development, manufacture and sales of cellular medicine consisting of iPS cell-derived retinal pigment epithelial cells. Through these and other activities, we are not only filling out our pipeline, but we are also rapidly building an organization capable of advanced research and development by leveraging the knowledge and technology of various venture companies and academia.

As for strengthening our business management structure, we have been striving to make our management leaner. Specifically, in terms of our organization, systems and culture, the entire company worked together to establish an organization where decisions can be made quickly in response to current conditions, introducing a personnel system that incentivizes taking on challenges and fostering a culture of willingness to take on challeng-

es. First, to increase efficiency, we launched a campaign aimed at eliminating unnecessary or low-priority business tasks. Then, we conducted companywide job analyses, which produced the concrete positive results of not only redefining each employee's job responsibility but also streamlining work flows to improve efficiency and realigning the company organization to make it more dynamic. Thus, the new personnel system we have been working to introduce and establish over the past two years has finally taken hold along with the culture of willingness to take on challenges.



Could you describe the effects of the closure of new enrollment for the global Phase III clinical study of BBI608 as monotherapy for colorectal cancer?

#### \*Disease Control Rate:

The ratio of patients in whom the disease is controlled. Disease control is defined as an objective assessment categorized as complete response, partial response or stable disease according to the Response Evaluation Criteria in Solid Tumors (RECIST).



We will develop a recovery plan to minimize the effects of the delay in the launch of BBI608 and are committed to seeing it through to its successful conclusion.

In light of the findings of an interim analysis of the global Phase III clinical study of BBI608 as a monotherapy for colorectal cancer, we closed the enrollment of new participants and discontinued the drug administration to enrolled participants in May 2014. There were no observed safety concerns, but the futility analysis, based on the disease control rate (DCR)\*, met protocol defined criteria for stopping. This sets back the U.S. launch by approximately two years from our initial target of fiscal 2015. This does not, however, mean the denial of the value of BBI608 and does not change its position as an important drug in development for the company. With BBI608, we aim to prove its anti-tumor effect as the first drug in the world targeting cancer stem cells. It is a small molecular drug with a new mechanism for inducing death in both cancer stem cells (cancer cell with stem cell-like properties) and differentiated cancer cells. By targeting cancer stem cells in addition to differentiated cancer cells, it is expected to be effective against treatment resistance, recurrence and metastasis, which are challenges in cancer treatments. Phase I to Phase III clinical studies of BBI608 in combination with other anticancer drugs for a variety of cancer types are currently ongoing. The global Phase III clinical study in combination therapy with paclitaxel, an anticancer drug for gastric cancer, started in March 2014.

Sumitomo Dainippon Pharma will continue to devote its efforts to the successful development of BBI608. We will develop a recovery plan to minimize the impact of the delayed launch of BBI608 and follow it through



How would you characterize the Company's approach to business in fiscal 2014?



In fiscal 2014 we aim to establish a strong business foundation in Japan and pursue further growth in overseas markets by focusing our management resources on global strategic products. We will also strive to achieve the rapid maximization of new product sales.

In Japan, we are strengthening the marketing of strategic products and new products as well as rationalizing the business management. Specifically, we aim to maximize sales in Japan by increasing our use of e-promotions in addition to having MRs provide health care professionals with information about strategic products and new products. At the same time, we are streamlining our assets and thoroughly reviewing operating expenses as we promote a companywide project to strengthen our business foundation with the aim of achieving lean management.

Meanwhile in North America, we are concentrating our management resources on LATUDA®, which gained a new indication for the treatment of bipolar depression. Our aim is to make it a blockbuster drug with targeted sales of ¥72.0 billion in fiscal 2014 from the 2013 actual of ¥42.1 billion. To this end, we are actively conducting marketing activities, including television advertisements. Also, we are working to rapidly expand sales of APTIOM®, which was launched in the North American market in April 2014. We have posted about 120 MRs to strengthen the sales structure with the goal of achieving ¥3.5 billion in sales in the first year.

We will promote the expansion of the marketing area of LATUDA® into Europe and elsewhere, either directly or through possible alliances.

Q

How would you describe Sumitomo Dainippon Pharma's business model for value creation?

## A

The company's value creation is oriented toward: "First-in-class" and "First in the world." We aim to develop and offer pharmaceuticals that no other company in the world can match.

The company operates based on the stated Corporate Mission to "broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide" as well as the core ideal of working to address unmet medical needs. We seek to strengthen our R&D capabilities as we continue to create a full-scale R&D-based company capable of discovering new innovative drugs. In parallel, we seek to offer first-in-class products and be first in the world in areas where we can differentiate ourselves from the competition. We will focus on those fields where we excel, striving to be the leader in the areas where we operate. The areas in which we choose to focus research and development are therefore very important. We foresee the development of pharmaceuticals shifting from small-molecule drugs to biological drugs and regenerative medicine & cell therapy. The research and development the company is currently undertaking for SB623 and cell therapies using iPS cells are a step in this direction. In addition, in the field of small-molecule drugs, the Leigh syndrome therapeutic agent EPI-743 in-licensed from Edison Pharmaceuticals is a drug that affects the metabolism of mitochondria, which impacts the basic physiology of human beings. We expect to see a number of possible new fields of development and treatments to emerge for Leigh syndrome and other mitochondrial diseases for which there are no effective treatments.

Q

Please share your thoughts on the company's aim to raise the ratio of overseas net sales to 50% or more and to develop global human resources.

### A

## We need a large pool of human resources who can think from a global perspective and take decisive action.

We are promoting a program to dispatch young researchers to overseas affiliates. This is to help them gain first-hand experience overseas now so that when we make a full-scale entry into the overseas market, we can survive amid the global competition. In fiscal 2013, fiscal 2013, around 30 of our core personnel, technical specialists as well as managers, were on loan to overseas subsidiaries. Moving to a different country, learning to accept cultural differences, gaining experience in managing projects in a different environment, working with the local staff and achieving results, that is what creates truly global human resources. I strongly encourage our young employees to use this opportunity to develop themselves into globally competitive talents. Apart from these assignments overseas, Sumitomo Dainippon Pharma



employees made roughly 1,000 overseas business trips in total in fiscal 2013. I consider such trips to be opportunities for our employees to develop into global human resources by successfully carrying out business tasks at various locations outside Japan. Sumitomo Dainippon Pharma will continue to strengthen training for global human resources in pursuit of globalizing the company.

Q

How would you describe your ideal of CSR management for a pharmaceutical company?

## A

As is also enshrined in our Corporate Mission, helping all people lead healthy, fulfilling lives by leveraging our drug discovery technology and experience cultivated over many years is Sumitomo Dainippon Pharma's duty as a pharmaceutical company.

Under the third Mid-term Business Plan, we are striving to implement its basic policy of fostering a culture where a willingness to take on challenges is encouraged and each and every employee takes the initiative to work toward renovation and innovation. Because Sumitomo Dainippon Pharma is a pharmaceutical company and thus held to higher ethical standards, we need to ensure legal compliance and continually strengthen our risk management in order to win the support of local communities for our endeavors. Top management considers these two considerations to be of the highest priority and robustly promotes related activities. And, in research and development, we constantly aim for development that is "first in class" and "first in the world." We are actively working in areas in which there are high unmet medical needs and no effective treatments. Successful development in these areas means that we can provide drugs for diseases that previously had none. Simply by pursuing our core business of producing new pharmaceuticals, we will be making significant social contributions. As a pharmaceutical company, Sumitomo Dainippon Pharma firmly believes it must stay at the forefront of cutting-edge technology in order to tackle issues that cannot be solved with conventional technology.

As a new initiative in fiscal 2013, we made a successful full-scale entry into the new tuberculosis vaccine business. We established an R&D network for this vaccines as the first step in contributing to global health and will continue to pour our efforts into the vaccine business.

Q

In closing, is there anything you would like to add for the stockholders, investors and other stakeholders? A

We will continue to further solidify our growth trajectory, with everyone in the company working together to promote the basic policy laid out in the third Mid-term Business Plan.

We consider fiscal 2014 to be the year in which we will advance another level toward achieving the targets set for fiscal 2017, the final year of the Mid-term Business Plan. Those targets are to further reinforce our strong business foundation in Japan, increase profitability in North America and expand into Europe and Asia while building up our global pipeline and developing leading-edge science fields. Our policy is to continue carrying out business activities to achieve those goals.

The company views the regular and consistent return of profits to shareholders as one of its most important management policies. We believe that it is important to allocate profits in a way that accurately reflects business performance. We take a comprehensive view that includes giving due consideration to the importance of raising corporate value through aggressive investment in future growth, solidifying our operating base and enhancing our financial position. In fiscal 2013, we paid out a year-end dividend of ¥9 per share and an interim dividend of ¥9 per share for a total annual dividend of ¥18 per share. To maintain stable dividends, the total annual dividend for fiscal 2014 is expected to remain ¥18 per share.

Going forward, we will sustainably raise our corporate value by tenaciously developing our business and live up to the trust placed in us by all of our stakeholders. We ask for your continued support.

## Governance

We broadly contribute to society for the betterment of healthcare and fuller lives of people world-wide. At the same time, we are committed to maintaining and improving our business foundation through corporate governance and internal control, which act as support structures for these efforts.

#### Corporate Governance

#### Basic Approach to Corporate Governance

Sumitomo Dainippon Pharma promotes the development of a system that maintains soundness and transparency while enabling rapid decision making. At the same time, we further strengthen internal control, including risk management. Within this framework, we strive to further enhance corporate governance and continuously maximize its corporate value.



Front row, from left: Hiroshi Noguchi, Masayo Tada, Makoto Hara, Back row, from left: Hidehiko Sato, Yoshihiro Okada, Masaru Ishidahara, Hiroshi Nomura, Hiroshi Sato

Member, Board of Directors(Outside)

Audit & Supervisory Board Member

Harumichi Uchida

Kazuto Nishikawa

Nobuo Takeda

Yasuji Furutani

Yutaka Atomi

**Audit & Supervisory Board Members** 

Audit & Supervisory Board Member (Outside)

Audit & Supervisory Board Member (Outside)

Audit & Supervisory Board Member (Outside)

### Board Members and Executive Officers (As of September 1, 2014) Board Members

#### Masayo Tada

Representative Director, President and Chief Executive Officer

#### Hiroshi Noguchi Representative Director, Senior Executive Vice

President
Executive Director, Drug Research; Global R&D Office;
Global Oncology Office

#### Makoto Hara

Member, Board of Directors, Executive Vice President Sales & Marketing; Legal Affairs; Intellectual Property; International Business Management

#### Yoshihiro Okada

Member, Board of Directors, Senior Executive Officer Executive Director, Manufacturing; Technology Research & Development

#### Masaru Ishidahara

Member, Board of Directors, Senior Executive Officer Corporate Communications; Personnel; General Affairs; Procurement; Corporate Service Center

#### Hiroshi Nomura

Member, Board of Directors, Senior Executive Officer Global Corporate Management; Global Strategy & Business Development; External Affairs; Corporate Secretariat & Industry Affairs; Finance & Accounting; Regenerative & Cellular Medicine Office

#### Hidehiko Sato Member, Board of Directors (Outside) Hiroshi Sato

Senior E Executive

#### Nobuhiko Tamura

Senior Executive Officer
Vice Chair, Executive Vice President, Sunovion
Pharmaceuticals Inc.; Head of
Global Clinical Development for Sumitomo Dainippor
Pharma Group

#### Yoshinori Oh-e

Senior Executive Officer
Executive Director, Corporate Regulatory Compliance &
Quality Assurance; Regulatory Affairs

#### Yoshihiro Shinkawa Executive Officer Deputy Executive Director, Sales & Marketing

Yoshiharu Ikeda
Executive Officer
Executive Director, Technology Research &
Development; Information Systems Planning

#### Mutsuo Taiji

Executive Officer Senior Advisor, Drug Research

#### **Executive Officers**

#### Susumu Nakajima Senior Executive Officer Executive Director, Sales & Marketing

cutive Officer Executive Officer
ector, Sales & Marketing Executive Director, Drug Development

#### Hitoshi Odagiri

Nobuyuki Hara

Executive Officer
Director, Personnel; Career Development Support
Kazuo Koshiya

#### President, Boston Biomedical Pharma, Inc.; Head of Global Oncology Office

Hiroyuki Baba

#### Executive Utilicer Executive Vice President, Sunovion Pharmaceuticals Inc.

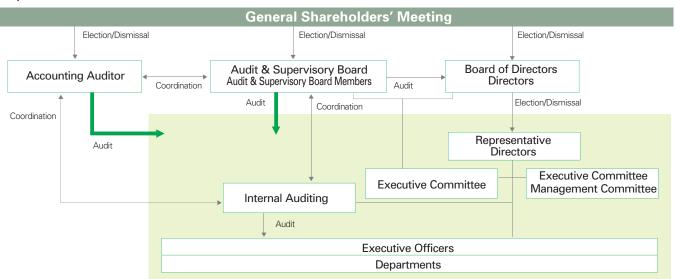
Antony Loebel

## Executive Officer Executive Vice President and Chief Medical Officer, Sunovion Pharmaceuticals Inc.

Officer, Sunovion Pharmaceuticals Inc.
Chiang J. Li

#### Executive Officer President, Chief Executive Officer and Chief Medical Officer, Boston Biomedical, Inc.; Head of Global Oncology for Sumitomo Dainippon Pharma Group.

#### Corporate Governance Structure



#### Management Structure

Sumitomo Dainippon Pharma has adopted an executive officer system under the Board of Directors to separate management supervision from business execution. In addition, we have adopted an Audit & Supervisory Board system independent of the Board of Directors to audit the execution of duties by the directors.

The Board of Directors consists of eight members, including an outside director who was elected in fiscal 2013 and an additional outside director who also was elected in fiscal 2014 in order to strengthen our management function.

Organizational Body	Composition	Convenes	Purpose	Convened in Fiscal 2013
The Board of Directors	Eight members, including two outside directors*	Once a month as a rule	Deciding and reporting on important management matters	14 times
The Audit & Supervisory Board	Five members, including three outside members	Once a month as a rule	Discussing and deciding important audit-related matters	13 times
Management Committee	The members of the Board of Directors and the Audit & Supervisory Board and Executive Officers	Twice a month as a rule	Assisting the Representative Director, President and CEO in decision making as a consultative body and deliberating on important management matters, guided by the basic policies set by the Board of Directors	21 times
Executive Committee	Top managers, including the members of the Board of Directors and the Audit & Supervisory Board and Executive Officers	Once a month as a rule	Ensuring that top managers, including the members of the Board of Directors and the Audit & Supervisory Board and Executive Officers, are fully aware of the status of business execution and related important matters	11 times

<sup>\*</sup> The Board of Directors has eight members and includes two outside directors, one of whom was elected at the 194th ordinary general meeting of stockholders.

All outside board members are independent, and the company designated two outside directors as independent director as defined by the Tokyo Stock Exchange, Inc., and reported the same to the said exchange.

#### **Audit System**

The Audit & Supervisory Board, composed of all the Audit & Supervisory Board members, determines audit policy, task allocation among members and other matters. In line with these matters, each member works to create an environment for greater audit effectiveness, including through regular meetings with the representative directors, proactive reporting from and discussions with the other directors and employees, cooperation with the accounting auditor and the Internal Auditing Department, and furthermore, cooperation among all parties involved in auditing. In addition, members attend key business meetings including those of the Board of Directors to confirm the legality and appropriateness of management decisions by the directors and proactively audit the operational status of the internal control system through measures that include receiving reports from directors and

employees on the status of task execution, requesting explanations as necessary and viewing significant approval forms and other documents. The Audit & Supervisory Board Secretariat has been established as a dedicated support staff for the Audit & Supervisory Board members to raise the effectiveness of their audits and to ensure the smooth accomplishment of auditing tasks.

Accounting audits are conducted by KPMG AZSA LLC, based on an audit agreement. Internal audits are carried out by the Internal Auditing Department, which reports directly to the President of Sumitomo Dainippon Pharma. The basic elements for achieving the objectives of internal control, including subsidiaries, are audited from a fair and independent standpoint.

Audit & Supervisory Board members, accounting auditors and internal auditors meet periodically to exchange information.

#### Accounting Audits, Remuneration

Amount to be paid (Mill	ions of Yen)
Consideration to be paid for the services (audit attestation services) described in Paragraph 1 of Article 2 of the Certified Public Accountant Act (Act No. 103 of 1948)	69
Total amount of fees to be paid in cash or otherwise by the company or subsidiaries of the company	94

(Note) 1. Under the Audit Agreement between the company and the Accounting Auditor, there is no distinction between the compensation and the like for an audit under the Companies Act and the Financial Instruments and Exchange Act. Moreover, the two amounts cannot be substantially distinguished from each other. Thus, the amount of compensation and the like related to the audit attestation services reflects the total sum of these two amounts.

2. Among the significant subsidiaries, Sunovion Pharmaceuticals Inc., Boston Biomedical, Inc. and Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. were auditing firms other than the Accounting Auditor of the Company.

#### Establishment of an Internal Control System

In accordance with Japan's Companies Act, the Board of Directors of Sumitomo Dainippon Pharma passed a resolution on the basic policies for the establishment of a system to ensure appropriate business operation. The status of imple-

mentation efforts pursuant to the basic policies for each year is reported at the Board of Directors meeting held in the last month of the fiscal year, and the basic policies are revised as necessary to improve the system.

#### Internal Control over Financial Reporting

In accordance with Japan's Financial Instruments and Exchange Act, Sumitomo Dainippon Pharma designs and operates a system in line with the company's basic framework for internal control over financial reporting and conducts assessment of internal control to ensure the reliability of financial reporting. The scope of the assessment encompasses the

companywide internal control system at Sumitomo Dainippon Pharma and those of its major consolidated subsidiaries, as well as business processes with the potential for significant impact on finances. Sumitomo Dainippon Pharma assessment the effectiveness of the design and implementation of internal control.

#### **Executive Remuneration**

Remuneration for directors consists of basic remuneration and bonuses. Basic remuneration is set according to position, such as representative director, while bonuses are determined based on company and individual performance using methods approved by the Board of Directors, within the scope of total remuneration approved at the annual shareholders' meeting. Remuneration for Audit & Supervisory Board members consists of basic remuneration determined by the Audit & Supervisory Board, within the scope of total remuneration approved at the annual shareholders' meeting.

		Amount of Remuneration and the like (Millions of Yen)
Directors	8	300
Audit & Supervisory Board Members	8	87
Total	16	388

(Note) 1. The table includes the amount of remuneration and the like for the Outside Director and the four (4) Outside Audit & Supervisory Board Members, which is 45 million yen in total.

2. The above includes the three (3) Audit & Supervisory Board Members who retired upon the conclusion of the 193<sup>rd</sup> Annual Shareholders' Meeting held on June 21, 2013.

3. The respective amounts of remuneration and like for Director and Audit & Supervisory Board Members that were determined in the Shareholders' Meeting do not exceed 400 million yen annually for Directors, and 100 million yen annually for Audit & Supervisory Board Members.

4. The amount of remuneration and the like for Director includes the amount of 37 million yen, which represents the bonuses for Directors to be paid after the 194<sup>th</sup> Annual Shareholders' Meeting to be held in June 2014.

#### Communication with Shareholders and Investors

#### Appropriate Information Disclosure

Sumitomo Dainippon Pharma recognizes the importance of conducting business activities in a manner that emphasizes transparency in maintaining the trust of society and, as such, strives to disclose corporate information in a timely, appropriate and fair manner to its stakeholders.

We undertake disclosure of information under due recognition of Japan's Financial Instruments and Exchange Act, the Timely Disclosure Rules of the Tokyo Stock Exchange (TSE),

our in-house regulations for management and disclosure of information, and other rules. Information that requires timely disclosure, such as the company's financial results, is promptly disclosed through the TSE's TDnet (Timely Disclosure Network) and also published on our corporate website. We also actively disclose information not requiring timely disclosure through news releases to media outlets and our own corporate website.

#### Annual Shareholders' Meeting

Sumitomo Dainippon Pharma sends out a notice of convocation of the annual shareholders' meeting approximately three weeks before the date of the meeting to facilitate the exercise of voting rights. For foreign shareholders, Sumitomo Dainippon Pharma posts an English translation of the convocation notice on the company's website together with the Japanese version on the day the convocation notices are sent. Methods of voting include electronic voting platforms and other digital methods (such as

the Internet) in addition to conventional voting in writing.

In addition, Sumitomo Dainippon Pharma takes measures to enliven its annual shareholders' meetings, such as providing video presentations of the business report during the meeting. Details of the results of resolutions on proposals at the annual shareholders' meeting are submitted in an extraordinary report and disclosed on our website.

#### IR Activities

Sumitomo Dainippon Pharma regularly holds meetings for analysts and institutional investors worldwide. In Japan, meetings are held to coincide with financial results announcements at the end of the second and fourth quarters, while conference calls are carried out for announcements of financial results of the first and third quarters. In addition, meetings focused on specific topics are held as appropriate. In fiscal 2013, we held a meeting on research and development for new fields.

For overseas investors, representatives of Sumitomo Dainippon Pharma visited investors in Europe and the United States in April 2013 and investors in the United States alone in November 2013. In addition, Sumitomo Dainippon Pharma presents webcasts of meetings held in Japan and conference calls with an overdubbed English translation (including question and answer sessions) on its website. For retail investors, Sumitomo Dainippon Pharma holds meetings at branches of securities firms. In fiscal 2013, the company held a meeting in August 2013 in Tokyo. In addition, Sumitomo Dainippon Pharma presents financial information, news releases, presentation materials for investors, annual reports, and other materials in both English and Japanese on its website as appropriate.

#### Compliance

Sumitomo Dainippon Pharma considers the promotion of compliance the foundation of all business activities, and in its Declaration of Conduct, Sumitomo Dainippon Pharma states both internally and publicly its commitment to "abide by laws and regulations, and conduct corporate activities in a transparent and fair manner with high ethical standards." To put this declaration into practice and ensure compliance, Sumitomo Dainippon Pharma has established the Compliance Standards for business activities.

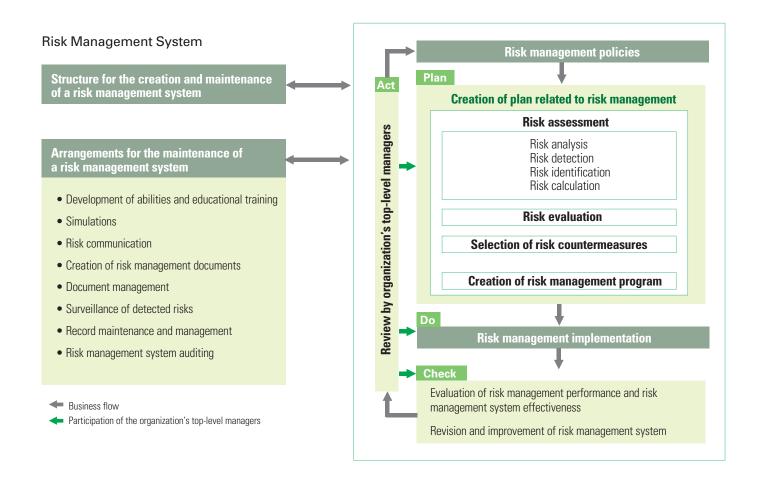
In fiscal 2013, the Compliance Committee, presided over by the executive officer in charge of compliance, met two times. The committee ascertained the status of compliance efforts throughout Sumitomo Dainippon Pharma and issued appropriate reminders, recommendations, and advice to the parties

In addition, Sumitomo Dainippon Pharma conducted education and training for all employees on many topics, including the Compliance Standards, corruption, insider trading, the harmful effects of drugs and harassment. As a global initiative, the Global Compliance Committee, which is composed of members from Sumitomo Dainippon Pharma and its Group companies in the United States, China and Europe, met two times to share information and exchange opinions. Sumitomo Dainippon Pharma also set up a compliance hotline to provide consultation or accept reports internally or externally in the event that an employee has questions or has obtained information concerning violations related to compliance.

#### Risk Management

To deal with risks that might affect its business activities, Sumitomo Dainippon Pharma has established in-house Risk Management Regulations and has organized a Risk Management Committee that is chaired by the president. In addition, a risk management program is established each fiscal

year to enable all of the corporate departments to make systematic efforts to solve their respective issues. Sumitomo Dainippon Pharma has also established Emergency Response Rules to codify procedures in the event of an emergency.



#### Subsidiary Management Structure and Governance

Sumitomo Dainippon Pharma has established rules for operation and management so that Group companies implement appropriate business operations. Sumitomo Dainippon Pharma has designated managing divisions for each Group company and a division to govern them, and endeavors to monitor and administer the management and execution of duties at Group

companies. Sumitomo Dainippon Pharma also provides appropriate support for business execution. In addition, the Sumitomo Dainippon Pharma Group is implementing unified CSR management, including the establishment of a global governance structure, enhancement of compliance, strengthening of risk management, and social contribution activities.

#### Major Subsidiaries

		Investment Ratio(%)	Principal Business
Japan	DSP Gokyo Food & Chemical Co., Ltd.	100	Manufacturing and sales of food ingredients, food additives, chemical product materials and the like.
	DS Pharma Animal Health Co., Ltd.	100	Manufacturing, and sales of veterinary medicines and the like.
	DS Pharma Biomedical Co., Ltd.	100	Manufacturing and sales of Diagnostics and the like.
Overseas	Sunovion Pharmaceuticals Inc.	100(100)	Manufacture and sale of medical drugs.
	Boston Biomedical, Inc.	100	Research and development in the oncology areas.
	Sumitomo Pharmaceuticals(Suzhou) Co., Ltd.	100	Manufacture and sale of medical drugs.

(Note) The figure indicated in parentheses under the Investment Ratio column indicates the indirect ownership ratio (%) vis-a -vis the total ownership ratio.

#### Factors That Could Significantly Influence Corporate Governance

Sumitomo Chemical Co., Ltd. is the parent company of Sumitomo Dainippon Pharma with a 50.22% share of voting rights. Respect for autonomy is affirmed by the parent company and management independence is maintained, with no restraints on approvals or other matters by the parent company concerning our business operations.

Furthermore, no directors of Sumitomo Chemical sit on the Sumitomo Dainippon Pharma Board of Directors. Sumitomo Dainippon Pharma retains some personnel seconded from the parent company based on its own judgment, and believes this has no influence on its management or business operations. Respect for autonomy is affirmed by the parent company and our independence is maintained.

Based on the above, Sumitomo Dainippon Pharma believes that the interests of its retail shareholders are not impaired by its parent company.

#### **Message from the Newly Elected Outside Director**

I am very pleased to have been elected a member, the Board of Directors (outside) of Sumitomo Dainippon Pharmaceuticals Co., Ltd. on June 19, 2014.

Pharmaceutical companies, which serve to improve the quality of human life, have noble missions to always listen carefully to the voices of patients and health-care professionals, to develop novel products, to manufacture high-quality products and to deliver them to patients around the world. In this endeavor, it is most essential for a life science company, I am convinced, to face up to the challenge squarely even if a hardship should

My role as an outside director in the pharmaceuticals company is to offer my views to the management from different perspectives, using the judgment criteria I have nurtured through my career in a different industry. Drawing on my managerial experience, I will participate in the decision-making process of the Board of Directors to help Sumitomo Dainippon Pharmaceuticals promote further innovations and continue growing as a truly global company.

#### Reason for the Election of the Outside Director

Dr. Hiroshi Sato has considerable experience and a wide range of knowledge, which he has acquired in his career as a corporate manager. The company recommended his election as an Outside Director in the hope that he will contribute to the management of the company using his experience and knowledge.



Hiroshi Sato Member, Board of Directors (Outside)

Career History April 1970: Joined Kobe Steel, Ltd. June 1996: Elected Director June 2003: Senior Managing Director

April 2004: Executive Vice President and Representative April 2009: President, CEO and Representative Director

April 2013: Chairman of the Board and Representative Director of Kobe Steel, Ltd. (current) June 2014: Member, Board of Directors (Outside), Sumitomo

# Special Feature Innovation

#### **New Opportunities in Regenerative Medicine & Cell Therapy**

In its third Mid-term Business Plan (the 3rd MTBP), Sumitomo Dainippon Pharma points to the strategic development of regenerative medicine & cell therapy and is pursuing research and development focused on clinical applications for intractable diseases.



**Toru Kimura**Director, Regenerative & Cellular Medicine Office

## Strengths and Activities of Sumitomo Dainippon Pharma

## Reason for Focusing on the Regenerative Medicine & Cell Therapy

After formulating the 3rd MTBP, which emphasizes the quest for further innovation, Sumitomo Dainippon Pharma conducted a variety of surveys and studies. We reached the conclusion that with the general trend in pharmaceuticals research moving away from conventional small molecule drugs to cell therapy, there is a much higher likelihood of discovering groundbreaking drugs in cell therapy. We therefore decided to ramp up efforts in regenerative medicine & cell therapy research and development to facilitate our full-scale entry into this new field.

Our more than 20 years of pursuing joint basic research in cooperation with academic institutions in the area of regenerative medicine & cell therapy has positioned us well in this leading-edge field, with established connections and reliable relationships already in place. Our extensive knowledge base includes that gleaned from a huge volume of applied research using ES and iPS cells as well as regenerative medicine research conducted on nerve regeneration inhibitor semaphorin. We are in a prime position in the regenerative medicine & cell therapy business.

## Regenerative medicine-related research started with the investigation of neurite outgrowth inhibitor, Semaphorin

- Abundant know-how and experience in regenerative medicine-related research
- Consecutive collaboration with academia
- Joint research with Prof. Okano (Keio University) etc.

#### Knowledge acquired through applied research of ES cell & iPS cell

•Joint research with CiRA\* (Director: Prof. Yamanaka) etc. \*Center for iPS Cell Research and Application

## Platform research using hES cell (Sumitomo Chemical)

•Extensive research performance, know-how and patents in the fields of the eye

## Partnership with a biotech company (SanBio)

- •Technology and know-how of cell pharmaceutical products
- Preparation for the development and regulation

## ES cell & iPS cell-related basic technology (DS Pharma Biomedical)

•Sales and development of regenerative medicine-related products such as medium and culture vessel etc., and tissue culture educator

Sumitomo Dainippon Pharma is poised to become a leading company in regenerative and cellular medicine business in Japan with favorable environment

## The central nervous system (CNS) Regeneration

In the area of neurology, it has long been thought that once the cells of the CNS finish growing, regeneration is difficult. However, thanks to recent advances in regenerative medicine & cell therapy, especially in iPS cell research, excitement over the possibility of regenerating such cells has been mounting. As its first step toward regenerative treatment of the CNS, Sumitomo Dainippon Pharma is conducting research in ophthalmology, specifically, the optic nerve.

There are numerous reasons we decided to focus on ophthalmology. First of all, transplanted eyes trigger a comparatively weak immune response and are therefore less likely to be rejected. Also, the risk of carcinogenesis, which is a significant concern in regenerative medicine & cell therapy, is clinically low. And, because eyes can be easily monitored and operated on from outside the body, they are superior to other organs in terms of clinical application and safety.

Our research effort is the first regenerative medicine initiative in the world to involve human studies and will form the company's business foundation in the regenerative medicine & cell therapy area.

## New Opportunities and the Future Potential of Regenerative Medicine & Cell Therapy

Sumitomo Dainippon Pharma has obtained rights for joint development and exclusive marketing in North America from U.S. Sanbio, Inc. for SB623, a therapeutic agent for stroke recovery. The therapeutic cells are injected into the damaged areas of the brain, releasing various nerve cell repair and regrowth factors. It is expected to improve the motor deficits and cognitive impairment of patients. We signed an agreement with Healios K.K. to jointly develop iPS cell-derived retinal pigment epithelial (RPE) cells in Japan. We are aiming to obtain manufacturing and marketing approval for using iPS-derived RPE cells in cell therapy indicated for age-related macular degeneration and other eye diseases. In addition, we are working in conjunction with RIKEN to promote commercialization in the eye disease area, including retinitis pigmentosa. Sumitomo Dainippon Pharma is working with Keio University and National Hospital Organization Osaka National Hospital on regenerative medicine for spinal cord injury using neural precursor cells of iPS cell origin.

We are pursuing further innovation in the regenerative medicine & cell therapy business by bringing these cell therapies to market.

#### Research Base for Regenerative Medicine & Cell Therapy Established in Kobe

In April 2014, Sumitomo Dainippon Pharma commenced operations at the Kobe Regenerative & Cellular Medicine Center established on Port Island in Kobe. The KOBE Biomedical Innovation Cluster is an area where many life science companies are setting up bases. In this area, world-class research institutes, leading hospitals, the Pharmaceuticals and Medical Devices Agency (PMDA) Cooperation Center and other government institutions, and over 270 companies and organizations collaborate to develop practical and clinical applications for drugs, regenerative medicine and medical equipment. The center is a research base for regenerative medicine & cell therapy and is promoting research activities that leverage the environment to access the latest information.



## Research & Development

Sumitomo Dainippon Pharma is actively investing its resources in the focus therapeutic areas of psychiatry & neurology and oncology as well as the new areas of development comprising disease fields where no approved drugs exist and regenerative medicine & cell therapy.

#### **Basic Strategy**

To address unmet medical needs\* with innovative new drugs created through leading-edge technologies, Sumitomo Dainippon Pharma is working to expand its global pipeline under the basic strategy of "increased speed and efficiency."

\* Specifically, diseases for which treatments are lacking or are not fully satisfactory

#### Sumitomo Dainippon Pharma's Therapeutic Focus Areas and New Areas of Development

**Focus Therapeutic Areas** 

- Psychiatry & Neurology
- Oncology

Sumitomo Dainippon Pharma is aiming to create innovative drugs in its focus therapeutic areas of psychiatry & neurology and oncology. We are doing all we can to develop businesses in leading-edge fields and advanced technical areas, including pursuing in-house research as well as collaborative research with biotech companies and academia and acquiring the latest technology. We plan to move eight compounds in oncology and ten compounds in non-oncology areas, including psychiatry & neurology, into clinical stages by fiscal 2017, when the third Mid-term Business Plan period is set to come to a close.

In the initial stages of research, we are working to improve efficiency by leveraging proprietary cutting-edge technologies, including genomics, proteomics and metabolomics. We're also promoting initiatives that apply iPS cells and other advanced

#### **New Areas of Development**

- Disease fields where no approved drugs exist
- **■** Regenerative Medicine & Cell Therapy

technologies to drug discovery. Moreover, we are pursuing collaborative research with the Center for iPS Cell Research and Application (CiRA) at Kyoto University aimed at discovering therapeutic agents for rare intractable diseases. We are also actively participating in the Research Center Network for Realization of Regenerative Medicine, a national project involving industry, government and academia.

In the latter stages of research and in the development stage, we are optimizing the entire Group portfolio from a global point of view, especially in focus therapeutic areas. In addition, we are actively working on product life cycle management, including developing formulations with the aim of maximizing product value.



#### Research Organization

We have a research organization in place to consistently create products worldwide and are working to create new, innovative drugs.

Research Center/Laboratories	Organization	Role
Innovative Drug Discovery Laboratories	Drug Research Division	Responsible for early stage drug discovery from exploratory to the lead generation (LG) stage, with an emphasis on innovation
Drug Development Research Laboratories	Drug Research Division	Efficiently and quickly progresses research programs and projects from the lead optimization (LO) stage onward, with an emphasis on clinical practically.
Preclinical Research Laboratories	Drug Research Division	Supports drug candidate compound selection and clinical development through regulatory science, leveraging its superior safety and pharmacokinetic technology.
Genomic Science Laboratories	Drug Research Division	Conducts research and development of drug discovery, diagnostic systems and diagnostic drugs using cutting-edge science and technology, including screening technologies, omics technologies and <i>in silico</i> drug discovery methods.
Sumitomo Dainippon Pharma Cancer Institute	Independent organization under the direct supervision of the President	In charge of research and development aimed at continually creating revolutionary products in the oncology area
Kobe Regenerative & Cellular Medicine Center	Regenerative & Cellular Medicine Office	Conducts research for the regenerative medicine & cell therapy business using iPS and other cells
Process Chemistry Research & Development Laboratories	Technology Research & Development Division	Conducts research and development related to manufacturing active pharmaceutical ingredients using advanced synthetic chemistry technology
Formulation Research & Development Laboratories	Technology Research & Development Division	Conducts research and development related to dosage forms and manufacturing methods of formulations using advanced technology and research and development related to creative dosage forms aimed at maximizing product value
Analysis Research & Development Laboratories	Technology Research & Development Division	Conducts the development of quality evaluation methods for active pharmaceutical ingredients and formulations using advanced analytical technology and creates quality control strategies aimed at investigational and new drug applications







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## Drug Discovery

## Progressing Research and Increasing Efficiency

#### **Drug Discovery Research Using Genomic Science**

Genomic Drug Discovery is a rational approach in the research and development of new drugs effective for certain diseases or pathological conditions based on data related to the human genome. Compared to earlier techniques, in which drug candidates were selected by synthesizing and then ruling out a large number of compounds based on empirical rules or new medical discoveries, genomic drug discovery is expected to offer a drastic improvement in success rates. It is also expected to reveal innovative drugs with new mechanisms that cannot be found using traditional approaches.

#### In Silico Drug Discovery

Traditionally, about one in every 30,000 candidate compounds actually makes it through to launch as a drug. Moreover, it usually takes 9 to 17 years from discovery to launch.

To improve our success rate, we became one of the first pharmaceutical companies in Japan to pursue *in silico* drug discovery using a supercomputer, the "K computer," through which we are actively searching for promising candidate compounds. Based on the data on pathogens or the structures of proteins or other targets, the computer is first used to sift

through a wealth of data on such factors using compound structures and their actions. Finally, computer simulations are run that test effects and safety and thus efficiently identify the most promising candidate compounds that correspond to the proteins or other targets. This process of selection will lead to higher success rates in clinical trials and shorter development periods, and it is our aim to get these promising drugs to patients faster than before.

#### **Alliances with Outside Research Institutions**

In the discovery of new drugs, Sumitomo Dainippon Pharma is promoting not only its own in-house research but also joint research with universities and other research institutions in Japan and overseas. We also actively maintain alliances with

biotechnology companies possessing innovative technologies. In this way, we are tackling the creation of innovative new drugs based on leading-edge science.

#### Main Research Partners

Partner	Details
The Laboratory for Malignancy Control Research (the DSK Project) at Kyoto University	Kyoto University, which boasts a wealth of knowledge in basic and clinical medicine, and Sumitomo Dainippon Pharma, which focuses on oncology, have brought together their human, capital, knowledge and resources to collaborate on research and also make use of each other's intellectual property. Through this joint research, we aim to identify new drug targets and Biomarkers—the biological indicators of disease, the changes in disease status and the level of healing—and to create unique anticancer drugs, diagnostic techniques and treatments by advancing the search for candidate substances.
The Center for iPS Cell Research and Application (CiRA) at Kyoto University	Through this collaboration of academia and industry, we are focusing on a rare intractable disease that is caused by a genetic mutation and, by using disease-specific iPS cells, we will reveal the mechanism by which the disease progresses. The plan is to identify disease markers specific to patients then search for therapeutic agents to control those pathways. We aim to create groundbreaking treatments that suppress the progression of the disease in patients.
The NDDC at the Graduate School of Osaka University	The Graduate School of Osaka University formed the Neuropsychiatric Drug Discovery Consortium (NDDC) from five courses in the medical research department and the pharmaceutical research department. The NDDC is working to discover innovative drugs that present characteristics not found in previous drugs by addressing the mechanism of mental disease onset at the genetic and molecular levels.
Edison Pharmaceuticals, Inc.	In collaboration with the U.S. biotechnology company Edison Pharmaceuticals, Inc., Sumitomo Dainippon Pharma is pursuing research and development focused on redox systems, which play a critical role in the regulation of metabolism, and aims to discover 10 novel candidate pharmaceutical compounds. Both companies are hopeful this joint research will lead to the development of treatments for intractable diseases, including mitochondrial diseases and oxidative stress-induced neuropsychiatric disorders.



#### K Computer

The K computer is a supercomputer jointly developed by Fujitsu and RIKEN Advanced Institute for Computational Science. It achieved a computational speed of 10 petaflops, making it the world's fastest computer at the time of its inception. It is expected to be used in a wide range of disciplines and greatly accelerate the development of scientific technologies.

## Intellectual Property Main Concept

As a pharmaceutical manufacturer, Sumitomo Dainippon Pharma recognizes that activities involving intellectual property are an essential part of its business strategy. Our basic

policy is to develop our own robust intellectual portfolio, while at the same time respecting the intellectual property rights of others.

## Comprehensive Action of Intellectual Property from Research Accomplishment to Business Development

We file patent applications covering inventions and products created at each laboratory to secure Sumitomo Dainippon Pharma's leading position. We also actively file patent applications covering inventions created in cooperation with outside research institutions. The Company currently has about 1,800 patents/patent applications. We especially focus on filing patent applications covering inventions created at the initial stage of research by cooperating with each laboratory and Intellectual Property Department to acquire effective patents and rights.

To comprehensively protect each of our products, we build up a patent portfolio including not only substance patent application but also patent applications that encompass uses, manufacturing processes and formulations. In this way, the Company's activities regarding intellectual property are closely related to business development. Furthermore, in view of our global business development, we need to protect our products using intellectual properties in countries around the world. For that purpose, our Intellectual Property Department organizes, Patent Committee meetings with heads of research and development-related departments. The subjects at Patent Committee meetings includes sharing of intellectual property information on individual products and discussions of future intellectual property strategies.

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## Development

Sumitomo Dainippon Pharma is promoting clinical development around the world, with the Drug Development Division in Japan, Sunovion and Sumitomo Pharmaceuticals (Suzhou) all collaborating very closely. In the oncology area, Boston Biomedical, Inc. and the Drug Development Division in Japan also work in close collaboration.

#### **Psychiatry & Neurology Area**

In the psychiatry and neurology areas, Sumitomo Dainippon Pharma selects the post-LATUDA candidates and invests in the selected one in the global market, while continuing active development of LATUDA® in the domestic market.

Focusing largely on improvement of current treatments that do not sufficiently result in adequate symptom relief, as well as on the treatment of the patients who do not respond enough to existing medicines, the Sumitomo Dainippon Pharma Group continues to promote research and development of therapeutic agents in schizophrenia, depression, Alzheimer's disease, neuropathic pain, developmental disorders, neurodegeneration and other disorders.

Brand name/Product code	Generic name	Proposed indication D	evelopment location	Phase I	Phase II	Phase III	Submitted
LATUDA <sup>®</sup>	lurasidone	Schizophrenia	Taiwan				
(SM-13496)	hydrochloride	Schizophrenia	Japan / China				
		Bipolar I depression, Bipolar maintenance	Japan				
		(New indication) Bipolar maintenance	U.S. / Europe, etc				
		(New indication) MDD with mixed features	U.S. / Europe, etc				
APTIOM <sup>®</sup>	eslicarbazepine acetate	Epilepsy- Adjunctive therapy	Canada				
(SEP-0002093)		(New indication) Epilepsy- Monotherapy	U.S.				
LONASEN®	blonanserin	Schizophrenia	China				
		(Addition of pediatric usage) Schizophrenia	Japan				
		(New formulation: Transdermal patch) Schizophrenia	Japan				
AS-3201	ranirestat	Diabetic neuropathy	Japan				
EPI-743	TBD	Leigh syndrome	Japan				* *
SEP-225289	dasotraline	Attention-deficit hyperactivity disorder (ADHD	) U.S.				
TRERIEF®	zonisamide	(New indication) Parkinsonism in Dementia with Lewy Bodies (DLB)	Japan				
DSP-2230	TBD	Neuropathic pain	U.K./U.S.				
SEP-363856	TBD	Schizophrenia	U.S.				
(as of July 30, 2014)						ved / Preparir II/III study	ng for launch
		LATUDA® (Iuranialna na lauralna na laurialna) in	مامي بمستفسم المستمين بعمل سم		ب بدالد ما ما عدما		

#### ■ LATUDA® (lurasidone hydrochloride) Atypical antipsychotic

LATUDA® (lurasidone hydrochloride) is an atypical antipsychotic agent that is believed to have an affinity for dopamine D2, serotonin 5-HT2A and serotonin 5-HT7 receptors where it has antagonist effects. In addition, LATUDA® is a partial agonist at the serotonin 5-HT1A receptor and has no appreciable affinity for histamine or muscarinic receptors. Phase III clinical studies are currently under way in Japan, targeting schizophrenia, depressive episodes associated with bipolar I disorder (bipolar depression) and bipolar maintenance treatments. We are also aiming to bring this drug to market in China and Southeast Asian countries.

## ■ SEP-225289 (dasotraline) Attention-deficit hyperactivity disorder (ADHD)

SEP-2258529 is a novel chemical entity that inhibits the reuptake of dopamine and norepinephrine (DNRI: dopamine-norepinephrine reuptake inhibitor). In clinical studies, SEP-225289 maintains stable concentrations over the course of the day. SEP-2258529 is being developed as a once-daily, steady-state treatment of ADHD symptoms in adults, children and adolescents.

#### ■ DSP-2230 Neuropathic pain

DSP-2230 is a novel compound that selectively inhibits voltage-gated sodium channels Nav1.7 and Nav1.8 with higher potencies than those against the other sodium channel subtypes studied. In addition, the drug has demonstrated antiallodynic effects in animal models of neuropathic pain that have been shown to be predictive of efficacy in humans. Due to its novel mechanism, DSP-2230 is expected not to produce cardiovascular system or CNS side effects, which are present with the current drugs, such as non-selective sodium channel blockers and anti-epilepsy medicines.

#### SEP-363856 Schizophrenia

SEP-363856 is an antipsychotic with a novel mechanism of action. Compared to existing antipsychotics that are effective for positive symptoms of schizophrenia, the drug also shows efficacy for negative symptoms. Even in combination treatment with atypical antipsychotics, extrapyramidal side effects were not observed. High efficacy and improved QOL are expected for the treatment for schizophrenia.

#### **Oncology Area**

Sumitomo Dainippon Pharma is working hard in oncology in the focused therapeutic areas where unmet medical needs exist.

We are devoting our attention to the successful development of BBI608 and BBI503, targeting cancer stem cells. In

addition to these two drugs, we are putting considerable efforts into the research and development of first-in-class anticancer drugs. We are aiming to successively create ground-breaking products.

Brand name/Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
CALSED® (Brand name in Japan)	amrubicin hydrochloride	Small cell lung cancer	China				
BBI608	TBD	Colorectal cancer (Monotherapy) (Global clinical trial)	U.S. / Canada / Japan, etc.	Accrual of r	new patients	has been s	stopped
		Gastric cancer, Gastro-esophageal junctic adenocarcinoma (Combination therapy) (Global clinical trial)	U.S. / Canada				
		Colorectal cancer (Combination therapy)	U.S. / Canada				
		Solid tumors (Combination therapy)	U.S. / Canada			*	
		Gastrointestinal cancer (Combination therapy	v) U.S. / Canada				
		Gastric cancer (Combination therapy)	Japan				
BBI503	TBD	Solid tumors (Monotherapy)	U.S. / Canada			*	
		Renal cell carcinoma, Urothelial carcinoma Hepatocellular carcinoma, Cholangiocarcinoma, Gastrointestinal stro mal tumor (Monotherapy)	Canada				
WT4869	TBD	Myelodysplastic syndromes	Japan		* *		
		Solid tumors	Japan				
WT2725	TBD	Solid tumors, Hematologic cancers	U.S.				
		Solid tumors	Japan				

(as of July 30, 2014)

■ BBI608, BBI503 Solid tumors BBI608 and BBI503 are small-molecule compounds with novel mechanisms that block the self-renewal of cancer stem cells (CSCs, cancer cells with stem cell-like properties) and induces cell death in CSCs as well as other heterogeneous cancer cells. By targeting CSCs in addition to heterogeneous cancer cells, efficacy is expected in the current challenges in therapy against cancer, such as treatment resistance, metastasis and recurrence.

■ WT4869, WT2725 Solid tumors, Hematologic cancer WT4869 and WT2725 are therapeutic cancer vaccine candidates using peptides derived from Wilms' tumor gene 1 (WT1) protein. These drugs are expected to treat patients with various types of hematologic cancers and solid tumors that overexpress WT1 through the induction of WT1-specific cytotoxic T-lymphocytes.

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<sup>\*</sup> Phase II of Phase I/II study

\*\* Phase I of Phase I/II study

#### **Other Areas**

Brand name/Product code	Generic name	Proposed indication	Development location	Phase I	Phase II	Phase III	Submitted
Respiratory A	irea						
SUN-101	glycopyrrolate bromide	Chronic obstructive pulmonary disease (COPD)	U.S				
DSP-3025	TBD	Bronchial asthma/Allergic rhinitis	Japan				
			·				

#### Cardiovascular / Diabetes Area

METGLUCO <sup>®</sup>	metformin hydrochloride	(Addition of pediatric usage) Type 2 diabetes	Japan		
SUREPOST <sup>®</sup>	repaglinide	(New indication) Type 2 diabetes (All combination therapies including DPP-4 inhibitors)	Japan		

#### **Other Areas**

DSP-1747	obeticholic acid	Nonalcoholic steatohepatitis (NASH)	Japan		
DSP-6952	TBD	IBS with constipation, Chronic idiopathic constipation	Japan		

(as of July 30, 2014)

## SUN-101 (glycopyrrolate bromide)

Chronic obstructive pulmonary disease (COPD)

SUN-101 is a proprietary solution formulation of glycopyrrolate bromide, delivered by a customized eFlow® Nebulizer System (originated by and licensed from PARI Pharma GmbH), which was developed to optimize medication delivery and allow ease of use. Including products on the market and in development in this therapeutic area, SUN-101 is currently the only LAMA (long-acting muscarinic antagonist) in nebulized form.



## Disease Fields Where No Approved Drugs Exist Regenerative Medicine & Cell Therapy

Sumitomo Dainippon Pharma is actively engaged in new areas, including in disease fields where no approved drugs exist and regenerative medicine & cell therapy.

In the intractable diseases, we are pursing research and development focused on mitochondrial disease including Leigh syndrome, oxidative stress-induced neuropsychiatric disorders

and so on. In regenerative medicine & cell therapy, we aim to be a global pioneer in the treatment of eye diseases with iPS cells by promoting the collaborative development with Healios K.K. As for the vaccine business, we will construct the business basis through advanced technologies of our own.

#### ■ EPI-743 Leigh syndrome

EPI-743, in-licensed from Edison Pharmaceuticals, is to synchronize energy generation in the mitochondria with the counterbalancing of redox stress. This drug is expected to be a world first treatment for mitochondrial diseases beginning with Leigh syndrome. EPI-589 is a next-generation drug after EPI-743 that is expected to be developed for neurodegenerative indications arising through redox stress based on defects in mitochondrial function.

#### DSP-1747 (obeticholic acid) Nonalcoholic steatohepatitis (NASH), Primary biliary cirrhosis (PBC)

DSP-1747, In-licensed from Intercept Pharmaceuticals Inc., is an agonist to farnesoid X receptor (FXR) whose ligand is the primary human bile acid chenodeoxycholic acid, the natural endogenous FXR agonist. The compound is expected to be effective for hepatic dysfunction and hepatic fibrosis associated with an increase of bile acid in the liver.

## ■ SB623 Stroke cell therapy

SB623 is a candidate compound for cell therapy for stroke recovery. Sumitomo Dainippon Pharma acquired rights for joint development and exclusive marketing in North America from SanBio, Inc. This innovative development candidate is expected to have efficacy in treating a variety of disabilities caused by strokes for which there are no treatments as of yet.

#### ■ HLS001 iPS cell-derived RPE cells

HLS001 is iPS cell-derived RPE cells. In December 2013, we signed a joint development agreement with Healios K.K. to develop iPS cell-derived RPE cells as a cell therapy indicated for eye diseases including age-related macular degeneration. In February 2014, both companies established Sighregen K.K. as a joint venture to manufacture and market the drug. We are still strengthening our foundation in regenerative medicine & cell therapy.

#### ■ New TB Vaccine

Create Vaccine Company, Ltd., a joint venture established by Sumitomo Dainippon Pharma and Japan BCG Laboratory, is engaged in a tripartite joint development program together with National Institute of Biomedical Innovation, Independent Administrative Agency ("NIBIO") and Aeras, a nonprofit biotech organization (Headquarters: Maryland, USA) for the development of new TB vaccines, incorporating a novel recombinant human parainfluenza Virus type-2 (rhPIV2) vector technology developed by NIBIO. The vaccines would be the world's first TB vaccines based on a novel rhPIV2 vector technology. They are called mucosal immunity induction vaccines because they target the patient's mucous membranes to keep bacteria causing TB from making an entry into the lungs. The vaccines are designed to prevent TB in adults, who are most susceptible to developing the active, infectious form of the disease.

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## Marketing

The efficacy, safety, and tolerability of the atypical antipsychotic LATUDA® have been assessed and confirmed through numerous clinical studies.

#### **Special feature: Global strategic product**

## ATUDA®—Iurasidone hydrochloride

The atypical antipsychotic LATUDA® is a global strategic product that Sunovion Pharmaceuticals Inc. released in the United States in February 2011 for the treatment of schizophrenia in adults.

Aiming to maximize the product value of LATUDA® we are expanding our sales territory and the drug's indications. In June 2013, LATUDA® became the first atypical antipsychotic to be approved by U.S. FDA for the treatment of depressive episodes associated with bipolar I disorder (bipolar depression) in adults as a monotherapy and as an adjunctive therapy with lithium or valproate. In Canada as well, on top of the original indication for the treatment of schizophrenia in adults, an additional indication for the treatment of bipolar depression was approved in March 2014. Furthermore, LATUDA® was approved in Switzerland in September 2013 and the European Union and Australia in March 2014 for the treatment of schizophrenia in adults.

We are still working hard to realize the rapid market penetration of this renowned drug.





Annual meeting of the APA

At the May 2013 Annual Meeting of the American Psychiatric Association (APA), the world's largest such meeting, we announced the results of large-scale clinical studies of the efficacy of LATUDA® in treating patients with schizophrenia and those with bipolar depression. We also worked to raise awareness of the brand among the doctors and other medical professionals attending, setting up an exhibition booth for LATUDA® where we presented videos about the drug while explaining its pharmacological properties. At the APA meeting in May 2014, we announced the results of clinical studies of the efficacy of LATUDA® in treating patients with bipolar depression. In addition, we are working to inform doctors and patients of LATUDA® as a new treatment option for bipolar

depression by leveraging our direct-to consumer (DTC) promotion capabilities, including television and Internet (LATUDA.com) advertising, synchronizing these efforts with those of medical representatives.

In order to increase our ability to disseminate information regarding the drug's additional indication of bipolar depression in adults, a national internal sales meeting was held in September of 2013. During this meeting, multiple training workshops were conducted on new promotional materials and training was conducted on how to use newly introduced sales promotion tools employing iPads. We will continue to focus efforts on marketing activities.

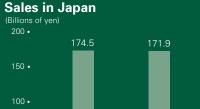
Japanese Pharmaceuticals Business

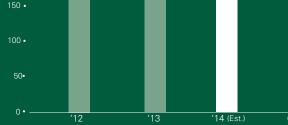
## Japanese Market

Net sales: ¥171.9 billion

Number of MRs: 1,400

\*MR: medical representative





#### **Key Measure**

Concentrate on strategic, new and specialty

#### **Focus Marketing Areas**

Cardiovascular/Diabetes Area, Psychiatry & Neurology Area, and Specialty Areas

#### **Key Products for Sales and Marketing**

Strategic products AIMIX® (cardiovascular), AVAPRO®

(cardiovascular), LONASEN® (psychiatry & neurology), TRERIEF® (psychiatry & neurology)

New products

Paxil® CR (psychiatry & neurology), METGLUCO® (diabetes), SUREPOST® (diabetes)

Specialty products AmBisome®(infectious diseases), MIRIPLA® (cancer), REPLAGAL® (Anderson-Fabry disease)

#### **Summary of Fiscal 2013 Results and Forecasts**

Sumitomo Dainippon Pharma worked to further expand sales of its four strategic products: AIMIX®, a therapeutic agent for hypertension, AVAPRO®, a therapeutic agent for hypertension, LONASEN®, an atypical antipsychotic, and TRERIEF®, a therapeutic agent for Parkinson's disease. In addition, we actively disseminated product information to medical professionals in a bid to significantly expand sales of METGLUCO®, a biguanide oral hypoglycemic, and other products. To increase the opportunities to interact with medical professionals, in conjunction with visits by MRs, we are actively using e-promotion, including disseminating product information over the Internet, streaming webcasts of lectures and distributing e-mail newsletters for healthcare professionals. Moreover, we have launched a customizable personal webpage service for medical professionals—an industry first—available via our official website (Japanese only). This newly introduced online system allows medical professionals and MRs to communicate directly with each other over the Internet.

In fiscal 2014, we aim to further expand sales of our three antihypertensives, focusing on AIMIX® but also including AVAPRO® and AMLODIN®, which is also a therapeutic agent for angina pectoris. We are concentrating our management resources on growth products, including LONASEN® and TRERIEF® in the psychiatry & neurology area, METGLUCO® in the diabetes area and the rapid-acting insulin secretagogue SUREPOST®.

#### **Sales of Major Products**

(Before reduction of rebates: Billions of ven)

Brand Name	Therapeutic Indication	FY 2013	FY 2012
AIMIX®	Therapeutic agent for hypertension	6.9	2.0
AVAPRO®	Therapeutic agent for hypertension	12.1	11.7
LONASEN®	Atypical antipsychotic agent	12.6	10.7
TRERIEF®	Therapeutic agent for Parkinson's disease	9.5	7.0
METGLUCO®	Biguanide oral hypoglycemic agent	15.8	12.0
SUREPOST®	Rapid-acting insulin secretagogue	1.7	0.7
AmBisome®	Therapeutic agent for systemic fungal infection	4.8	4.6
MIRIPLA®	Therapeutic agent for hepatocellular carcinoma	1.2	1.1
REPLAGAL®	Anderson-Fabry disease drug	9.8	9.9
AMLODIN®	Therapeutic agent for hypertension	27.0	29.2



In the cardiovascular area, Sumitomo Dainippon Pharma strives to be a partner in antihypertensive treatment, handling a variety of antihypertensive products with a lineup consisting of an angiotensin II receptor blocker (ARB), calcium channel blocker (CCB), diuretic, angiotensin-converting enzyme (ACE) inhibitor and alpha-beta blocker. We are expanding sales by disseminating information about the antihypertensive area as a whole, including about the drugs AVAPRO® and AMLODIN®, but with a focus on AIMIX®.

In the diabetes area, we have been promoting activities that will quickly maximize sales of new products METGLUCO<sup>®</sup>, the only metformin drug in Japan approved for a maintenance dose of 1,500 mg per day, and SUREPOST<sup>®</sup>, a rapid-acting insulin secretagogue.

#### **Psychiatry & Neurology Area**

Sumitomo Dainippon Pharma handles therapeutic agents for schizophrenia, Parkinson's disease, mood disorders, epilepsy and so on. We are focusing on expanding sales of the strategic products LONASEN® and TRERIEF®. We enhanced our marketing organization by dissolving the CNS Sales & Marketing Department in fiscal 2013 and reorganizing it as psychiatry departments under regional divisions. This change enables regional divisions to tailor sales approaches to market conditions in their areas and strengthens their cooperative relationships with MRs responsible for marketing to primary care providers. This will also accelerate sales expansion in the psychiatry & neurology area.

#### Specialty Areas (Cancer, Infectious Diseases, **Rare Diseases**)

In fiscal 2013, we established specialty areas—cancer, infectious diseases, rare diseases, and so on-in which we can use our high level of expertise as a competitive advantage. We have made them focus marketing areas in which we are working to expand sales.

In the cancer area, we are focusing on expanding sales of MIRIPLA®, a therapeutic agent for hepatocellular carcinoma. With this product, as well as the natural interferon alpha SUMIFERON<sup>®</sup>, we aim to contribute to the total care of those with liver diseases. In the area of infectious diseases, we are working to disseminate information mainly about AmBisome®, a therapeutic agent for systemic fungal infection, while also promoting the appropriate use of MEROPEN®, a carbapenem antibiotic, and highlighting the advantages of HIBITANE®, an antimicrobial agent for general antiseptic purposes. In the area of rare diseases, we are focusing on expanding sales of REPLAGAL®, an Anderson-Fabry disease drug. In addition, we are raising awareness of rare diseases through such activities as establishing a website to provide information on rare diseases to medical professionals and patients.

#### **Sumitomo Dainippon Pharma's MR Training**

Self-development and on-the-job training serve as the basis of our approach to MR training. We are training our MRs to learn on their own and think for themselves. Those with less than three years of experience are considered new and go through a training program entitled "Sumitomo Dainippon Pharma—MR Basic Program." MRs gradually attain, from various perspectives, the knowledge, mind-set and skills needed to carry out their activities.

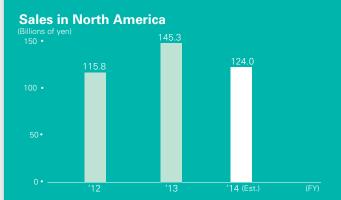
Furthermore, to meet needs arising on the medical frontlines, every MR participates in continuing training to ensure they acquire the latest medical information. We are also building an online training system replete with self-study tools and other useful content. We are developing human resources as professional MRs who can contribute meaningfully to the medical community.



**Overseas Pharmaceuticals Business** 

## North American **Market**

Net sales: **¥145.3** billion



#### **Key Measures**

- Maximize profits from the atypical antipsychotic LATUDA®
- Seek rapid market penetration for our newest drug APTIOM®
- Promote greater management efficiency

#### **Summary of Fiscal 2013 Results and Forecasts**

The subsidiary Sunovion Pharmaceuticals Inc. (Sunovion) is responsible for the Sumitomo Dainippon Pharma Group's marketing activities in North America.

Further growth in demand for market-favorite LUNESTA®, which has strong support from medical professionals, and a significant expansion in sales of LATUDA® thanks to its successful rapid market penetration after the receipt of approval for the treatment of bipolar depression offset a decrease in sales of XOPENEX®, a short-acting beta-agonist inhalation solution, whose period of exclusivity expired in the previous fiscal year. Also, business structure improvement, including the dissolution of the allergy sales team, helped to reduce labor costs and thus gave a substantial boost to segment profit. We will continue working hard to increase sales of LATUDA®, which received approval for a new indication the treatment of bipolar depression in adults as a monotherapy and as an adjunctive therapy with lithium or valproate, aiming to lift it to the level of blockbuster drug. At the same time, we are aiming for the rapid sales expansion of APTIOM®, for the treatment of partial onset seizures, which was launched in the United States in April 2014. At the same time, Sunovion works hard to minimize the influence of sales decrease of LUNESTA® whose exclusivity expired in April this year.

#### Sales of Major Products (Billions of yen)

Brand Name	Therapeutic Indication	FY 2013	FY 2012
LUNESTA®	Sedative hypnotic	58.0	44.8
LATUDA®	Atypical antipsychotic	42.2	16.1
BROVANA®	Long-acting beta-agonist	16.8	12.7
XOPENEX®	Short-acting beta-agonist	12.1	25.3
ALVESCO®	Inhaled corticosteroid	4.2	3.1
OMNARIS®	Corticosteroid nasal spray	2.1	1.9
ZETONNA®	Corticosteroid nasal aerosol	1.9	0.4

#### **Business activities**

Following the approval of the new indication for LATUDA® in fiscal 2013, Sunovion placed priority on penetrating the market. Vigorous promotion by MRs dedicated exclusively to LATUDA®, undertaken in conjunction with television commercials and other DTC promotional activities, led to a steady increase in the number of prescriptions. The drug's promotion as a treatment for bipolar depression kicked off in late July 2013, with marketing materials being distributed from late September 2013 and such DTC advertising as television commercials launching in January 2014. The rollout of these measures boosted the drug's fiscal 2013 sales to \$421 million. Sunovion will continue working to strengthen measures for brand penetration to further maximize the product's value.

Turning to LUNESTA®, a non-narcotic sedative hypnotic indicated for insomnia, anticipating the launch of generic versions in fiscal 2014, we disbanded the MR team and shifted promotion to less costly approaches, such as digital advertising and patient-oriented marketing. Surprisingly, despite expectations of a decrease, fiscal 2013 sales surpassed the initial revenue target, climbing to \$579 million.

In addition, in preparation for the 2014 launch of the antiepileptic drug APTIOM®, which received FDA approval in November 2013, Sunovion hired 120 MRs. We successfully launched the drug in April 2014 and will continue promotional activities to increase its use in epilepsy treatments, targeting \$35 million in fiscal 2014 sales. In fiscal 2014, Sunovion will submit an application in the United States for the additional indication as monotherapy treatment for partial onset seizures.

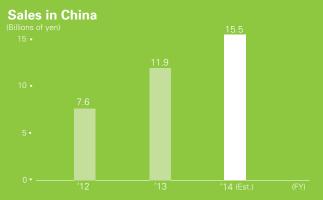




**Overseas Pharmaceuticals Business** 

### **Chinese Market**

Net sales: ¥11.9 billion



### **Key Measure**

- Expand profit from existing products
- Introduce new product

#### **Summary of Fiscal 2013 Results and Forecasts**

The Sumitomo Dainippon Pharma Group conducts marketing activities in China through its local subsidiary Sumitomo Pharmaceuticals (Suzhou) Co., Ltd., which currently sells four products: MEPEM® (brand name in Japan: MEROPEN®), a carbapenem antibiotic, ALMARL®, a therapeutic agent for hypertension, angina pectoris and arrhythmia; SEDIEL®, a serotonin-agonist anti-anxiety drug, and GASMOTIN®, a gas-

In fiscal 2013, sales of MEPEM® continued to increase. and ALMARL® and the other drugs experienced firm growth. In order to quickly capture a share of this large market, Sumitomo Pharmaceuticals (Suzhou) has reinforced and enhanced its sales structure, focusing on departments that handle sales promotion and marketing. As of the end of



March 2014, the company has 390 MRs in 30 sectors (major urban, administrative and self-governing areas).

In fiscal 2014, the company will continue to conduct scientific promotion activities focused on the large-scale hospital market.

#### **Sales of Major Products**

Brand name	Therapeutic Indication	FY 2013	FY 2012
MEROPEN®	Carbapenem antibiotic	9.8	6.3

#### **Future Business Expansion**

In September 2013, Sumitomo Pharmaceuticals (Suzhou) applied for the regulatory approval of the atypical antipsychotic blonanserin, which is sold in Japan under the brand name LONASEN®, with an anticipated indication of treating schizophrenia. The drug will join SEDIEL® in China, which the company already sells in the psychiatry & neurology area. The company also applied in August 2012 for regulatory approval of the small cell lung cancer treatment amrubicin hydrochloride (brand name in Japan: CALSED®). The two drugs awaiting regulatory approval show a lot of promise as new products in the Chinese market.

The global strategic product LATUDA® entered into a Phase III clinical study for schizophrenia in China in July 2013.

We will maximize the scale of business and earnings by constantly promoting development in China while enhancing the marketing structure and continuously launching new products.

## Non-pharmaceuticals **Business**

Developing business in a broad range of fields through cooperation with the pharmaceuticals business

#### Food Ingredients, Food Additives and Chemical **Product Materials**

DSP Gokyo Food & Chemical Co., Ltd. http://www.dsp-gokyo-fc.co.jp/english/

The food ingredients, food additives and chemical product materials business is handled by Sumitomo Dainippon Pharma subsidiary DSP Gokyo Food & Chemical Co., Ltd. In the food ingredients and food additives business, the company develops and sells ingredients and additives for use in manufacturing safe, highquality foods. Products include polysaccharides, primarily GLYLOID® (tamarind gum), the first product of its kind successfully produced on an industrial scale; seasonings such as soup bouillon; and sweeteners such as MIRASEE®, an easy-to-use preparation based on neotame, a high-intensity sweetener. The chemical product materials business encompasses such products as cosmetic materials, active pharmaceutical ingredients, electronic chemicals and coating materials. Leveraging Sumitomo Dainippon Pharma's technologies and know-how from the pharmaceuticals business, and through cooperation with domestic and overseas suppliers, we are expanding these business units as a company that integrates research, development and sales operations to continually create the value that customers require.

#### **Animal Health Products**

DS Pharma Animal Health Co., Ltd. http://animal.ds-pharma.co.jp/eng/index.html

The animal health products business is conducted by Sumitomo Dainippon Pharma subsidiary DS Pharma Animal Health Co., Ltd., and the major products are veterinary medicinal products and therapeutic nutritional formulas for companion animals, primarily dogs and cats, as well as for livestock such as cattle, swine, poultry, horses and aquacultured fish. In the companion animal business, its main focus, DS Pharma Animal Health provides various veterinary medicinal products, including PRONAMID®, a canine gastroprokinetic agent for the improvement of canine gastrointestinal motility, VICTAS®S, a series of antibacterial formulations for dogs and cats, APINAC®, a chronic heart failure ameliorating for dogs, ISOFLU®, an inhalant anesthetic, as well as medicinal products used for joint

diseases in dogs, canine heartworm preventives, and in the field of ophthalmology and dentistry. In addition to its veterinary medicinal products the company supports the total wellbeing of companion animals through providing a full line of nutritious pet foods developed by Hill's Pet Nutrition. Inc. including Prescription Diet®, special foods of therapeutic nutritional formulas, and Science Diet Pro®, the ones of wellness nutritional formulas. For the livestock industries, DS Pharma Animal Health provides URSO®, a bile acid product for cattle, EQVALAN® paste, an oral anthelmintic for horses, and other products. For the aquaculture industry, the company provides vaccines and other products including anesthetics and synthetic antibacterial drugs for fish and crustaceans, contributing to security and safety of food. In addition, the company deals in feed additives and mixed feeds for maintaining animal's health and improving productivity. As a research and developmentbased animal health company, we create high-quality products that deliver new value that support the well-being of animals and strive to promote a blissful society where animals and people live together harmoniously.

#### **Diagnostics and Research Materials**

DS Pharma Biomedical Co., Ltd.

http://www.dsp-bio.com/

Sumitomo Dainippon Pharma subsidiary DS Pharma Biomedical Co., Ltd. conducts a diagnostics and research materials business. In the diagnostics business, to help ensure accurate and timely treatment, the company develops and supplies point-ofcare testing (POCT) products, such as diagnostics for infectious diseases like influenza and Streptococcus, and the Rapicheck® H-FABP diagnostics kit for acute myocardial infarction. It has also developed Osteolinks TRAP5b® and other in-vitro diagnostic reagents for bone resorption markers, as well as the Whole PTH SUMITOMO, a third-generation parathyroid hormone (PTH) assay kit, and diagnostics for central nervous system disorders. The company is also developing biomarkers for use in companion diagnostics, which are performed to predict the efficacy and side-effects of drugs before they are administered.

In addition, to facilitate advanced research related to medical care, the company also develops and supplies these research materials including S-Medium, a feeder-free, chemically defined medium, and POCA®, a series of ready-to-use assay models effective in drug discovery research, can both be applied in regenerative therapy using iPS and other human stem cells. In the research and development of early-stage drug discovery assay systems related to these and other cell culture technologies, the company leverages the synergistic effects of its operations with the regenerative medicine and cell therapy business of Sumitomo Dainippon Pharma to contribute to the development of medicine.



#### A Supply Chain That Supports Global Business

To maintain an optimal product supply system, Sumitomo Dainippon Pharma operates four factories in Japan as its primary manufacturing bases while promoting contract manufacturing under technology alliances and production at its Group facilities. To further strengthen our stable supply system, we will reinforce our supply chain based on global expansion, including the overseas procurement of raw materials and pharmaceutical intermediates.

#### **Quality Assurance**

The production of pharmaceuticals requires a high level of quality assurance. Consequently, rigorous GMP (Good Manufacturing Practice) standards have been established in many countries. Pharmaceuticals are exported around the world after obtaining regulatory approvals from government institutions of importing nations, including the FDA (U.S. Food and Drug Administration), EMA (the European Medicines Agency), and TGA (Australia's Therapeutic Goods Administration). Therefore, operating standards in the Sumitomo Dainippon Pharma Group are consistent with the GMP standards of Europe and the United States. Furthermore, we have established a high level of facility design and a quality assurance system to pass audits by overseas partner companies while meeting strict quality standards at the global level by following the guidelines of the ICH (International Conference on Harmonisation), which deliberates on the harmonization of EU, U.S. and Japanese pharmaceutical regulations.

The standards for quality assurance are expected to become increasingly rigorous. The Sumitomo Dainippon Pharma Group is therefore making proactive investments in manufacturing facilities—including a new solid dosage form facility and RABS (restricted access barrier system) that increases the level of sterility assurance—to meet future standards. We are focusing our efforts on strengthening our supply system to continue providing pharmaceuticals of increasingly high quality.

#### A Trusted Pharmaceutical Company

Sumitomo Dainippon Pharma is striving to swiftly respond to requests from medical institutions and patients by, for example, improving package and label designs in an effort to help prevent medical errors.

We continue to reduce production costs and conduct ecofriendly production activities through the automation of facilities and other laborsaving measures, the optimization of production sites, appropriate inventory control and the introduction of co-generation systems. Moreover, we are working to strengthen the complementary functions of distribution centers in eastern and western Japan to maintain a stable supply in not only normal times but also in the case of a disaster or other emergency.

#### **Supply Chain Management** (Procurement of Raw Materials)

To ensure the stable and sustainable procurement of the raw materials and other items used in its pharmaceuticals, Sumitomo Dainippon Pharma continuously and systematically promotes measures to prevent the interruption of its supply of raw materials, including the use of multiple suppliers, taking alternative products into consideration and maintaining appropriate inventories. Currently, the company is working on measures for individual products, and in fiscal 2013 it devised specific measures for raw materials for drug formulation related to its strategic and new products. To conduct fair, open and transparent transactions, Sumitomo Dainippon Pharma concludes basic agreements on transactions with business partners, complies with relevant laws and regulations including the Act against Delay in Payment of Subcontract Proceeds, Etc. to Subcontractors, and continuously evaluates business partners.

In its overseas procurement, in addition to dealing speedily with problems as a matter of course, we work to prevent problems from occurring and eliminate supply uncertainties by building deeper relationships of trust through smooth communication with overseas business partners and trustworthy procurement activities.

#### **Domestic Plants**

Sumitomo Dainippon Pharma has four factories in Japan. The Suzuka Plant is our main factory serving global supply. It conducts integrated pharmaceutical manufacturing from the pro-

duction of active pharmaceutical ingredients to packaging The Ibaraki Plant, which is also the main base of the Technology Research & Development Division, is a development-driven pharmaceutical plant able to flexibly accommodate a range of processes from commercial production to quality control. The Ehime Plant is a manufacturing base for biopharmaceutical products. The Oita Plant is our core facility for the production of active pharmaceutical ingredients. Each of these factories manufactures pharmaceuticals while constantly ensuring the safety of the products based on GMPcompliant manufacturing equipment, processes and testing. To date, all four factories have also acquired ISO 14001 certification, have maintained their certification and plan to continue to do so going forward.

#### **Overseas Plants**

The plant at Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. in China serves as a Sumitomo Dainippon Pharma Group production facility and packages products for sale in the local market. The expansion of the facility is progressing in stages, with the construction of a warehouse completed in October 2012. Fully integrated production, from formulation to packaging, is scheduled to start in the future.

#### **Production Sites in Japan**

#### Suzuka Plant (Suzuka City, Mie Prefecture)



The Suzuka Plant is a worldclass core plant fully compliant with cGMP (the latest U.S. GMP), with a state-ofthe-art dosage formulation facility constructed in 2008 and operational since January 2009. The plant maintains integrated phar-

maceutical manufacturing facilities at which a full range of operations is conducted, from the production of active pharmaceutical ingredients and finished products to packaging. The Suzuka Plant is responsible for manufacturing such major drugs as LONASEN®, PRORENAL®, GASMOTIN® and EBASTEL®.

#### Ibaraki Plant (Ibaraki City, Osaka Prefecture)



The Ibaraki Plant, which is also the main base of the Technology Research and Development Division, is a development-driven pharmaceutical plant able to flexibly accommodate new products and technologies, from drug formulation

research through commercialization and production. It produces drugs in a broad range of dosage forms. The Ibaraki Plant is responsible for manufacturing AIMIX®, AVAPRO®, AMLODIN® and a multitude of investigational drugs.

#### **Ehime Plant (Niihama City, Ehime Prefecture)**



The Ehime Plant is a key manufacturing base for biopharmaceuticals with one of the world's largest biopharmaceutical production facilities. It produces a stable supply of biopharmaceutical products that require a superior control

technology. The plant produces CALSED®, a sterile formulation and a crude intermediate solution of SUMIFERON®, and also produces a sterile formulation CALSED®

#### Oita Plant (Oita City, Oita Prefecture)



The Oita Plant is our core facility for the production of active pharmaceutical ingredients and its equipment is cGMP-compliant. MEROPEN® is manufactured from its active ingredient to the final product in an integrated way for use in

Japan and overseas. The plant also produces the active pharmaceutical ingredients for LATUDA®, AMLODIN®, DOPS®, and other major

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#### **Entering the Vaccine Business**

Tuberculosis (TB) is one of the three major infectious diseases plaguing the world, each year, more than 8.6 million people become sick with TB and 1.3 million people die of the disease. It is widespread, particularly in Asia and Africa. This disease is commonly diagnosed in the 15 to 44 age group—the most economically productive—greatly damaging society. Moreover, conventional BCG derived vaccines are much less effective against adult tuberculosis, making the health-related economic burden on individual countries that much heavier.

Sumitomo Dainippon Pharma reaches beyond national boundaries to realize its Corporate Mission of "To broadly contributing to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide." We have entered the TB vaccine business as one of the new fields of business identified as a target in the third Mid-term Business Plan. In this, we have taken the first step to promoting global health, especially in emerging and developing countries.

#### Framework of the New TB Vaccine Development Project

This Project provides a framework for promoting joint development between Japan's National Institute of Biomedical Innovation(NIBIO), Aeras and Create Vaccine Company, Ltd (a joint venture established by Sumitomo Dainippon Pharma and Japan BCG). In November 2013, it has received a funding from The Global Health Innovative Technology Fund ("GHIT Fund"). In May 2014, Innovation Network Corporation of Japan (INCJ), Japan BCG Laboratory and Sumitomo Dainippon Pharma invested a total sum of ¥845 million into Create Vaccine Company with the aim of accelerating this development.

The project aims to develop new TB vaccines incorporating a novel recombinant human parainfluenza virus type-2 (rhPIV2) vector technology developed by NIBIO. The vaccines are called mucosal immunity induction vaccines because they target the respiratory mucous membranes to prevent *Mycobacterium tuberculosis* from colonizing (infecting) the lungs. If successful, the vaccines would prevent the spread of TB in adults, who are most susceptible to developing the active, infectious form of the disease.

#### Promoting Global Health through Our Work

We expect the promotion of this vaccine business to help build our future business foundation. Taking a long-term, 10 to 15-year perspective, we have begun establishing a R&D organization dedicated to finding vaccines against infectious diseases in emerging nations. This decision was based on the Company's Corporate Mission as well as a sincere desire to improve patients' lives and uphold human dignity. Sumitomo Dainippon Pharma is aiming for sustainable growth through the realization of its Corporate Mission.

# Social Responsibility

Sumitomo Dainippon Pharma's CSR

#### **Basic Approach**

Sumitomo Dainippon Pharma sets forth its commitment to serving society in the Company's Corporate Mission, and the aim of its operations, which are focused on its stakeholders, in the Management Mission.

Our Declaration of Conduct describes our corporate philosophy and values in more concrete terms, and serves as the basis of our approach to CSR. We are committed to providing through our business activities products that are truly needed, ensuring that these activities are in line with our Declaration of Conduct, and pursuing them as a responsible corporate citizen.

#### Value Chain and ISO26000 Core Subjects

Working to fulfill our social responsibilities through our business activities, Sumitomo Dainippon Pharma places special emphasis on the following three core subjects outlined in the ISO

26000 standard: human rights, the environment, and consumer issues.

#### air and transparent Manufacturing Logistics Post marketing Research Development corporate activities Core Subjects: **Core Subjects:** Core Subjects: Core Subjects: Core Subjects: • Fair Operating Practice **Human Rights** Consumer Issues • The Research Ethics • Commitment to CSR Our approach to Distribution system Prompt response to Committee on Uses of providing stable supplies ships products within procurement inquiries made to Quality Respect for intellectual property Human Tissues of high-quality Information System Core Subjects: Compliance pharmaceuticals Development of Initiatives to ensure Core Subjects: Environment Establishing a stable product safety environmental Environment Development of sunnly system conservation systems Encouragement of proper Safe management of use of safety-related recombinant DNA conservation systems **Core Subjects:** information Provision of information · Safety of genetic Development of using the product information search facilities conservation systems system Prevention of radiation Safety of facilities handling radionuclides Development of conservation systems

#### Human Rights

#### Clinical Studies Put the Human Rights of Subjects First

We conduct human clinical studies in accordance with the requirements for new drug applications and with the utmost consideration to the subjects' human rights. Since clinical studies are conducted during the intermediate stages of confirming the efficacy (effectiveness) and safety (or side effects) of drug candidates, our clinical studies follow such regulations as Japan's ministerial ordinance on GCP (Good Clinical Practice), which was established to protect the human rights, maintain the safety and improve the welfare

of subjects participating in studies.

In clinical studies, we endeavor for the "promotion of development activities based on common sense and conscience" while always keeping in mind the risk of "unpredictable side effects." We secure the safety of cases by collecting, reporting and evaluating any kind of information, including that necessary for judging whether each case can cooperate with the trials, throughout the studies.

#### Elimination of Discrimination in the Workplace

#### Respect for the Dignity of the Individual

Sumitomo Dainippon Pharma respects the human rights of all people involved with the Company, and in its "Declaration of Conduct (Guidebook for Daily Application)"

#### **Initiatives to Prevent Harassment**

Power harassment and sexual harassment in the workplace, as actions that harm the dignity of individuals, are important issues related to the violation of human rights. To prevent harassment, Sumitomo Dainippon Pharma clearly stipulates anti-harassment policies within its office regulations and makes clear that violations will result in disciplinary action. We ensure proper knowledge of issues through evaluator training and grade-specific training, and engage in raising

clearly rejects any discrimination based on race, nationality, origin, religion, ideology, creed, sex, physical disability, age or form of employment.

anti-harassment awareness. We have also established consultation services at our Head Offices and other major work-places and a system that ensures a quick, sincere response to complaints and proper consultation.

All parties related to the company are eligible to receive these services and the entire company is committed to preventing harassment.

#### Labor Practices

#### Creating a Workplace Environment That Allows Employees to Focus Confidently on Their Work

Sumitomo Dainippon Pharma has an established "Health and Safety Policy" on the basis of which it has enacted a variety of health and safety measures. We have worked tire-lessly to prevent work-related accidents by uncovering risks, evaluating those risks and then implementing PDCA cycles to deal with them. Moreover, to prevent the occurrence of a fire, explosion, or other major work-related accident, Sumitomo Dainippon Pharma has implemented measures to ensure the safety of everyone on site by automating equipment and eliminating dangerous tasks. We have also introduced a number of measures in preparation for a large-scale natural disaster, including measures and rules regarding equipment to minimize any potential impact.

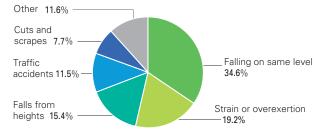
In addition to these measures, we believe it is important

to instill an awareness of health and safety among employees themselves. Also, information about work-related accidents that occur at Sumitomo Dainippon Pharma is shared with the entire company via our intranet. These examples help foster awareness about health and safety among all employees through the recognition of accidents as close-athand events. Toward this end, the Secretariat of Environmental and Safety Committee trains all new hires about workplace accident prevention, encouraging them to reexamine their assumptions about basic concepts, such as what exactly health and safety entails and why health and safety initiatives are necessary, for the purpose of crisis prevention and management.

#### **Analysis of Work-Related Accidents**

In analyzing the causes and types of work-related accidents that occurred in the four years from fiscal 2010 to fiscal 2013 (excluding accidents involving sales fleet vehicles), we found that falls accounted for 35% of the total. While there were various contributing factors to many of the falls—including sidewalk curbs, wet floors and icy pavements—many cases seemed to involve rushing, hasty actions or psychological factors resulting in inattentiveness amid a dangerous situation. These findings demonstrated the importance of promoting not only company policies but safety awareness among employees. As a result, we resolved to take advantage of Japanese National Safety Week to foster safety awareness.

#### Classification of Work-related Accidents



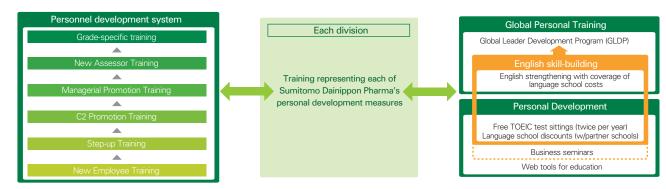
Fiscal 2010 to 2013 Data

#### Creating an Environment in which Employees Can Fully Exercise Their Capabilities

As part of our management mission, we seek "to create an environment in which employees can fulfill their potential and increase their creativity," and we therefore aim to foster a corporate climate where employees can independently pursue their own skills development, where the company actively supports employee growth, and where the corporate environment allows employees to demonstrate their full potential.

Personnel development primarily consists of OJT (on-thejob training) where employees learn through doing actual tasks and taking on challenges. As a supplement to this, a variety of Off-JT (off-the-job training) programs are offered in the form of strengthening/support programs, training sessions and more. By combining OJT and Off-JT with job rotation, effective personnel development is carried out in an environment that encourages employees to maximize their potential. Sumitomo Dainippon Pharma has introduced its self-reporting system to motivate employees to take the initiative in their work. The primary purpose of the self-reporting system is to help supervisors understand the circumstances, issues and hopes of each employee under them while considering their long-term growth and skills development.

Supervisors hold face-to-face meetings with individual employees based on their self-reporting, providing them with the opportunity to focus on their future in the company and to reevaluate their resolve, interests and aspirations. Supervisors reflect on the company's training policies and day-to-day duties and, by linking this to OJT and Off-OJT, support the growth of individual employees.



#### Diversification

Aiming to make Sumitomo Dainippon Pharma more global, we are taking active steps toward diversification.

"Diversity" is often viewed from the points of view such as male or female, experienced employee or new employee, midcareer hire or new university graduate hire, Japanese or foreign national, and regular or contract employee. By recognizing differences and encouraging mutual respect, we are working to enable each and every employee to realize their full potential.

We have twice received official recognition from the director of the OSAKA Labor Bureau as a company that supports child-rearing; once in 2010 and once in 2013. We are now raising the bar on the initiatives that support childrearing. And everyone in the company is working together to eliminate the gender-based division of roles, which is rooted in outdated beliefs and is also a particular problem in Japanese companies. Specifically,



we are working to raise awareness, revise our systems and adjust the working environment to enable female employees to make the full use of their capabilities and expedite their advancement

#### **Establishing Consultation Desks**

Sumitomo Dainippon Pharma established several consultation desks to foster a workplace environment in which every employee is able to work comfortably and with a sense of security.

Consultation Desk	Purpose
Compliance Hotline	Providing consultation or accepting reports internally or externally in the event that an employee has questions or has obtained information concerning violations related to compliance
Sexual Harassment Consultation Desk	Providing consultation or accepting reports internally in the event that an employee has questions or has obtained information concerning violations related to sexual harassment
Mental Health Consultation Desk (Outside)	Providing consultation or answering questions concerning mental health externally
General Consultation Desk	Providing consultation or accepting reports internally in the event that an employee has questions or has obtained information concerning violations related to compliance as well as in the event that an employee has problems or concerns related to daily work life

#### Fair Operating Practices

#### Guidelines for Transparency in Partnerships with Patients and Medical Institutions

The mission of an R&D-oriented pharmaceutical company is to contribute to the health of people and medical care around the world by continually researching and developing new drugs and steadily bringing them to market with the objective of creating patient-centric medical care.

In order to fulfill this mission, it is essential to collaborate with research organizations, including medical institutions and universities, in at all stages from drug discovery to postmarketing information provision activities that ensure the proper use of pharmaceuticals.

With representatives of patient groups sitting on an increasing number of government committees and investigative commissions as governments and the community put greater emphasis on the "voice of the patient," patient groups have become important stakeholders in the mission to improve medical care.

At Sumitomo Dainippon Pharma, we believe that it is critical to raise awareness and increase understanding throughout society that activities designed to improve coordination between medical institutions and patient groups are undertaken in accordance with high ethical standards.

JPMA (The Japan Pharmaceutical Manufacturers Association) issued its Guidelines for Transparency in Relationships between Corporate Activities and Healthcare Institutions on January 19, 2011, and its Transparency Guidelines for the Relationship between Corporate Activities and Patient Associations on March 14, 2012.

As a member of the JPMA, we established our own Guidelines for Transparency in Partnerships with Medical Institutions in October 2011 and Guidelines for Transparency in Partnerships with Patient Associations in April 2012.

In accordance with these guidelines, we publicly disclose information on our corporate website of our payments to medical institutions, medical professionals, patient groups and support groups.

#### Information Security

"Information" is an important asset in our corporate activities, and how it is used and protected is of particular importance to the company. We have set global policies for records and information management as well as various rules for information security to appropriately manage risks. In addition, each Group company enforces its own equivalent set of rules.

As part of its information security measures, Sumitomo Dainippon Pharma constantly reviews its technological protections as well as internal rules and standards in light of social changes and advances made in information technologies. We also work to strengthen security at Group companies.

We focus on education aimed at ensuring that employees recognize the importance of information security and ensure full compliance with rules and regulations. In addition, we continue to provide information security training over our intranet to promote higher awareness about information security.

#### Consumer Issues

#### Launched a Medical Information Site for Medical Professionals

Through this Japanese-language medical information site, we provide medical professionals with information that is useful in their line of work, including basic product information, notices of various revisions to product information and information about the seminars we hold.

#### Launched a Health Information Site

Through this Japanese-language health information site, we provide the general public with basic information, the latest news and tips to help people enjoy healthy lives. Site content

includes data on causes of and treatments for diseases, tips on healthy living and warnings about the misuse of drugs

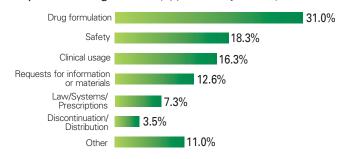
#### Pages and Content on the Health Information Site

Page title	Content
Disease Info	On this web site, visitors can search for information related to illness by disease name or symptom. There are also easy to understand explanations about common maladies, including lower back pain and high blood pressure. Visitors can also check out "the Message from a Doctor" to get clear explanations from specialists in their neighborhood about treatments or tips on daily activities.
Life Tips	This fascinating page features "The Practical Health Navigator," where you can learn about healthy living, including proper diet and exercise. There's also "Health Tips," where you can learn fun facts about clothes, food and communities through witty columns and illustrations, and "The Ah Hah! Guide to Taking Medicine" where visitors can learn about the effects, side-effects and efficacy of drugs.
Medicine Guide	On this web site, visitors can search for information related to medicine, including actions, effects, side-effects, usage warnings or other key terms using the drug name.

#### An Exclusive Commitment to Handling Inquiries: Product Information Center

Sumitomo Dainippon Pharma established the Product Information Center in order to respond to inquiries about its ethical pharmaceuticals. Going forward, we will continue swiftly and politely providing accurate information regarding the appropriate use of medicines to support the health of patients

#### Inquiries during FY2013 (Approximately 60,000)



#### Initiatives Aimed at Social Issues as a Pharmaceutical Company

Our aim, "To broadly contribute to society through value creation based on innovative research and development activities for the betterment of healthcare and fuller lives of people worldwide" mean not only focusing on pharmaceutical but

also contributing to the development of worldwide local communities through our corporate activities while maintaining respect for local cultures and customs regardless of their location.

#### Officer and Employee Participation in Activities

Sumitomo Dainippon Pharma and its officers and employees contribute to organizations that conduct activities reflecting our corporate slogan, "Healthy bodies, healthy lives." In fiscal 2013, we donated to the nonprofit organization Support Network for Chronic Sick Children of Japan ("Nanbyonet") and to the Japan Clubhouse Coalition, which is certified by

the International Center for Clubhouse Development.

Officers and employee volunteers also continued to raise funds to support the reconstruction of the areas affected by the Great East Japan Earthquake.

#### The Japan Epilepsy Research Foundation

Funded by donations from Sumitomo Dainippon Pharma and other interested parties, the Japan Epilepsy Research Foundation conducts the following activities to promote

research into the treatment of epilepsy and to contribute to better health and medical care in Japan:

#### Monetary support activity

- 1. Provides grants for basic and applied clinical research
- 2. Subsidizes the dispatch of Japanese researchers overseas
- 3. Provides fellowships to researchers from other Asian countries to study in Japan
- 4. Subsidizes the publication of the Journal of the Japan **Epilepsy Society**

#### **Commendations**

1. Awards research prizes to researchers or research groups that achieve significant results through continuous research

2. Awards research service prizes to researchers who have made a notable contribution to and played a leading role in the progress of epileptology over many

To publicize these support initiatives, the foundation holds meetings to present research findings and publishes the Research Annual Report. We will continue to contribute to the improvement of medical care and welfare by supporting this foundation.

#### Activities to Support Reconstruction since the Great East Japan Earthquake

To provide long-term support for reconstruction since the Great East Japan Earthquake, on May 1, 2011, we established the Earthquake Reconstruction Support Office as an organization dedicated to providing long-term assistance. Since then, we have been continually involved in the reconstruction of the affected regions. The Earthquake Reconstruction Support

Office has been relocated under the Corporate Communications Division and continues to support reconstruction activities.

Moreover, officers and employees are continuing to raise funds through the NPO ASHINAGA to support children who lost their parents or guardians in the earthquake disaster.

#### International Contribution Activities

Sumitomo Dainippon Pharma recognizes that global health initiatives that seek to improve healthcare are important and that pharmaceutical companies, including us, should participate in them. Accordingly, we are engaged in the following activities to support all of our various stakeholders working to improve healthcare around the world.

#### **Donation Activities**

We donate to Future Code, an NGO active in human resource development and the provision of tuberculosis exams in such developing countries as Haiti. In addition, as a cooperator and supporter, Sumitomo Dainippon Pharma donates to "Malaria

No More Japan," an NPO that aims to raise awareness and advise on policies regarding the elimination of Malaria around the world, especially Asia

#### Participation in "The TABLE FOR TWO Program"

From October 2012, we have taken part in "The TABLE FOR TWO Program" through the employee cafeterias of its Osaka Head Office, Tokyo Head Office, the Central Research Laboratories and the Suzuka Plant. Under this program, for every specified lunch set eaten, a ¥20 donation is made to the nonprofit organization TABLE FOR TWO International, which uses it to purchase a school lunch for a child in a developing country.

School lunches not only assuage the hunger of these children but are also seen as improving children's learning ability and basic physical fitness while aiding in the prevention of disease, thus playing a key role in resolving poverty. In fiscal 2013, we provided

Going forward, Sumitomo Dainippon Pharma will continue to promote initiatives for "The TABLE FOR TWO Program."

#### Support for Measures against Counterfeit Drugs

Counterfeit drugs include not only those without therapeutic effect but also those that put patients' lives at risk through unexpected side effects. The threat of these drugs is increasing globally, with the amount in distribution in 2010 alone reported to have reached \$75 billion. Furthermore, as a ready source of funds for organized crime or terrorist organizations, counterfeit drugs have taken on the dimension of an international problem.

Toward that end, 29 pharmaceutical companies(including

Sumitomo Dainippon Pharma and seven other Japanese companies) engaged in global business will make a joint contribution of €4.5 million to the international police organization Interpol over three years, beginning in 2013. The funds will be used to promote awareness of counterfeit drugs among the general public, to educate investigators specialized in pharmaceutical-related crimes and to promote other initiatives to prevent such crimes.

## Environment

Sumitomo Dainippon Pharma recognizes its responsibility for its environmental impact and strives to reduce environmental impact in all areas of its business operations.

Established in fiscal 2005, our Basic Environmental Policies underpin all our environmental activities. Under the Basic Environmental Policies, we formulated a Mid-term Environmental Plan that specifies goals of special importance and objectives for three years (from fiscal 2013 to fiscal 2015). In addition, every year we draft an Annual Implementation Plan. In this way, we ensure that our environmental activities are systematic and effective.

#### **Basic Environmental Policies**

Aware that the global environment is now facing a serious crisis, we at Sumitomo Dainippon Pharma will make concerted efforts to preserve the environment and help create a recycling-oriented society through all our corporate activities. Our mission is to protect human lives and promote health, thereby helping to create a prosperous and pleasant world.

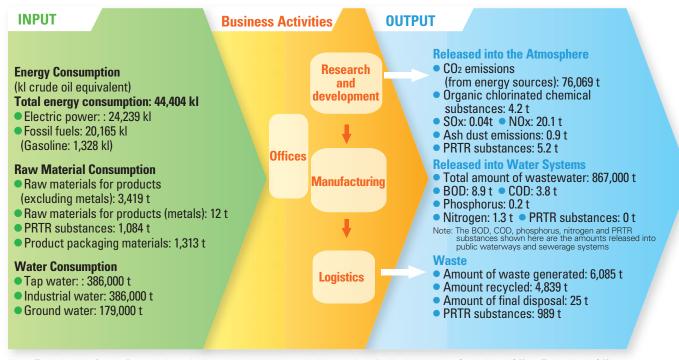


Sumitomo Dainippon Pharma has formulated basic environmental policies as pillars of environmental activities that the Company should undertake.

#### Overview of Environmental Impact

Our business activities affect the environment in various ways at every stage of research and development, manufacturing, logistics and marketing, as well as in the use of our products

by customers. All our employees are aware of this environmental impact and work to reduce it.



Note: Totals include figures for workplaces in Japan only (plants, research laboratories, distribution centers, Osaka Head Office, Tokyo Head Office, branches and business offices)

#### Mid-term Environmental Plan (fiscal 2013–2015)

Sumitomo Dainippon Pharma has clarified key issues related to its environmental activities and has established its Midterm Environmental Plan as an action plan to realize these goals and make continuous improvements toward them. The targets of the Environmental Plan are as follows: (1) Reduce emissions of chemical substances, (2) Promote energy saving and address climate change, (3) Avert power shortages, (4) Reduce waste, (5) Promote communication with Group companies, (6) Promote communication with local communities,

(7) Address biodiversity, (8) Enhance environmental education, (9) Train employees. During fiscal 2013, we made steady progress in most areas, except for a few objectives. In the future, we will continue to pursue further improvements.

Note: Although the Mid-term Environmental Plan is a three-year plan. it is reviewed each year to adjust for changes in the situation within and outside the Company.

 $\textbf{Degree of progress: } \\ \textcircled{\textbf{O}Goal achieved } \\ \textcircled{\textbf{S}teady progress made toward objective} \\ \triangle \\ \textbf{Progress somewhat behind schedule} \\ \times \\ \textbf{Progress significantly behind schedule} \\ \\ \textbf{X} \\ \textbf{Y} \\$ 

Goals of Special Importance	Objectives	Progress in FY2013	Degree of Progress
Reduce emissions of chemical substances	(1) Properly manage chemical substances, and continually strive to reduce emissions of chemical substances (PRTR substances, etc.) into the environment	(1) With decrease in the volume of PRTR substances handled, atmospheric emissions of these substances decreased approximately 56% over the previous fiscal year	0
	[1] Numerical targets:	[1] Numerical targets:	
	(1) Reduce CO2 emissions for the whole Company to 23% of FY2005 levels by FY2020	(1) Company-wide CO2 emissions in FY2013 stood at 92.7% of the level in FY2005 and 98.9% of the previous fiscal year	0
	(2) Improve per-unit energy consumption and CO2 emissions for the whole Company by 1% or more per year, respectively	(2) Per-unit energy consumption: 96.6% of FY2012 Per-unit CO2 emissions: 96.2% of FY2012	0
	[2] Activity targets:	[2] Activity targets:	
2. Promote energy savings and	(1) Promote greening of the Company's work sites	(1) Considered various measures at each work site and in General Affairs Department	$\triangle$
address climate change	(2) Promote the introduction of energy-efficient equipment and machinery at the Company's work sites	(2) Introduced energy-efficient equipment and machinery. This included replacing the gas boiler at the Suzuka Plant and upgrading air-conditioning equipment at the Ehime Plant.	0
	(3) Promote the use of renewable energy at the Company's work sites	(3) Currently operating and in the process of installing solar power generation equipment at the Central Research Laboratories and the Osaka Research Center	0
	(4) Promote energy saving at the Company's work sites	(4) Implemented across the whole Company and at each work site	0
	(5) Promote transparency in energy use at work sites	(5) Considered various measures at each work site	0
3. Avert power shortages	Consider and implement measures to reduce energy use in summer and winter	Each work site set unique targets and implemented measures to reduce energy use	$\circ$
	(1) Maintain final landfill disposal by the whole Company at less than 1% of waste generated	(1) Maintained at less than 1% (FY2013 result 0.4%)	0
4. Reduce waste	(2) Plants and research laboratories: Maintain final landfill disposal of industrial waste at less than 1% of amount generated	(2) Zero emissions goal achieved at four plants and one research laboratory, but goal not achieved at one research facility in FY2013 (1.6%)	$\triangle$
	(3) Other sites: Continue complete recycling of recyclable waste	(3) Other sites made progress in recycling recyclable waste	0
5. Promote communication with Group companies	(1) Support environmental and safety activities of Group companies	(1) Conducted environmental and safety audits at two Group companies in Japan, and held meeting in March 2014 to exchange information on the energy manage- ment of domestic Group companies	0
	(1) Understand environmental risks that corporate activities can present to the local community	(1) Gained understanding of most risks and implemented countermeasures	$\circ$
6. Promote communication with local communities	(2) Disclose information to the local community in an appropriate way	(2) Implemented appropriately	0
	(3) Participate actively in local environmental activities	(3) Actively implemented at each work site	0
7. Address biodiversity	(1) Deepen understanding of biodiversity	(1) Carried out activities to raise awareness of biodiversity	$\bigcirc$
8. Enhance environmental education	(1) Develop and implement educational programs	(1) Created and implemented a scheme for grade-specific education, education of all employees, and support for education conducted at work sites	0

#### Activities to Conserve Energy and Address Climate Change

In addition to the active introduction of new energy technologies that emit lower levels of greenhouse gas (CO2). Sumitomo Dainippon Pharma is undertaking efficient energy use in all of its business activities and working to reduce emissions of CO2.

In fiscal 2013, we added measures to conserve energy in both the summer and winter months to the initiatives already in place to introduce energy-saving equipment to operations and hybrid vehicles to our leased sales fleet. As a result, we were able to maintain companywide CO2 emissions at the same level as the previous fiscal year. As of the end of fiscal 2013, hybrid vehicles accounted for about 67% of our sales fleet companywide.

Climate change is currently the most pressing issue worldwide. We will continue to actively introduce new technologies throughout all of our business activities, and will continue tackling the reduction of CO2 emissions while using energy efficiently.

Note: We use our own fixed value for the CO2 conversion coefficient. This is to eliminate the influence of external factors, such as the operational status of nuclear power plants, and to make the results of our efforts clear. As such, the figures may differ from those reported in accordance with Japan's Act on Promotion of Global Warming Countermeasures.

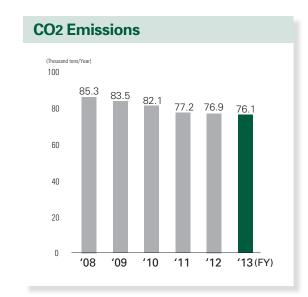
#### Waste Reduction

To make effective use of our limited resources, we practice the "3Rs" of waste management (reduce, reuse, recycle).

In fiscal 2013, the volume of waste generated was 6,085 tons, a decrease of approximately 30% from the previous fiscal year. This decrease was primarily attributable to the decline in waste generation due to the temporary suspension of production at the Oita plant. Along with this decrease, we recorded a corresponding decrease in the volume of waste recycled, which, at 4,839 tons, was approximately 31% lower than the previous fiscal year. The companywide final landfill waste volume increased approximately 74% over the previous fiscal year to 25.2 tons. Nevertheless the companywide final waste disposal rate (ratio of volume of final landfill waste to volume of waste generated) was approximately 0.4% in fiscal 2013, meeting our companywide objective of final landfill industrial waste of less than 1%, as we did in the previous

At our plants and research laboratories, we are pursuing zero emissions, which we have defined as a volume of final landfill industrial waste that is less than 1% of waste generated. In fiscal 2013, four of our plants and one research laboratory achieved zero emissions, while one research laboratory did not (final landfill industrial waste was 1.6%). The main reason for the failure to achieve zero emissions was an increase in unrecyclable waste due in part to the reorganization of the Osaka research center.

Throughout the company, we will continue to actively pursue thorough waste separation and consignment to waste recyclers, and strive to further reduce landfill waste.





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# Financials

#### **Overview**

Financial Section

In the pharmaceutical industry, the development cost continues to increase while the level of developing new medicines is becoming higher and higher. Moreover, generic medicines are used more than ever on the back of the global hold down of medical costs. Facing the continued severe business environments where the approval reviews are getting strict, new business domains are actively exploited as shown by practical realization of regenerative medical techniques.

Under such conditions, the Sumitomo Dainippon Pharma Group positioned four major products as strategic products in the domestic market, which are AIMIX® and AVAPRO®, therapeutic agents for hypertension, LONASEN®, an atypical antipsychotic, and TRERIEF®, a therapeutic agent for Parkinson's disease for further sales expansion, focusing on information providing activities for the purpose of maximizing the sales of METGLUCO®, a biguanide oral hypoglycemic, and other products.

In the overseas markets, Sunovion, one of our subsidiary companies in the US, invested its management resources and developed business activities for LATUDA®, an atypical anti-psychotic which was approved in June last year as an additional indication of Bipolar depression. This March, Takeda Pharmaceutical Company Limited, one of our partners, was granted the marketing authorization for LATUDA®, while the Company was granted the marketing authorization in Australia.

Sunovion obtained the approval in the US for APTIOM®, an antiepileptic drug in November last year.

For the launch in the US market of a therapeutic agent for solid cancer BBI608 being developed by Boston Biomedical, Inc., the Sumitomo Dainippon Pharma Group established Boston Biomedical Pharma, Inc. in October last year as a distributor in the US of anti-cancer drugs.

#### **Results of Operations**

#### **Net Sales**

Consolidated net sales ended up with ¥387.7 billion (an 11.5 % increase from the previous fiscal year), overcoming the fall in revenue in the domestic market coming from a decrease in sales of GASMOTIN®, a gastroprokinetic due to the expiration of the patent duration, resulted from a drastic sales increase in the US market partially contributed by the boost in sales of LATUDA® and the weakened yen in spite of a decrease in sales of XOPENEX®, a short-acting beta-agonist due to the expiration of the exclusivity.

#### **Cost of Sales and Gross Profit**

Cost of sales increased ¥2.4 billion, or 2.4%, year on year to ¥104.1 billion, and the cost of sales ratio decreased 2.4 % to 26.8%. As a result, gross profit increased ¥37.6 billion, or 15.3%, to ¥283.6 billion.

#### **Selling, General and Administrative Expenses**

The selling, general and administrative expenses increased, influenced by the weakened yen in spite of our continued efforts for a cost reduction. Among these expenses, research and development costs increased ¥10.0 billion, or 16.6%, to ¥69.8 billion. Excluding research and development costs, SG&A expenses increased ¥10.5 billion, or 6.5%, overall to ¥171.6 billion due to factors such as increased advertising expenses.

#### **Operating Income**

As a result of the large increase in net sales, the operating income was ¥42.1 billion (a 68.3% increase from the previous fiscal year).

#### Other Income (Expenses) and Net Income

In other income, we recorded a gain on sales of investment securities and a fair value adjustment of contingent consideration in the United States. In other expenses, we recorded an impairment loss and business structure improvement costs. As a result, net income for fiscal 2013 increased ¥10.0 billion, or 99.7%, year on year to ¥20.1 billion.

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### Management's Discussion and Analysis

**Analysis of Financial Position** 

Analysis of Assets, Liabilities, Net Assets and Cash Flows and Summary of Assets, Liabilities and Net Assets

#### **Total Assets**

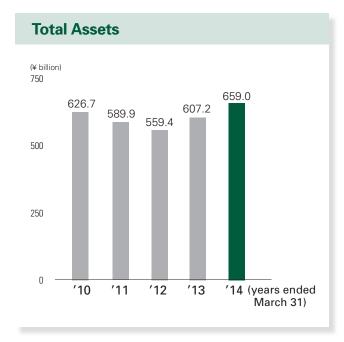
Total assets as of March 31, 2014 amounted to ¥659.0 billion, an increase of ¥51.8 billion from the end of the previous fiscal year. This reflected the significant effect of the yen's depreciation on overseas subsidiaries' cash and time deposits as well as their goodwill, trade accounts and other intangible assets. In addition, property, plant and equipment increased due to the construction of the New Chemistry Research Building in Osaka Research Center.

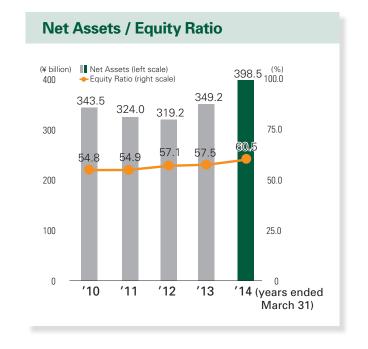
#### **Total Liabilities**

Total liabilities as of March 31, 2014 were ¥260.5 billion, an increase of ¥2.5 billion from a year earlier. Despite the repayment of long-term debt and the partial redemption of straight corporate bonds, the increase was primarily due to a rise in accrued expenses in the United States and a rise in income taxes payable attributable to increased taxable earnings in Japan.

#### **Net Assets**

Net assets as of March 31, 2014 were ¥398.5 billion, an increase of ¥49.3 billion from a year earlier, reflecting an increase in retained earnings and an increase in foreign currency translation adjustments due to the depreciation of the yen. The equity ratio (the ratio of net assets to total assets) was 60.5% as of March 31, 2014.





#### **Cash Flows**

#### **Net Cash Provided by Operating Activities**

Net cash provided by operating activities was ¥49.9 billion, ¥29 million higher than in the previous fiscal year. The primary factor was an increase in income before income taxes and minority interests.

#### **Net Cash Used in Investing Activities**

Net cash used in investing activities was ¥26.2 billion, compared with ¥55.0 billion for fiscal 2012. The primary factors were the disbursement of a large amount of funds in connection with the purchase of investments in subsidiaries resulting from changes in the scope of consolidation in the previous fiscal year. In addition, there were outflows arising from purchases of property, plant and equipment in connection with the establishment of the New Chemistry Research Building at Osaka Research Center.

#### **Net Cash Used in Financing Activities**

Net cash used in financing activities was ¥27.2 billion, compared with ¥20.2 billion for fiscal 2012. Primary factors included the partial redemption of straight corporate bonds in addition to the repayment of debt and dividends paid.

#### **Cash and Cash Equivalents**

As a result of the above, cash and cash equivalents as of March 31, 2014 increased ¥2.5 billion from a year earlier to ¥73.9 billion. Additional items contributing to this figure included the negative ¥2.0 billion impact of a change in the fiscal year-end at overseas subsidiaries and the positive ¥8.0 billion impact of the effect of exchange rate changes on cash and cash equivalents.

#### **Major Cash Flow Indicators**

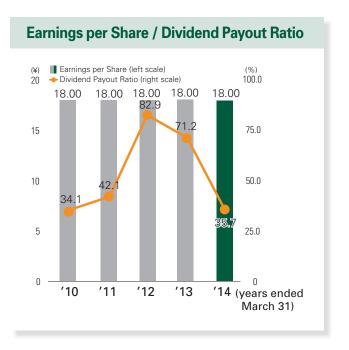
	2010/3	2011/3	2012/3	2013/3	2014/3
Equity Ratio (%)	54.8%	54.9%	57.1%	57.5%	60.5%
(Based on Market Value) (%)	54.3%	52.2%	62.3%	114.8%	98.9%
Cash Flow to Interest-bearing Debt (%)	431.2%	218.4%	205.4%	195.9%	172.9%
Interest Coverage Ratio	42.7	37.4	57.9	56.9	60.2

#### **Dividend Policy and Dividends**

The Company views the regular and consistent return of profits to shareholders as one of its most important management policies.

The Company's basic policy is to pay dividends from retained earnings twice a year, with the first payment being an interim dividend and second a year-end dividend. The Board of Directors and the general meeting of shareholders determine the interim and year-end dividends, respectively.

We believe that it is important to allocate profits to our shareholders in a way that accurately reflects our business performance. When determining the amount of dividends to be distributed, we take a comprehensive view that includes consideration of the importance of raising corporate value through aggressive investment in future growth, solidifying our operating base and enhancing our financial position. We also take into consideration the importance of paying stable dividends.



#### **Business Risks**

Below is a discussion of the most significant risks that could negatively impact the operating results and financial position of the Sumitomo Dainippon Pharma Group.

Forward-looking statements in the discussion of risks below reflect the judgment of the Group as of March 31, 2014.

#### (i) Risk relating to research and development of new products

The Group works to research and develop highly original and globally viable products. The Group strives to maintain an extensive product pipeline and to bring products to market as early as possible. Nevertheless, the Group can envision scenarios in which not all products under development will progress smoothly to eventual sale, as well as instances in which the development of certain products must be halted. Depending on the nature of the product under development, such cases could have a significant and negative impact on the Group's operating results and financial position.

#### (ii) Problems concerning adverse events

The Group conducts rigorous safety testing of its pharmaceutical products at different stages of development, with products receiving approval only after rigorous screening by the competent authorities in all the countries.

These efforts notwithstanding, previously unreported adverse events are sometimes discovered only after a drug has already been marketed. The appearance of such unexpected adverse events once a product has been sold could have a significant and negative impact on the Group's operating results and financial position.

#### (iii) Healthcare system reforms

Japan's low birthrate and the rapid rise in the country's elderly population are the prime factors causing the financial state of Japan's healthcare insurance system to deteriorate. In this climate, measures continue to emerge aimed at curbing healthcare costs, and how to best reform the country's healthcare system continues to be debated. The direction that any healthcare system reforms might take, including mandated NHI price revisions, could ultimately have a significant and negative impact on the Group's operating results and financial position. In addition, pharmaceutical products are subject to various kinds of regulations in foreign countries and, therefore, have a possibility that they might be significantly affected depending on the way administrative measures are implemented.

#### (iv) Risk relating to the sale of products

The Group can envision scenarios in which sales of its pharmaceutical products may decrease due to competition with the products of the same area of other manufacturers or the launch of generic products following the expiration of a patent period or otherwise. Such cases could have a significant and negative impact on the Group's operating results and financial position.

#### (v) Risk relating to intellectual property rights

The Group utilizes a wide range of intellectual property during the course of its R&D activities, including both property owned by the Group and property that the Group lawfully uses with the authorization of the property's owner. Nevertheless, the Group recognizes the possibility, no matter how slight, that some use might be deemed an infringement of a third party's intellectual property rights. Consequently, legal disputes pertaining to intellectual property rights could arise and have a significant and negative impact on the Group's operating results and financial position.

#### (vi) Termination of partnerships

The Group enters into a variety of partnerships with other companies for the sale of purchased goods, the establishment of joint ventures, co-promotion, the licensing in and out of products under development, collaborative research and other purposes. The termination, for whatever reason, of such partnerships could have a significant and negative impact on the Group's operating results and financial position.

#### (vii) Prerequisites for primary business activities

The Group's core business is the ethical pharmaceutical products business. Accordingly, the Group requires licenses and other certifications to engage in R&D and the manufacture and sale of drugs pursuant to Japan's Pharmaceutical Affairs Law and other laws and regulations related to pharmaceuticals. The Company has obtained licenses and other certifications, including Type 1 and Type 2 Pharmaceuticals Manufacturing and Sales Business licenses (both valid for five years). In addition, in order to engage in the ethical pharmaceutical products

business in overseas countries, the Group also has obtained licenses as needed under laws and regulations related to pharmaceuticals of those countries. These licenses and other certifications will cease to be valid unless procedures as stipulated by the applicable laws and regulations are gone through. These laws and regulations also stipulate that these licenses and certifications may be revoked and/or that the Group may be ordered to suspend part of or all of its operations for a fixed period of time or be subject to other measures in the event that the Group violates these laws and regulations. The Group currently has no knowledge of any facts that would warrant the revocation of its licenses or other certifications.

However, an order to revoke the Group's licenses or other certifications could have a significant and negative impact on the Group's operating results and financial position.

#### (viii) Risk relating to litigation

There is a possibility that a suit may be brought to court in terms of an adverse effect of a pharmaceutical product, product liability, labor issues, fair trade, etc., relating to the business activities of the Group. Depending on the development thereof, such cases could have a significant and negative impact on the Group's operating results and financial position.

#### (ix) Risk relating to closedown or shutdown of a plant

The Group can envision scenarios in which the Group's plant is closed down or shut down due to technical problems, stoppage of supply of raw materials, fire, earthquake, or any other disaster where the supply of products is delayed or halted. Such cases could have a significant and negative impact on the Group's operating results and financial position.

#### (x) Impact of financial market situation and foreign exchange fluctuations

A sluggish equity market will give rise to a loss on valuation or sale of shares held, and the interest rate trend may increase interest expenses on borrowings, etc., and the deterioration of financial market situation will cause the retirement benefit obligations to increase. All these factors could have a significant and negative impact on the Group's operating results and financial position. Furthermore, foreign exchange fluctuations may have a material impact on importing and exporting transactions and the conversion of operating results of consolidated subsidiaries into yen.

#### (xi) Impact of impairment of fixed assets

The Group owns various types of tangible and intangible fixed assets, such as business assets and goodwill. In the future, in the event of substantial deterioration of operating results or reduction in values, the need to treat the impairment will arise, which could have a significant and negative impact on the Groups operating results and financial position.

#### (xii) Transactions with the parent company

The Company and its parent company, Sumitomo Chemical Co., Ltd., have concluded agreements for the leasing of land for the Osaka Research Laboratories, Ehime Plant and Oita Plant, as well as for the purchase of raw materials used in the production of active pharmaceutical ingredients at these sites and other locations. These agreements involve prices that are determined based on discussions between the two parties with reference to general market prices. These agreements are customarily renewed every year. The Company also accepts employees on loan from the parent company. Furthermore, during the year we also made short-term loans to our parent company to raise capital efficiency.

The Company's policy is to continue these transactions and other ties with the parent company. However, changes in these agreements, including changes in the transaction terms specified therein, could have a significant and negative impact on the Group's operating results and financial position.

#### (xiii) Risk relating to overseas operations

The Group conducts global business activity mainly in the regions of North America and China. The risks such as change of local restrictions, worsening of diplomatic relations and political uncertainties are inherent in these activities. In the event the Group faces such risks, it could have a significant and negative impact on the Group's operating results and financial position.

The Group also faces risks other than those discussed

## Consolidated Balance Sheets

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries March 31, 2014 and 2013

	Millions o	Thousands of U.S. dollars (Note 1)	
ASSETS	2014	2013	2014
CURRENT ASSETS:			
Cash and time deposits (Notes 3 and 5)	¥ 22,746	¥ 18,753	\$ 220,835
Marketable securities (Notes 3, 5 and 6)	81,953	86,463	795,660
Receivables:			
Trade notes (Note 5)	2,188	2,897	21,243
Trade accounts (Note 5)	110,299	95,093	1,070,864
Due from parent company, unconsolidated subsidiaries			
and affiliates (Notes 5 and 13)	41,803	34,574	405,854
Allowance for doubtful receivables	(120)	(105)	(1,165)
Total	154,170	132,459	1,496,796
Inventories (Note 4)	59,143	62,689	574,204
Deferred tax assets (Note 9)	37,282	30,098	361,961
Other current assets	4,318	2,977	41,923
Total current assets	359,612	333,439	3,491,379

#### PROPERTY, PLANT AND EQUIPMENT:

Land	10,339	10,277	100,379
Buildings and structures	100,804	92,586	978,679
Machinery and equipment	109,750	105,353	1,065,534
Construction in progress	3,081	5,799	29,913
Total	223,974	214,015	2,174,505
Accumulated depreciation	(151,285)	(144,153)	(1,468,787)
Net property, plant and equipment	72,689	69,862	705,718

#### **INVESTMENTS AND OTHER ASSETS:**

Total investments and other assets TOTAL	226,732 ¥ 659,033	203,918 ¥ 607,219	\$ 6,398,379
Other assets	5,824	4,047	56,544
Deferred tax assets (Note 9)	8,602	7,570	83,515
Asset for retirement benefit (Note 10)	4,686	4,952	45,495
Other intangible assets	20,055	24,352	194,709
In-process research and development	56,072	50,664	544,388
Goodwill	80,669	71,294	783,194
Investment securities (Notes 5 and 6)	49,626	40,059	481,806
Investment in unconsolidated subsidiaries and affiliates	1,198	980	11,631

	A 4717	Thousands of U.S. dollars		
LIADILITIES AND NET ASSETS	Millions o	2013	(Note 1) 2014	
LIABILITIES AND NET ASSETS  CURRENT LIABILITIES:	2014	2013	2014	
Current portion of long-term debt (Notes 5 and 8)	¥ 10,000	¥ 20,000	\$ 97,087	
Payables:	+ 10,000	¥ 20,000	\$ 37,007	
Trade notes (Note 5)	74	176	718	
Trade accounts (Notes 5, 6 and 7)	42,072	44,518	408,466	
Due to parent company, unconsolidated subsidiaries	42,072	44,510	400,400	
and affiliates (Notes 5 and 13)	1,738	2,118	16,874	
Total	43,884	46,812	426,058	
Income taxes payable (Note 5)	10,524	2,115	102,175	
	53,499	44,404		
Accrued expenses  Other current liabilities	13,301	•	519,408	
Total current liabilities		11,500	129,136	
Total current habilities	131,208	124,831	1,273,864	
LONG-TERM LIABILITIES:				
Long-term debt (Notes 5 and 8)	85,000	95,000	825,243	
Liability for retirement benefits (Note 10)	13,892	11,030	134,874	
Deferred tax liabilities (Note 9)	15,705	14,494	152,476	
Other liabilities (Note 8)	14,688	12,616	142,602	
Total long-term liabilities	129,285	133,140	1,255,195	
COMMITMENTS AND CONTINGENT LIABILITIES (Notes 14 and 18):  NET ASSETS:				
Shareholders' equity (Note 11)				
Common stock: authorized — 1,500,000,000 shares in the years ended March 31, 2014 and 2013; issued — 397,900,154 shares in the	22.400	22.400	247 470	
years ended March 31, 2014 and 2013	22,400	22,400	217,476	
Capital surplus	15,860	15,860	153,981	
Retained earnings	318,862	308,557	3,095,747	
Treasury stock, at cost: 593,962 shares in the year ended	(CE7)	(CE1)	(C 270)	
March 31, 2014 and 590,246 shares in the year ended March 31, 2013	(657)	(651)	(6,379)	
Total shareholders' equity	356,465	346,166	3,460,825	
Accumulated other comprehensive income (loss)	17 240	14 101	167.456	
Unrealized gains (losses) on available-for-sale securities	17,248	14,121	167,456	
Deferred gains (losses) on hedges	(1)	(11,000)	(10)	
Foreign currency translation adjustments	26,792	(11,039)	260,117	
Remeasurements of defined benefit plans	(1,964)		(19,068)	
Total accumulated other comprehensive income (loss)	42,075	3,082	408,495	
Total net assets	398,540	349,248	3,869,320	
TOTAL	¥659,033	¥607,219	\$6,398,379	

See Notes to Consolidated Financial Statements.

### Consolidated Statements of Income

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2014 and 2013

	Millions o	Thousands of U.S. dollars (Note 1)	
	2014	2013	2014
NET SALES (Notes 12 and 13)	¥387,693	¥ 347,724	\$3,764,010
COST OF SALES (Notes 12 and 13)	104,100	101,686	1,010,680
Gross profit	283,593	246,038	2,753,330
SELLING, GENERAL AND ADMINISTRATIVE EXPENSES (Notes 2 and 13)	241,450	220,994	2,344,175
Operating income	42,143	25,044	409,155
OTHER INCOME (EXPENSES):			
Interest and dividend income (Note 13)	1,100	1,091	10,680
Interest expense	(1,007)	(1,072)	(9,777)
Fair value adjustment of contingent consideration	1,284	_	12,466
Impairment loss (Notes 2 (i) and 16)	(7,638)	(417)	(74,155)
Gain on sales of investment securities (Note 6)	2,773	_	26,922
Restructuring (Note 17)	(2,342)	(4,841)	(22,738)
Loss on litigation	_	(1,090)	_
Other — net	(1,604)	(557)	(15,572)
Other income (expenses) — net	(7,434)	(6,886)	(72,174)
INCOME BEFORE INCOME TAXES	34,709	18,158	336,981
INCOME TAXES (Note 9):			
Current	14,784	6,788	143,534
Deferred	(136)	1,326	(1,320)
Total income taxes	14,648	8,114	142,214
NET INCOME	¥ 20,061	¥ 10,044	\$194,767
	Yen		U.S. dollars (Note 1)
PER SHARE OF COMMON STOCK:			
Basic net income	¥ 50.49	¥ 25.28	\$0.49
Cash dividends applicable to the year	18.00	18.00	0.17

See Notes to Consolidated Financial Statements.

## Consolidated Statements of Comprehensive Income (Loss)

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries

Years Ended March 31, 2014 and 2013	Millions of	Thousands of U.S. dollars (Note 1)	
	2014	2013	2014
NET INCOME	¥20,061	¥10,044	\$194,767
OTHER COMPREHENSIVE INCOME (LOSS):			
Unrealized gains (losses) on available-for-sale securities (Note 18)	2,854	6,105	27,709
Deferred gains (losses) on hedges (Note 18)	(1)	_	(10)
Foreign currency translation adjustments (Note 18)	22,251	21,025	216,029
Total other comprehensive income (loss) (Note 18)	25,104	27,130	243,728
COMPREHENSIVE INCOME (LOSS)	45,165	37,174	438,495
COMPREHENSIVE INCOME (LOSS) ATTRIBUTABLE TO:			
Owners of the parent	45,165	37,174	438,495
Minority interests	_		_

See Notes to Consolidated Financial Statements.

## Consolidated Statements of Changes in Net Assets Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries

Years Ended March 31, 2014 and 2013

	Thousands	of shares						Millions of ye	en				
		Shareholders' equity						Accumulated other comprehensive income (loss)					
	Issued number of shares of common stock	Number of treasury stocks	Common stock	Capital surplus	Retained earnings	Treasury stock	Total share- holders' equity	Unrealized gains (loss- es) on avail- able-for-sale securities	Deferred gains (losses) on hedges	Foreign currency translation adjust- ments	Remeasure- ments of defined benefit plans	Total accumu- lated other comprehen- sive adjust- ments income (loss)	Total net assets
BALANCE, APRIL 1, 2012	397,900	(589)	¥22,400	¥15,860	¥305,664	¥(649)	¥343,275	¥ 8,016	¥—	¥(32,064)	¥—	¥(24,048)	¥319,227
Cash dividends, ¥18.00 per share					(7,151)		(7,151)						(7,151)
Net income					10,044		10,044						10,044
Purchases of treasury stock		(1)				(2)	(2)						(2)
Sales of treasury stock		0			(0)	0	0						0
Net change in items other than shareholders' equity								6,105	_	21,025	_	27,130	27,130
BALANCE, MARCH 31, 2013	397,900	(590)	¥22,400	¥15,860	¥308,557	¥(651)	¥346,166	¥14,121	¥—	¥(11,039)	¥—	¥ 3,082	¥349,248
BALANCE, APRIL 1, 2013	397,900	(590)	¥22,400	¥15,860	¥308,557	¥(651)	¥346,166	¥14,121	¥—	¥(11,039)	¥—	¥ 3,082	¥349,248
Cash dividends, ¥18.00 per share					(7,152)		(7,152)						(7,152)
Net income					20,061		20,061						20,061
Purchases of treasury stock		(4)				(6)	(6)						(6)
Sales of treasury stock		0		0		0	0						0
Decrease due to change in fiscal period of consolidated subsidiaries (Note 2(a))					(2,604)		(2,604)						(2,604)
Net change in items other than shareholders' equity								3,127	(1)	37,831	(1,964)	38,993	38,993
BALANCE, MARCH 31, 2014	397,900	(594)	¥22,400	¥15,860	¥318,862	¥(657)	¥356,465	¥17,248	¥(1)	¥ 26,792	¥(1,964)	¥ 42,075	¥398,540

					Thousan	ds of U.S. dolla	ars (Note 1)				
		Sha	areholders' eq	uity				Accumula			
	Common stock	Capital surplus	Retained earnings	Treasury stock	Total share- holders' equity	Unrealized gains (loss- es) on avail- able-for-sale securities	Deferred gains (losses) on hedges	Foreign currency translation adjust- ments	Remeasure- ments of defined benefit plans	Total accumu- lated other comprehen- sive adjust- ments income (loss)	Total net assets
BALANCE, APRIL 1, 2013	\$217,476	\$153,981	\$2,995,699	\$(6,321)	\$3,360,835	\$137,097	\$—	\$(107,175)	\$—	\$ 29,922	\$3,390,757
Cash dividends, U.S.\$0.17 per share			(69,437)		(69,437)						(69,437)
Net income			194,767		194,767						194,767
Purchases of treasury stock				(58)	(58)						(58)
Sales of treasury stock		0		0	0						0
Decrease due to change in fiscal period of consolidated subsidiaries (Note 2(a))			(25,282)		(25,282)						(25,282)
Net change in items other than shareholders' equity	-					30,359	(10)	367,292	(19,068)	378,573	378,573
BALANCE, MARCH 31, 2014	\$217,476	\$153,981	\$3,095,747	\$(6,379)	\$3,460,825	\$167,456	\$(10)	\$ 260,117	\$(19,068)	\$408,495	\$3,869,320

### Consolidated Statements of Cash Flows

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2014 and 2013

	Millions of	· yen	Thousands of U.S. dollars (Note 1)	
_	2014	2013	2014	
OPERATING ACTIVITIES:				
Income before income taxes	¥ 34,709	¥ 18,158	\$ 336,981	
Adjustments for:			7 000,001	
Depreciation and amortization	21,723	31,312	210,903	
Impairment loss	7,638	417	74,155	
Amortization of goodwill	5,054	3,773	49,068	
Increase (decrease) in liability for retirement benefit	(778)	(228)	(7,553)	
Interest and dividend income	(1,100)	(1,091)	(10,680)	
Interest expense	1,007	1,072	9,777	
Restructuring	2,342	4,841	22,738	
Changes in assets and liabilities:	2,342	4,041	22,730	
Increase (decrease) in receivables	(15,113)	6,806	(146,728)	
Decrease (increase) in inventories	4,919	(3,732)		
Increase (decrease) in payables			47,757	
	(5,773)	(4,877)	(56,049)	
Other — net	6,875 61,503	6,837	66,748	
Subtotal		63,288	597,117	
Interest and dividend received	1,309	1,442	12,708	
Interest paid	(963)	(1,074)	(9,350)	
Payment for restructuring	(4,874)	(3,627)	(47,320)	
Income taxes paid	(7,032)	(10,115)	(68,272)	
Net cash provided by operating activities	49,943	49,914	484,883	
INVESTING ACTIVITIES:				
Net decrease in time deposits	6,170	(5,179)	59,903	
Purchases of property, plant and equipment	(10,332)	(7,818)	(100,311)	
Purchases of intangible assets	(11,225)	(2,209)	(108,981)	
Proceeds from sales of property, plant and equipment	51	18	495	
Net decrease (increase) in marketable securities	4,650	(4,926)	45,146	
Proceeds from sales of investment securities	2,809	3	27,272	
Purchases of investment securities	(9,144)	(2,344)	(88,777)	
Proceeds from redemption of investment securities	94	265	913	
Purchase of investments in subsidiaries	(2,826)		(27,437)	
Purchase of investments in subsidiaries resulting in change in scope of consolidation (Note 3)	(2,020)	(24,852)	(27,437)	
Payment of loan receivable	(6,407)	(7,981)	(62,204)	
Other — net	(49)	3	(475)	
Net cash used in investing activities	(26,209)	(55,020)	(254,456)	
Net cash used in investing activities	(20,203)	(55,020)	(234,430)	
FINANCING ACTIVITIES:				
Repayment of long-term borrowings	(10,000)	(13,000)	(97,087)	
Redemption of bonds	(10,000)	_	(97,087)	
Increase in treasury stock	(6)	(2)	(58)	
Dividends paid	(7,152)	(7,151)	(69,437)	
Other — net	(6)	(68)	(59)	
Net cash used in financing activities	(27,164)	(20,221)	(263,728)	
EFFECT OF EXCHANGE RATE CHANGES ON CASH AND CASH EQUIVALENTS	7,951	4,582	77,194	
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	4,521	(20,745)	(43,893)	
CASH AND CASH EQUIVALENTS, BEGINNING OF YEAR	71,434	92,179	693,534	
INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS RESULTING				
FROM CHANGE IN THE FISCAL PERIOD OF SUBSIDIARIES (Note 2(a))	(2,036)		(19,767)	
CASH AND CASH EQUIVALENTS, END OF YEAR (Note 3)	¥ 73,919	¥ 71,434	\$ 717,660	

See Notes to Consolidated Financial Statements

### Notes to Consolidated Financial Statements

Sumitomo Dainippon Pharma Co., Ltd. and Consolidated Subsidiaries Years Ended March 31, 2014 and 2013

1. BASIS OF **PRESENTING CONSOLIDATED FINANCIAL STATEMENTS** 

The accompanying consolidated financial statements have been prepared in accordance with the provisions set forth in the Japanese Financial Instruments and Exchange Law and its related accounting regulations and in conformity with accounting principles generally accepted in Japan, which are different in certain respects as to the application and disclosure requirements of the International Financial Reporting Standards.

The accounts of consolidated subsidiaries in the U.S. are prepared in accordance with U.S. generally accepted accounting principles, with adjustments for the specified five items as applicable according to Practical Issues Task Force No. 18 "Practical Solution on Unification of Accounting Policies Applied to Foreign Subsidiaries for Consolidated Financial Statements."

In preparing these consolidated financial statements, certain reclassifications and rearrangements have been made to the consolidated financial statements issued domestically in order to present them in a form which is more familiar to readers outside Japan.

The consolidated financial statements are stated in Japanese yen, the currency of the country in which Sumitomo Dainippon Pharma Co., Ltd. (the "Company") is incorporated and operates. The translations of Japanese yen amounts into U.S. dollar amounts are included solely for the convenience of readers outside Japan and have been translated at the rate of ¥103 to U.S.\$1.00, the approximate rate of exchange on March 31, 2014. These translations should not be construed as representations that the Japanese yen amounts could be converted into U.S. dollars at that or any other rate.

The Company and its consolidated subsidiaries (together, the "Group") have made certain reclassifications in the 2013 consolidated financial statements to conform to the classifications applied in 2014. These reclassifications have had no effect on the previously reported net income or retained earnings.

2. SUMMARY OF **SIGNIFICANT ACCOUNTING POLICIES** 

#### a. Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its 15 significant subsidiaries. Under the control or influence concept, those companies in which the Company directly or indirectly is able to exercise control over operations are consolidated.

Investments in the unconsolidated subsidiaries and all affiliates are stated at cost. If the equity method of accounting had been applied to the investments in these companies, the effect on the accompanying consolidated financial statements would not have been material.

Material intercompany balances, transactions and unrealized profit included in assets have been eliminated in consolidation.

There are 12 consolidated overseas subsidiaries. Among the consolidated subsidiaries, Boston Biomedical, Inc. ("BBI") and Sumitomo Pharmaceuticals (Suzhou) Co., Ltd., have a fiscal accounting year-end date of December 31.

In the preparation of the consolidated financial statements, the Company used BBI's financial statements as of fiscal accounting year-end date with necessary adjustments for material transactions arising in the period between its fiscal accounting year-end date and the balance sheet date.

In the year ended March 31, 2014, to unify the fiscal periods of overseas consolidated subsidiaries for the purpose of more appropriate disclosures, Sunovion Pharmaceuticals Inc. and its 9 consolidated subsidiaries changed their fiscal year-end from December 31 to March 31, and Sumitomo Pharmaceuticals (Suzhou) Co., Ltd., prepared its financial statements based on a provisional statements of accounts at March 31 for consolidation.

The Company included the above mentioned subsidiaries' operating results for the twelvemonths period from April 1, 2013 to March 31, 2014 in the consolidated statement of income for the year ended March 31, 2014, and included their operating results for the three-month

period from January 1, 2013 to March 31, 2013 in the consolidated statement of changes in net assets for the year ended March 31, 2014, by a charge to retained earnings as "Decrease due to change in fiscal period of consolidated subsidiaries. The company included decrease of cash and cash equivalents for the three-months period in the consolidated statement of cash flows for the year ended March 31, 2014 as "Increase (decrease) in cash and cash equivalents resulting from change in the fiscal period of subsidiaries".

#### b. Cash Equivalents

Cash equivalents are short-term investments that are readily convertible into cash and have no significant risk of change in value. Cash equivalents include time deposits and short term, highly liquid investments, all of which mature within three months from the date of acquisition.

#### c. Marketable and Investment Securities

All marketable and investment securities are available-for-sale securities, which are not classified as either trading securities or held-to-maturity debt securities. Available-for-sale securities are reported at fair value with unrealized gains and losses net of applicable taxes shown as a separate component of net assets. Non-marketable available-for-sale securities are stated at cost, determined by the moving average method. If the fair value of investment securities declines to below cost and the decline is material and other than temporary, the carrying value is reduced to net realizable value by a charge to income.

#### d. Inventories

Inventories are stated at the lower of weighted-average cost or net realizable value. Certain overseas consolidated subsidiaries use the FIFO (first-in, first-out) costing method for which inventories are stated at the lower of cost or net realizable value.

#### e. Property, Plant and Equipment (other than leased assets)

Property, plant and equipment are stated at cost less accumulated depreciation and accumulated impairment losses. Depreciation of all tangible fixed assets is computed using the straight-line method over the estimated useful life of the asset. Ranges of useful lives used in the computation of depreciation are as follows:

Buildings and structures 3–60 years Machinery and equipment 2-17 years

#### f. Intangible Assets

Intangible assets are stated at cost less accumulated amortization, which is computed using the straight-line method over the estimated useful lives from the date they are available for use.

Goodwill represents the excess of the purchase price over the fair value of the net assets of businesses acquired and is amortized using the straight-line method over 20 years.

#### h. Leases

Finance leases are to be capitalized and depreciated using the straight-line method over the lease period.

#### i. Impairment of Long-Lived Assets

Long-lived assets presented as property, plant and equipment, and intangible assets on the consolidated balance sheets are carried at cost less depreciation or amortization and are reviewed for impairment whenever events or changes in circumstances indicate that

the carrying amount of an asset or asset group may not be recoverable. An impairment loss is recognized if the carrying amount exceeds the sum of the undiscounted future cash flows expected to result from the continued use and eventual disposition of the asset or asset group. The impairment loss is measured as the amount by which the carrying amount exceeds its recoverable amount. The recoverable amount of an asset is the greater of its discounted cash flows and its fair value less cost to sell.

#### i. Retirement and Severance Benefits

Upon retirement or termination of employment, employees are normally entitled to lump-sum and/or annuity payments based on their rate of payment at the time of retirement or termination and length of service.

The Group has a lump-sum plan, a defined benefit pension plan and a defined contribution plan for employees. The asset and liability for retirement benefit is recognized based on projected benefit obligations and the fair value of plan assets at the balance sheet date.

The company and certain consolidated subsidiaries have retirement benefits plans that primarily consists of a lump-sum payment plan, defined benefit plans, and a defined contribution pension program.

The estimated amount of all retirement benefit to be paid at future retirement dates is allocated equally to each service year based on the estimated number of total service years. Past service costs are amortized using the straight-line method over a period of 15 years, which is within the average of the estimated remaining services years commencing with the current period. Actuarial gains and losses are amortized using the straight-line method over a period of 15 years, which is within the average of the estimated remaining service years commencing in the following period. Some domestic consolidated subsidiaries use the simplified method for the calculation of projected benefit obligation.

#### k. Research and Development Costs

Research and development costs are charged to income as incurred. Research and development costs included in selling, general and administrative expenses for the years ended March 31, 2014 and 2013 were ¥69,804 million (\$677,709 thousand) and ¥59,844 million, respectively.

#### I. Income Taxes

The asset and liability approach is used to recognize deferred tax assets and liabilities for the expected future tax consequences of temporary differences between the carrying amounts and the tax bases of assets and liabilities. Deferred tax assets and liabilities are measured at the tax rates that are expected to be applied to temporary differences when they reverse, based on the laws that have been enacted by the balance sheet date.

#### m. Foreign Currency Translation

All short-term and long-term monetary receivables and payables denominated in foreign currencies are translated into Japanese yen at the exchange rates prevailing at the balance sheet date. The foreign exchange gains and losses from translation are recognized in the consolidated statements of income.

Financial statements of overseas subsidiaries are translated into Japanese yen at the yearend rate for all assets and liabilities and at weighted average rates for income and expense accounts. Differences arising from such translation are shown as "Foreign currency translation adjustments" in a component of net assets.

#### n. Derivative Financial Instruments

Foreign exchange contracts are utilized to hedge the exposure risk arising from fluctuations in

foreign exchange rates. Derivative financial instruments are stated at fair value and accounted for using deferred hedge accounting. Recognition of gain or loss resulting from a change in fair value of a derivative financial instrument is deferred until the loss or gain on the related hedged item is recognized if the derivative financial instrument is used as a hedge and meets the hedging criteria. Foreign exchange contracts that the certain hedging criteria are accounted for under the allocation method. The allocation method requires recognized foreign currency receivables and payables to be translated using the corresponding foreign exchange contract rates. The effectiveness of hedges has been evaluated by comparing the accumulated changes in market value of hedged items with the accumulated changes in market value of hedging instruments. With regard to foreign exchange forward contracts, the effectiveness of such contracts has not been evaluated as important conditions for hedged items and hedging instruments are the same. The Group has established a hedging policy which includes policies and procedures for risk assessment and for the approval, reporting and monitoring of derivatives transactions. The Group does not hold or issue any derivative financial instruments for speculative trading purposes.

#### o. Per Share Information

Basic net income per share is computed by dividing net income available to common shareholders by the weighted average number of common shares outstanding for the period. The number of shares used in the calculation of net income per share was 397,308 thousand and 397,311 thousand for the years ended March 31, 2014 and 2013, respectively.

Cash dividends per share presented in the accompanying consolidated statements of income are dividends applicable to the respective years including dividends to be paid after the end of the year.

#### p. Use of Estimates

The preparation of the consolidated financial statements in conformity with accounting principles generally accepted in Japan requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities. Actual results could differ from those estimates.

## q. Changes in Accounting Polices

Effective from the year ended March 31, 2014, the Company has applied the "Accounting Standard for Retirement Benefits" (ASBJ Statement No. 26, May 17, 2012) and the "Guidance for the Accounting Standard for Retirement Benefits" (ASBJ Guidance No. 25, May 17, 2012) (excluding, however, the provisions found in the body text of Paragraph 35 of the Accounting Standard for Retirement Benefits and Paragraph 67 of the Guidance for the Accounting Standard for Retirement Benefits). Under the new standard, the Company revised its method of accounting for retirement benefit obligations, recording the amount deducting the plan assets from these obligations as net defined benefit liability, and accordingly, recording unrecognized actuarial differences and unrecognized past service costs as net defined benefit liability.

With regard to the application of the Accounting Standard for Retirement Benefits, in accordance with the provisions on transitional implementation indicated in Paragraph 37 of the Accounting Standard for Retirement Benefits, the effect of these changes is included in remeasurements of defined benefit plans within accumulated other comprehensive income of net assets as of March 31, 2014.

Consequently, 4,686 million yen of asset for retirement benefits and 13,892 million yen of liability for retirement benefits were posted as of March 31, 2014. In addition, the accumulated other comprehensive income declined by 1,964 million yen.

#### r. Accounting standards that have not been applied yet

Accounting Standard for Retirement Benefits (ASBJ Statement No. 26, May 17, 2012) Guidance on Accounting Standard for Retirement Benefits (ASBJ Guidelines No. 25, May 17, 2012)

#### 1) Summary

Under the amended rule, actuarial gains and losses and past service costs that are yet to be recognized in profit or loss would be recognized within the net assets section, after adjusting for tax effects, and deficit or surplus would be recognized as a liability or asset without any adjustments. For determining the method of attributing expected benefit to periods, the Standard now allows companies to choose either the benefit formula basis or the straight-line basis. The method for determination of discount rate has also been amended.

#### 2) Effective dates

Amendments relating to determination of retirement benefit obligations and current service costs are effective from the beginning of fiscal year ending on or after March 31, 2015.

#### 3) Effect of application of the standard

The Company and its consolidated domestic subsidiaries are currently in the process of determining the effects of these new standards on the consolidated financial statements.

#### s. Reclassifications

Certain reclassifications of the financial statements and accompanying footnotes for the year ended March 2013 have been made to conform the presentation for the year ended March 31, 2014.

## 3. SUPPLEMENTARY **CASH FLOW INFORMATION**

### 1) Cash and cash equivalents

Cash and cash equivalents as at March 31, 2014 and 2013 for purposes of the consolidated statements of cash flows consisted of the following:

	Millions of yen		Thousands of U.S. dollars	
	2014	2013	2014	
Cash and time deposits	¥22,746	¥18,753	\$220,835	
Time deposits with maturities over three months	(447)	(6,152)	(4,340)	
Marketable securities with a maturity of three months or less when purchased	51,620	58,833	501,165	
Cash and cash equivalents	¥73,919	¥71,434	\$717,660	

As at March 31, 2014 and 2013, a time deposit of ¥447 million (\$4,340 thousand) and ¥282 million is pledged as collateral for a letter of credit issued by a bank, respectively.

#### 2) Significant non-cash transactions

As a result of the acquisitions of BBI dated April 24, 2012 and Elevation Pharmaceuticals, Inc. (Current Sunovion Respiratory Development Inc. ("SRD")) dated September 5, 2012, the Company increased assets and liabilities in the amount of ¥52,106 million and ¥26,968 million, respectively. The following table summarizes the estimated fair values of the assets acquired

and liabilities assumed at the end of acquisitions and payments for acquisition of BBI and SRD, net of cash acquired, respectively.

	Millions of yen
Current assets	¥ 417
Fixed assets	48,215
Goodwill	3,474
Current liabilities	(208)
Long-term liabilities	(26,760)
Net assets acquired	25,138
Cash and cash equivalent of BBI and SRD	(286)
Payment for acquisitions	¥ 24,852

#### 4. INVENTORIES

Inventories at March 31, 2014 and 2013 consisted of the following:

	Million	Thousands of U.S. dollars	
	2014	2013	2014
Finished goods and semi-finished goods	¥46,378	¥45,357	\$450,272
Work-in-process	2,409	3,570	23,388
Raw materials and supplies	10,356	13,762	100,544
Total	¥59,143	¥62,689	\$574,204

## 5. FINANCIAL **INSTRUMENTS**

## 1) Policies for using financial instruments

The Group procures funds through bank loans and the issuance of corporate bonds. The fund are required for investment plans and other purposes in order to carry out business inside and outside of Japan. Temporary surplus funds are to be invested only in financial instruments with low risk. Derivative transactions are used only to avoid the risks described below, and speculative transactions are not undertaken.

## 2) Details of financial instruments and risks, policies and systems for risk management In order to reduce customer credit risk exposure of notes and accounts receivable, due dates and amounts outstanding balances are monitored by each customer in accordance with the company's procedures for credit management. In addition, the company periodically monitors the credit standing of major customers.

Marketable securities and investment securities consist primarily of negotiable certificates for deposit and stocks issued by the business partners. Stocks are exposed to risks associated with changes in market prices. The market values of the stocks and the financial condition of the issuers of these stocks are regularly monitored. The company regularly reviews holding status in consideration of relationships with the business partners.

Trade notes and trade accounts payable are all due within one year. Some of these payables consist of notes and accounts payable that are denominated in foreign currencies due to the import of raw materials, and they are exposed to exchange rate fluctuation risk. These risks if significant are hedged using foreign exchange forward contracts.

Loans payable and bonds are primarily for working capital and the last maturity date of the debt is five years from March 31, 2014. A portion of such debt is exposed to interest fluctuation Income taxes payable are mainly due within two months.

Trade accounts payable, loans payable and bonds are exposed to liquidity risks. These risks are managed by preparing cash flow plans on a monthly basis.

Derivative financial instruments of the Group include foreign exchange forward contracts for the purpose of hedging risks of fluctuations in exchange rates of receivables and payables denominated in foreign currencies. With respect to foreign exchange forward contracts, the Finance & Accounting Division formulates an implementation plan for hedging foreign currency risks every six months pursuant to the company's policies in respect of management of foreign currency risks. Upon reporting to the Representative Director and President, transactions are then executed and the related entries posted. The results of derivative transactions are also reported to the Representative Director and President. See "Derivative Financial Instruments" as stated in the above "Summary of Significant Accounting Policies" for information on hedging instruments, hedged items, hedging policy, and the method by which the effectiveness of hedging is evaluated, as they relate to hedge accounting.

#### 3) Supplemental information on fair values of financial instruments

The fair values of financial instruments are based on market prices. Reasonably estimated values are used as fair values of financial instruments with no available fair market prices. Various assumption used in the calculation the reasonably estimated values may affect calculation of values.

Book values and fair values of the financial instruments on the consolidated balance sheet as of March 31, 2014 and 2013 were as follows:

	Millions of yen	
2014		
Book values	Fair values	Difference
¥ 22,746	¥ 22,746	¥ —
2,188	2,188	_
110,299	110,299	_
41,803	41,803	_
120,945	120,945	_
¥297,981	¥297,981	¥ —
74	74	_
42,072	42,072	_
1,738	1,738	_
10,524	10,524	_
60,000	60,895	895
35,000	35,099	99
¥149,408	¥150,402	¥994
¥ 0	¥ 0	¥ —
	¥ 22,746 2,188 110,299 41,803 120,945 ¥297,981 74 42,072 1,738 10,524 60,000 35,000 ¥149,408	2014 Book values Fair values  ¥ 22,746 ¥ 22,746  2,188 2,188  110,299 110,299  41,803 41,803 120,945 120,945  ¥297,981 ¥297,981  74 74  42,072 42,072  1,738 1,738 10,524 10,524 60,000 60,895 35,000 35,099  ¥149,408 ¥150,402

(\*) Long-term borrowings include the amount of current portion of long-term borrowings.

		Millions of yen	
		2013	
	Book values	Fair values	Difference
(1) Cash and time deposits	¥ 18,753	¥ 18,753	¥ —
(2) Trade notes	2,897	2,897	_
(3) Trade accounts	95,093	95,093	_
(4) Due from parent company, unconsolidated subsidiaries and affiliates	34,574	34,574	_
(5) Marketable securities and investment securities	121,725	121,725	_
Total assets	¥273,042	¥273,042	¥ —
(1) Trade notes	176	176	_
(2) Trade accounts	44,518	44,518	_
(3) Due to parent company, unconsolidated subsidiaries and affiliates	2,118	2,118	_
(4) Income taxes payable	2,115	2,115	_
(5) Bonds payable	70,000	71,280	1,280
(6) Long-term borrowings (*)	45,000	45,144	144
Total liabilities	¥163,927	¥165,351	¥1,424
Derivative transactions	¥ —	¥ —	¥ —

<sup>(\*)</sup> Long-term borrowings include the amount of current portion of long-term borrowings.

		Thousands of U.S. dolla	irs
		2014	
	Book values	Fair values	Difference
(1) Cash and time deposits	\$ 220,83	5 \$ 220,835	\$ <b>—</b>
(2) Trade notes	21,24	3 21,243	_
(3) Trade accounts	1,070,86	4 1,070,864	_
(4) Due from parent company, unconsolidated subsidiaries and affiliates	405,85	4 405,854	_
(5) Marketable securities and investment securities	1,174,22	3 1,174,223	_
Total assets	\$2,893,01	9 \$2,893,019	<b>\$</b> —
(1) Trade notes	71	8 718	_
(2) Trade accounts	408,46	6 408,466	_
(3) Due to parent company, unconsolidated subsidiaries and affiliates	16,87	4 16,874	_
(4) Income taxes payable	102,17	5 102,175	_
(5) Bonds payable	582,52	4 591,214	8,690
(6) Long-term borrowings (*)	339,80	6 340,767	961
Total liabilities	\$1,450,56	3 \$1,460,214	\$9,651
Derivative transactions	\$	0 \$ 0	<b>\$</b> —
(*)			

<sup>(\*)</sup> Long-term borrowings include the amount of current portion of long-term borrowings.

(A) Methods of determining fair value of financial instruments, and matters related to securities and derivative transactions

#### Assets

(1) Cash and time deposits

The fair value of time deposits is approximately equal to book value.

(2) Trade notes, (3) Trade accounts, (4) Due from parent company, unconsolidated subsidiaries and affiliates

The fair value of these assets due within a year is approximately equal to book value.

(5) Marketable securities and investment securities The fair value of equity securities with fair value is based on the quoted market price. The fair value of bonds is based on the price offered by the corresponding financial institutions. The fair value of negotiable certificates of deposit is approximately equal to book value. See Note 2 (c), "Summary of Significant Accounting Policies — Marketable and Investment Securities" for notes pertaining to securities according to the purpose for which they are held.

#### Liabilities

(1) Trade notes, (2) Trade accounts, (3) Due to parent company, unconsolidated subsidiaries and affiliates, (4) Income taxes payable

The fair value of these liabilities due within a year is approximately equal to book value.

(5) Bonds payable

The fair value of corporate bonds is calculated according to market price.

(6) Long-term borrowings

The fair value of long-term borrowings is calculated as the present value of the total sum of principal and interest discounted by an assumed rate that would have been applicable had a new identical loan been undertaken.

#### Derivative transactions

See note 7 on "Derivative Transactions."

(B) Financial instruments for which the ascertainment of a fair value is deemed to be exceedingly difficult and are not included in "(5) Marketable securities and investment securities" are as follows:

Amount on consolidated balance sheet			
Million	Thousands of U.S. dollars		
2014	2014		
¥ 7,464	¥ 1,989	\$72,466	
1,198	980	11,631	
3,170	2,808	30,777	
	2014 ¥ 7,464 1,198	Millions of yen  2014 2013  ¥ 7,464 ¥ 1,989  1,198 980	

The fair value of unlisted shares and investment in unconsolidated subsidiaries and affiliates is not disclosed given the unavailability of quoted market prices because they are deemed to be exceedingly difficult to ascertain.

The fair value of investment in limited partnerships is not disclosed as their assets consist of those deemed to be exceedingly difficult to ascertain, such as unlisted shares.

(C) Maturity analysis for monetary claims and marketable securities and investment in securities

	Millions of yen				
	2014				
	Within 1 year	From 1 year to 5 years	From 5 years to 10 years	Over 10 years	
Cash and time deposits	¥ 22,746	¥—	¥—	¥—	
Trade notes	2,188	_	_	_	
Trade accounts	110,299	_	_	_	
Due from parent company, unconsolidated subsidiaries and affiliates	41,803	_	_	_	
Marketable securities and investment securities:					
Available-for-sale securities with terms of maturity (Negotiable certificates of deposit)	15,439	_	_	_	
Available-for-sale securities with terms of maturity (Bonds)	28,958	_	_	48	
Total	¥221,433	¥—	¥—	¥48	

		IVIIIION	s of yen		
	2013				
	Within 1 year	From 1 year to 5 years	From 5 years to 10 years	Over 10 years	
Cash and time deposits	¥ 18,753	¥—	¥—	¥ —	
Trade notes	2,897	_	_	_	
Trade accounts	95,093	_	_	_	
Due from parent company, unconsolidated subsidiaries and affiliates	34,574	_	_	_	
Marketable securities and investment securities:					
Available-for-sale securities with terms of maturity (Negotiable certificates of deposit)	26,941	_	_	_	
Available-for-sale securities with terms of maturity (Bonds)	29,193	_	_	42	
Total	¥207,451	¥—	¥—	¥42	

		Thousands of U.S. dollars			
	2014				
	V	Vithin 1 year	From 1 year to 5 years	From 5 years to 10 years	Over 10 years
Cash and time deposits	\$	220,835	<b>\$</b> —	<b>\$</b> —	<b>\$</b> —
Trade notes		21,243	_	_	_
Trade accounts	1	,070,864	_	_	_
Due from parent company, unconsolidated subsidiaries and affiliates		405,854	_	_	_
Marketable securities and investment securities:					
Available-for-sale securities with terms of maturity (Negotiable certificates of deposit)		149,893	_	_	_
Available-for-sale securities with terms of maturity (Bonds)		281,146	_	_	466
Total	\$2	,149,835	\$—	\$—	\$466

## 6. MARKETABLE **SECURITIES AND INVESTMENT SECURITIES**

Marketable securities and investment securities as of March 31, 2014 and 2013 consisted of the following:

	Millions of yen		Thousands of U.S. dollars
	2014	2013	2014
Current:			
Government / local government bonds	¥ 15,947	¥ 16,648	\$154,825
Corporate bonds	13,011	12,545	126,320
Negotiable certificates of deposits	15,439	26,941	149,893
MMF	37,556	30,329	364,622
Total	¥81,953	¥86,463	\$795,660
Noncurrent:			
Equity securities	¥38,944	¥35,220	\$378,097
Trust fund investments and other	48	4,839	466
Total	¥38,992	¥40,059	\$378,563

The carrying amount and aggregate fair value of marketable securities and investment securities as at March 31, 2014 and 2013 were as follows:

		Millions of yen			
	2014				
	Cost	Unrealized gains	Unrealized losses	Fair value	
Available-for-sale securities:					
Equity securities	¥14,414	¥24,558	¥28	¥38,944	
Government / local government bonds	15,947	1	1	15,947	
Corporate bonds	13,010	2	1	13,011	
Other securities	29	19	0	48	
		Millions	of yen		
		201	3		

	2010			
	Cost	Unrealized gains	Unrealized losses	Fair value
Available-for-sale securities:				
Equity securities	¥14,410	¥20,824	¥14	¥35,220
Government / local government bonds	16,647	2	1	16,648
Corporate bonds	12,563	1	19	12,545
Other securities	28	15	1	42
		Thousands of	U.S. dollars	

	Thousands of U.S. dollars				
	2014				
	Cost	Unrealized gains	Unrealized losses	Fair value	
Available-for-sale securities:					
Equity securities	\$139,942	\$238,427	\$272	\$378,097	
Government / local government bonds	154,825	5	5	154,825	
Corporate bonds	126,311	24	15	126,320	
Other securities	282	184	0	466	

Proceeds from sales of available-for-sale securities were ¥6,312 million (\$61,282 thousand) and ¥40,422 million for the years ended March 31, 2014 and 2013, respectively. Realized gains from sales of available-for-sale securities were ¥2,770 million (\$26,893 thousand) and ¥7 million for the years ended March 31, 2014 and 2013, and costs on sales of available-for-sale securities were ¥3,542 million (\$34,389 thousand) and ¥40,415 million for the years ended March 31, 2014 and 2013, respectively. The cost of securities sold in computing realized gains was determined by the moving average method.

On March 31, 2014, investment securities of ¥53 million (\$515 thousand) were pledged as collateral for accounts payable of ¥81 million (\$786 thousand). On March 31, 2013, investment securities of ¥48 million were pledged as collateral for accounts payable of ¥102 million.

## 7. DERIVATIVE **TRANSACTIONS**

The Group is exposed to certain market risk arising from its foreign exchange forward contracts. The Group is also exposed to the risk of credit loss in the event of non-performance by the counterparties to its currency contracts. However, the Group does not anticipate nonperformance by any of these counterparties as they are financial institutions with high credit ratings.

Derivative transactions to which hedge accounting is applied as of March 31, 2014 and 2013 were as follows:

Currency related transactions

#### 2014

Hedge accounting method	Transaction type	Main hedged items	Contrac	t amount		n over rear	Fair	value
Appropriation of foreign exchange	Foreign exchange contracts		Millions of yen	Thousands of U.S. dollars	Millions of yen	Thousands of U.S. dollars	Millions of yen	Thousands of U.S. dollars
forward contracts								
	Buy contracts							
	USD	Trade accounts	¥479	\$4,650	_	_	(*)	(*)
	EUR	payable	54	524	_	_	(*)	(*)
	GBP		8	78	_	_	(*)	(*)

2013								
Hedge accounting method	Transaction type	Main hedged items	Contrac	t amount		n over rear	Fair	value
Appropriation of foreign exchange forward	Foreign exchange contracts		Millions of yen	Thousands of U.S. dollars	Millions of yen	Thousands of U.S. dollars	Millions of yen	Thousands of U.S. dollars
contracts	Buy contracts							
	USD	Trade	¥137	\$1,457	_	_	(*)	(*)
	EUR	accounts payable	76	809	_	_	(*)	(*)
	GBP		2	21	_	_	(*)	(*)

<sup>(\*)</sup> As foreign exchange forward contracts subject to appropriation are processed in an integrated manner together with the hedged trade accounts receivable and payable, the fair value of the forward exchange contract is included in the fair value of the applicable trade accounts payable items and stated accordingly. (See note 5)

### 8. LONG-TERM DEBT

Long-term debt at March 31, 2014 and 2013 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2014	2013	2014
Unsecured loans from banks and financial institutions, due 2013 to 2017 with average interest rate of 0.6–0.7%	¥ 35,000	¥ 45,000	\$399,806
Unsecured bonds due 2014 with average interest rate of 0.53%	_	10,000	_
Unsecured bonds due 2016 with average interest rate of 0.78%	30,000	30,000	291,263
Unsecured bonds due 2016 with average interest rate of 0.54%	10,000	10,000	97,087
Unsecured bonds due 2018 with average interest rate of 1.11%	10,000	10,000	97,087
Unsecured bonds due 2018 with average interest rate of 0.82%	10,000	10,000	97,087
Total	¥ 95,000	¥115,000	\$922,330
Less current portion	(10,000)	(20,000)	(97,087)
Long-term debt, less current portion	¥ 85,000	¥ 95,000	\$825,243

The aggregate annual maturities of long-term debt were as follows:

Year Ending March 31	Millions of yen	Thousands of U.S. dollars
2015	¥10,000	\$ 97,087
2016	35,000	339,806
2017	22,000	213,592
2018	18,000	174,758
2019	10,000	97,087
Total	¥95,000	\$922,330

Other liabilities include deposits received from customers in the amount of ¥5,181 million (\$50,301 thousand) as of March 31, 2014, bearing interest at an average rate of 4.55%, and ¥4,655 million as of March 31, 2013, bearing interest at an average rate of 4.00%.

## 9. INCOME TAXES

The Company and its domestic subsidiaries are subject to Japanese national and local income taxes which, in aggregate, resulted in a statutory tax rate of approximately 38.0% for the years ended March 31, 2014 and 2013. Overseas subsidiaries are subject to income taxes of the countries in which they operate.

Major components of deferred tax assets and liabilities as of March 31, 2014 and 2013 were as follows:

	Millions of yen		Thousands of U.S. dollars
	2014	2013	2014
Deferred tax assets:			
Liability for retirement benefits	¥ 3,277	¥ 2,537	\$ 31,816
Accrued enterprise taxes	847	190	8,223
Accrued bonuses to employees	2,698	2,823	26,194
Reserve for sales rebates	11,134	6,421	108,097
Loss on devaluation of investment securities	647	1,039	6,282
Research and development costs	10,736	7,687	104,233
Inventories	2,842	2,374	27,592
Net operating loss carried forward	1,481	5,649	14,379
Amortization of intangible assets	13,655	11,962	132,573
Tax credit for research and development costs of overseas subsidiaries	8,227	11,464	79,874
Other	14,813	11,075	143,815
Gross deferred tax assets	70,357	63,221	683,078
Valuation allowance	(5,850)	(4,358)	(56,796)
Total deferred tax assets	¥ 64,507	¥ 58,863	\$ 626,282
Deferred tax liabilities:			
Unrealized gains on available-for-sale securities	¥ (8,377)	¥ (7,347)	\$ (81,330)
Deferred gain on sales of fixed assets	(882)	(854)	(8,563)
Tax effect of intangible assets related to business combination	(24,022)	(26,165)	(233,223)
Refund of capital surplus of a subsidiary	(471)	(471)	(4,573)
Undistributed earnings of foreign subsidiaries	(213)	(112)	(2,068)
Other	(1,075)	(807)	(10,438)
Total deferred tax liabilities	¥(35,040)	¥(35,756)	\$(340,195)
Net deferred tax assets	¥ 29,467	¥ 23,107	\$ 286,087

A reconciliation between the statutory tax rates and the effective tax rates reflected in the accompanying consolidated statements of income for the years ended March 31, 2014 and 2013 was as follows:

	2014	2013
Normal statutory tax rate	38.0%	38.0%
Increase (decrease) in taxes due to:		
Expenses not deductible for tax purposes	3.3	6.5
Non-taxable dividend income	(0.5)	(1.0)
Tax credits for research and development costs	(9.2)	(9.0)
Amortization of goodwill	5.5	7.9
Change in valuation allowance	3.0	(0.5)
Effect of revised corporate tax rate	2.0	1.1
Tax effects attributable to investments in subsidiaries	0.3	0.6
Other	(0.2)	1.1
Effective tax rate	42.2%	44.7%

## 10. RETIREMENT AND **SEVERANCE BENEFITS**

The liability for retirement benefits as at March 31, 2014 consisted of the following:

#### 1. Defined benefit plans

1) Movement in retirement benefit obligations, excluding retirement plans for which the simplified method is applied

	Millions of yen	Thousands of U.S. dollars
Balance at April 1, 2013	¥80,676	\$783,262
Service cost	3,094	30,039
Interest cost	1,613	15,660
Actuarial gain	4,295	41,699
Benefits paid	(4,165)	(40,437)
Prior service cost	(1,806)	(17,534)
Other	(4)	(39)
Balance at March 31, 2014	¥83,703	\$812,650

## 2) Movement in plan assets, excluding retirement plans for which the simplified method is applied

	Millions of yen	Thousands of U.S. dollars
Balance at April 1, 2013	¥71,357	\$692,786
Expected return on plan assets	1,326	12,874
Actuarial gain	1,473	14,301
Contributions paid by the employer	3,396	32,971
Benefits paid	(3,027)	(29,388)
Other	(40)	(389)
Balance at March 31, 2014	¥74,485	\$723,155

## 3) Movement in liability for retirement benefits for which the simplified method is applied

	Millions of yen	Thousands of U.S. dollars
Balance at April 1, 2013	¥ 83	\$ 806
Retirement benefit costs	(7)	(68)
Benefits paid	(3)	(29)
Contributions paid by the employer	(44)	(427)
Other	(41)	(399)
Balance at March 31, 2014	¥(12)	\$(117)

## 4) Reconciliation from retirement benefit obligations and plan assets to liability (asset) for retirement benefits

	Millions of yen	Thousands of U.S. dollars
Funded retirement benefit obligations	¥ 71,105	\$ 690,340
Plan assets	(75,791)	(735,835)
	(4,686)	(45,495)
Unfunded retirement benefit obligations	13,892	134,874
Total Net liability (asset) for retirement benefits at March 31, 2014	9,206	89,379
Liability for retirement benefits	13,892	134,874
Asset for retirement benefits	(4,686)	(45,495)
Total Net liability (asset) for retirement benefits at March 31, 2014	¥ 9,206	\$ 89,379
Note: Includes plan applied simplified method.		

## 5) Retirement benefit costs

	Millions of yen	Thousands of U.S. dollars
Service cost	¥ 3,094	\$ 30,039
Interest cost	1,613	15,660
Expected return on plan assets	(1,326)	(12,874)
Net actuarial loss amortization	649	6,301
Past service costs amortization	(216)	(2,097)
Retirement benefit costs applied simplified method	(6)	(58)
Total retirement benefit costs for the fiscal year ended March 31, 2014	¥ 3,808	\$ 36,971

## 6) Accumulated adjustments for retirement benefit

	Millions of yen	Thousands of U.S. dollars
Unrecognized past service costs	¥(2,122)	\$(20,602)
Unrecognized actuarial differences	5,171	50,204
Total balance at March 31, 2014	¥ 3,049	\$ 29,602

#### 7) Plan assets

i) Plan assets comprise:

Bonds	58.2%
Equity securities	14.2%
Cash and cash equivalents	6.7%
General account	11.8%
Other	9.1%
Total	100%

Note: Retirement benefit trusts set up for corporate pension plans account for 7.6 percent of total plan assets.

## ii) Long-term expected rate of return

Current and target asset allocations, historical and expected returns on various categories of plan assets have been considered in determining the long-term expected rate of return.

#### (8) Actuarial assumptions

The principal actuarial assumptions as at March 31, 2014 (expressed as weighted averages) were as follows:

Discount rate	1.5%
Long-term expected rate of return	2.0%

#### 2. Defined contribution plans

The amount of required contributions to the defined contribution plans of the Company and consolidated subsidiaries was ¥2,399 million (\$23,291 thousand).

The liability for employees' retirement benefits at March 31, 2013 consisted of the following:

	Millions of yen
	2013
Projected benefit obligation	¥ (81,912)
Fair value of plan assets	72,511
Unrecognized prior service cost	(532)
Unrecognized actuarial gain	2,998
Net retirement benefit obligation	(6,935)
Prepaid pension cost	4,095
Liability for employees' retirement benefits	¥ (11,030)

Certain consolidated subsidiaries have adopted a simplified calculation method for projected benefit obligation allowed for small business entities in Japan. The components of net periodic retirement benefit costs were as follows:

	Millions of yen
	2013
Service cost	¥ 3,204
Interest cost	1,614
Expected return on plan assets	(1,261)
Amortization of prior service cost	(218)
Recognized actuarial loss	893
Net periodic retirement benefit costs	¥ 4,232
Contribution payments to a defined contribution pension plan	2,586
Total	¥ 6,818

Retirement benefit cost for early retirement option of ¥4,784 million, which was included in restructuring expense for the year ended March 31, 2013, was incurred in addition to the above.

The Company has a lump-sum payment plan, a non-contributory defined benefit pension plan and a defined contribution pension plan.

Assumptions used for the years ended March 31, 2013 were as follows:

	2013
Method of attributing benefits to periods of service	Straight-line basis
Discount rate	2.0%
Expected rate of return on plan assets	2.0%
Amortization period for prior service cost	15 years
Recognition period for actuarial gain/loss	15 years

## 11. SHAREHOLDERS' **EQUITY**

Under the Japanese Corporate Law ("the Law") and regulations, the entire amount paid for new shares is required to be designated as common stock. However, a company may, by a resolution of the Board of Directors, designate an amount not exceeding 50% of the price of the new shares as additional paid-in capital, which is included in capital surplus.

Under the Law, in cases where a dividend distribution of surplus is made, the smaller of an amount equal to 10% of the dividend or the excess, if any, of 25% of common stock over the total of additional paid-in capital and legal reserve must be set aside as additional paid-in capital or legal reserve. Legal reserve is included in retained earnings in the accompanying consolidated balance sheets.

Under the Law, legal reserve and additional paid-in capital could be used to eliminate or reduce a deficit by a resolution of the shareholders' meeting or could be capitalized by a resolution of the Board of Directors. Under the Law, both of these appropriations generally require a resolution of the shareholders' meeting.

Additional paid-in capital and legal reserve may not be distributed as dividends, but may be transferred to other capital surplus and retained earnings respectively, which are potentially available for dividends.

The maximum amount that the Company can distribute as dividends is calculated based on the unconsolidated financial statements of the Company in accordance with the Law and regulations.

At the annual shareholders' meeting held on June 19, 2014, the shareholders approved year-end cash dividends of ¥9.00 (\$0.09) per share, amounting to ¥3,576 million (\$34,718 thousand). These appropriations have not been accrued in the consolidated financial statements as of March 31, 2014. Such appropriations are recognized in the period in which they are approved by the shareholders. Together with the interim cash dividends, the total annual dividends were ¥18.00 (\$0.17) per share.

## **12. TRANSACTIONS WITH PARENT** COMPANY, **UNCONSOLIDATED SUBSIDIARIES AND AFFILIATES**

Transactions of the Group with the parent company, Sumitomo Chemical Co., Ltd., unconsolidated subsidiaries and affiliates for the years ended March 31, 2014 and 2013 were as follows:

	Millions	Millions of yen		
	2014	2013	2014	
Sales	¥ 315	¥ 209	\$3,058	
Purchases	6,386	7,700	62,000	

## 13. RELATED PARTY **TRANSACTIONS**

Major transactions of the Group with the parent company, Sumitomo Chemical Co., Ltd., for the years ended March 31, 2014 and 2013 were as follows:

	Millions	Thousands of U.S. dollars	
	2014	2013	2014
Purchases of products	¥2,160	¥3,826	\$20,971
Payment of other expenses	1,219	1,222	11,835
Loans	6,407	34,401	62,204
Interest income	133	82	1,291

The balances due to or from the parent company, Sumitomo Chemical Co., Ltd., as at March 31, 2014 and 2013 were as follows:

	Million	Millions of yen		
	2014	2013	2014	
Receivables	¥41,811	¥34,572	\$405,932	
Payables	1,216	1,358	11,806	

## 14. LEASES

The minimum lease payments under non-cancelable operating leases as of March 31, 2014 and 2013 were as follows:

	Millions	Thousands of U.S. dollars	
	2014	2013	2014
Due within one year	¥ 209	¥ 99	\$ 2,029
Due after one year	6,683	2,902	64,884
Total	¥6,892	¥3,001	\$66,913

## 15. SEGMENT **INFORMATION**

## 1) Outline of reportable segments

The Group's reportable segments are the components of the Group whose operating results are regularly reviewed by the board of directors to make decisions about resources to be allocated to the segment and assess their performance, and for which discrete financial information is available.

The Group assesses its pharmaceutical business performance according to the reportable segments of the Group which consist of the following four segments: Japan, North America, China, Other regions.

## 2) Method of calculating sales and income/loss, assets, liabilities and other items by reportable segment

Accounting method for business segment reporting is the same as presentation on Note 2 "Summary of Significant Accounting Policies." Income by reportable segment is calculated based on operating income before R&D costs. Intersegment sales and transfers are calculated based on current market prices.

Assets and liabilities by reportable segment are not shown because such information is not used to make decisions regarding resource allocation and performance measurement.

## 3) Information on sales, income/loss and other items by reportable segment Segment information for the Group for the years ended March 31, 2014 and 2013 were as

	Millions of yen						
	2014						
	Japan	North America	China	Other Regions	Subtotal	Other Business	Total
Net sales							
Sales to customers	¥171,898	¥145,271	¥11,928	¥16,713	¥345,810	¥41,883	¥387,693
Intersegment sales and transfers	161	_	_	_	161	69	230
Total	172,059	145,271	11,928	16,713	345,971	41,952	387,923
Income of segment	60,827	33,877	3,182	11,359	109,245	2,673	111,918
Others							
Depreciation and amortization	3,925	12,965	347	258	17,495	196	17,691

Note: The "Other Business" category incorporates operations not included in reportable segments, including food ingredients, food additives, chemical product materials, veterinary drugs, diagnostics and other products.

2013 Other Regions ¥9,268	Subtotal	Other Business	Total
-		Other Business	Total
¥9,268	V007.100		
¥9,268	V007 100		
	¥307,199	¥40,525	¥347,724
_	257	86	343
9,268	307,456	40,611	348,067
4,341	81,863	2,997	84,860
•			•
242	28,083	177	28,260
	242		

			Tho	usands of U.S. dol	llars			
	2014							
	Japan	North America	China	Other Regions	Subtotal	Other Business	Total	
Net sales								
Sales to customers	\$1,668,913	\$1,410,398	\$115,806	\$162,262	\$3,357,379	\$406,631	\$3,764,010	
Intersegment sales and transfers	1,563	_	_	_	1,563	670	2,233	
Total	1,670,476	1,410,398	115,806	162,262	3,358,942	407,301	3,766,243	
Income of segment	590,553	328,903	30,893	110,282	1,060,631	25,951	1,086,582	
Others								
Depreciation and amortization	38,107	125,874	3,369	2,504	169,854	1,903	171,757	

## 4) Reconciliation of differences between the total of reportable segments and the amount in the consolidated financial statements

Net sales	Millior	Thousands of U.S. dollars	
	2014	2013	2014
Reportable segments total	¥345,971	¥307,456	\$3,358,942
Net sales of "Other Business" category	41,952	40,611	407,301
Elimination of intersegment transactions	(230)	(343)	(2,233)
Net sales in the consolidated statements of income	¥387,693	¥347,724	\$3,764,010
Income	•	ns of yen	Thousands of U.S. dollars
	2014	2013	2014
Reportable segments total	¥ 109,245	¥ 81,863	\$1,060,631
Income of "Other Business" category	2,673	2,996	25,951
Research and development costs	(69,804)	(59,844)	(677,709)
Elimination of intersegment transactions	29	29	282
Operating income in the consolidated statements of income	¥ 42,143	¥ 25,044	\$ 409,155
Other items	Millior	ns of yen	Thousands of U.S. dollars
	2014	2013	2014
Depreciation and amortization			
Reportable segments total	¥17,495	¥28,083	\$169,854
Other Business	196	177	1,903
Adjustment	2,898	1,996	28,136
The amount in the consolidated financial statements	¥20,589	¥30,256	\$199,893
Amortization of goodwill			
Reportable segments total	¥ 5,054	¥ 3,773	\$ 49,068
Other Business	_	_	_
Adjustment	_	_	_
The amount in the consolidated financial statements	¥ 5,054	¥ 3,773	\$ 49,068

## 5) Other information

Sales information by product or service for the Group for the years ended March 31, 2014 and 2013 were as follows:

Sales to customers	Million	Millions of yen		
	2014	2013	2014	
Pharmaceuticals	¥345,810	¥307,199	\$3,357,379	
Other products	41,883	40,525	406,631	
Total	¥387,693	¥347,724	\$3,764,010	

Geographical segment information for the Group for the years ended March 31, 2014 and 2013 were as follows:

Net sales	Million	Millions of yen		
	2014	2013	2014	
Japan	¥214,704	¥219,537	\$2,084,505	
U.S.	141,547	109,182	1,374,243	
Other regions	31,442	19,005	305,262	
Total	¥387,693	¥347,724	\$3,764,010	

Property, plant and equipment	Million	Thousands of U.S. dollars	
	2014	2013	2014
Japan	¥62,849	¥60,705	\$610,184
Other regions	9,840	9,157	95,534
Total	¥72,689	¥69,862	\$705,718

Sales information by major customer for the Group for the years ended March 31, 2014 and 2013 were as follows:

Net sales	Million	Thousands of U.S. dollars	
Name of major customer and related segment	2014	2013	2014
McKesson Corporation / North America	¥48,062	¥43,480	\$466,621
Cardinal Corporation / North America	41,030	32,449	398,350
Alfresa Corporation / Japan	37,537	36,297	364,437
Mediceo Corporation / Japan	36,653	36,298	355,854

6) Information on impairment loss of non-current assets, amortization and unamortized balance of goodwill by reportable segment.

_				Millions of yen			
_	2014						
	Japan	North America	China	Other Regions	Subtotal	Other Business	Total
Impairment loss	¥2,999	¥ 4,639	¥—	¥—	¥ 7,638	¥—	¥ 7,638
Amortization of goodwill	_	5,054	_	_	5,054	_	5,054
Balance of goodwill	_	80,669	_	_	80,669	_	80,669

				Millions of yen			
				2013			
	Japan	North America	China	Other Regions	Subtotal	Other Business	Total
Impairment loss	¥—	¥ 417	¥—	¥—	¥ 417	¥	¥ 417
Amortization of goodwill	_	3,773	_	_	3,773	_	3,773
Balance of goodwill	_	71,294	_	_	71,294	_	71,294

			Th	ousands of U.S. do	ollars		
•	2014						
	Japan	North America	China	Other Regions	Subtotal	Other Business	Total
Impairment loss	\$29,116	\$ 45,039	<b>\$</b> —	<b>\$</b> —	\$ 74,155	<b>\$</b> —	\$ 74,155
Amortization of goodwill	_	49,068	_	_	49,068	_	49,068
Balance of goodwill	_	783,194	_	_	783,194	_	783,194

#### **16. IMPAIRMENT LOSS**

Impairment loss of tangible assets and intangible assets for the years ended March 31, 2014 was as follows:

			Millions of yen	
Usage for	Item	Location	2014	2014
Research and development with respect to compound in development		U.S.	¥4,272	\$41,476
Welfare facilities	Building and structures, Land and Others	Japan	2,984	28,970
Production facilities	Construction in progress	U.S.	367	3,563
Production facilities	Buildings and structures, Machinery, equipment and carriers and Others	Japan	15	146

The Company and its consolidated subsidiaries reduced the book value of idle and unused-inthe-future tangible assets, as well as tangible assets and in-process research and development costs of which future economic benefits were expected to decline to recoverable amount.

The recoverable amount of idle and unused-in-the-future was based on net realizable value apprised by a third-party real-estate appraiser.

The recoverable amount of tangible assets without future economic benefit expected was based on value-in-use, which was determined as zero.

The recoverable amount of in-process research and development costs was also based on value-in-use, which was measured using the discount rate of 11.5%.

Impairment loss of intangible assets for the years ended March 31, 2013 was as follows:

		Millions	of yen
Usage for	Item	Location	2013
Research and development with respect to compound in development	In-process research and development	U.S.	¥417

The recoverable amount of in-process research and development costs was also based on value-in-use, which was measured using the discount rate of 14.0%.

## 17. RESTRUCTURING

Restructuring carried out in the year ended March 31, 2014 was with the purpose of improving the business structure and organization in the Company and its subsidiaries. Restructuring carried out in the year ended March 31, 2013 including an impairment loss of ¥169 million was attributable to improving the business structure and organization in the Company and its subsidiaries.

## 18. OTHER **COMPREHENSIVE INCOME (LOSS)**

Components of other comprehensive income (loss) for the years ended March 31, 2014 and 2013 were as follows:

	Millions of yen			Thousands of U.S. dollars		
	20	14	2	013	2	2014
Unrealized gains on available-for-sale securities						
Amount arising during the period under review	ount arising during the period under review ¥ 6,489 ¥ 8,861		3,861	\$ 63,000		
Reclassification adjustment for gain (losses) included in net income	(2,778)		(51)		(26,971)	
Before income tax effect adjustment	3,711		8,810		36,029	
Amount of income tax effect	(857)		(2,705)		(8,320)	
Unrealized gains on available-for-sale securities, net of tax	<b>¥ 2,854</b> ¥ 6,105		\$ 27,709			
Deferred gains or losses on hedges						
Amount arising during the period under review	¥	(1)	¥	_	\$	(10)
Amount of income tax effect		_		_		_
Deferred gains or losses on hedges	¥	(1)	¥	_	\$	(10)
Foreign currency translation adjustment						
Amount arising during the period under review	¥22,251		¥21,025		\$216,029	
Foreign currency translation adjustment	22,251		<b>51</b> 21,025		216,029	
Total other comprehensive income (loss)	¥25	,104	¥27	',130	\$24	13,728

## 19. CONTINGENT LIABILITIES

Contingent liabilities for guarantees as of March 31, 2014 and 2013 were as follows:

	Millions of yen		U.S. dollars	
	2014	2013	2014	
Guarantees of indebtedness— Bank loans guaranteed for an affiliate	¥ 31	¥264	\$ 301	
Loans guaranteed— Employee's housing loans guaranteed	119	137	1,155	

## Independent Auditor's Report

To the Board of Directors of Sumitomo Dainippon Pharma Co., Ltd.:

We have audited the accompanying consolidated financial statements of Sumitomo Dainippon Pharma Co., Ltd. and its consolidated subsidiaries, which comprise the consolidated balance sheets as at March 31, 2014 and 2013, and the consolidated statements of income, statements of comprehensive income (loss), statements of changes in net assets and statements of cash flows for the years then ended, and a summary of significant accounting policies and other explanatory information.

#### Management's Responsibility for the Consolidated Financial Statements

Management is responsible for the preparation and fair presentation of these consolidated financial statements in accordance with accounting principles generally accepted in Japan, and for such internal control as management determines is necessary to enable the preparation of consolidated financial statements that are free from material misstatements, whether due to fraud or error.

#### **Auditor's Responsibility**

Our responsibility is to express an opinion on these consolidated financial statements based on our audits. We conducted our audits in accordance with auditing standards generally accepted in Japan. Those standards require that we comply with ethical requirements and plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free from material misstatement.

An audit involves performing procedures to obtain audit evidence about the amounts and disclosures in the consolidated financial statements. The procedures selected depend on our judgement, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. In making those risk assessments, we consider internal control relevant to the entity's preparation and fair presentation of the consolidated financial statements in order to design audit procedures that are appropriate in the circumstances, while the objective of the financial statement audit is not for the purpose of expressing an opinion on the effectiveness of the entity's internal control. An audit also includes evaluating the appropriateness of accounting policies used and the reasonableness of accounting estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements.

We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our audit opinion.

#### **Opinion**

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Sumitomo Dainippon Pharma Co., Ltd. and its consolidated subsidiaries as at March 31, 2014 and 2013, and their financial performance and cash flows for the years then ended in accordance with accounting principles generally accepted in Japan.

#### **Convenience Translation**

The U.S. dollar amounts in the accompanying consolidated financial statements with respect to the year ended March 31, 2014 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 1 to the consolidated financial statements.

KPMG AZSA LLC

June 30, 2014 Osaka, Japan

# Information

## Shareholder Data

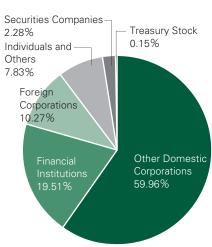
## Principal Shareholders (As of march 31, 2014)

Name	No. of Shares Held (Thousands of Shares)	Percentage of Shareholding
Sumitomo Chemical Co., Ltd.	199,434	50.20
Inabata & Co.,Ltd	27,282	6.87
The Master Trust Bank of Japan, Ltd. (Trust Account)	15,574	3.92
Japan Trustee Service Bank, Ltd. (Trust Account)	11,793	2.97
Nippon Life Insurance Company	8,529	2.15
Japan Trustee Service Bank, Ltd. (Trust Account for Sumitomo Mitsui Banking Corporation's Retirement Benefits)	7,000	1.76
Sumitomo Life Insurance Company	5,776	1.45
Sumitomo Dainippon Pharma Employee Shareholding Association	4,435	1.12
Aioi Nissay Dowa General Insurance Co., Ltd.	4,116	1.04
BNP Paribas Securities (Japan), Limited.	3,334	0.84

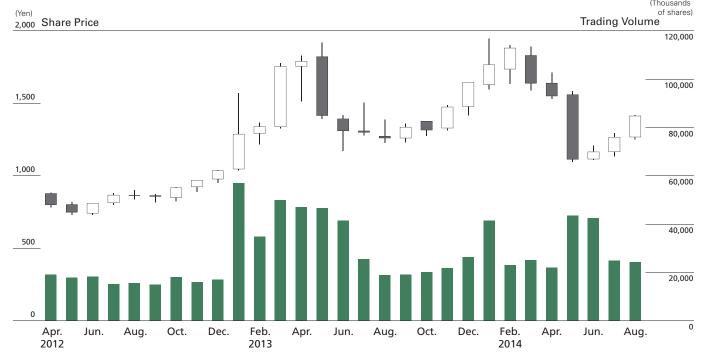
Note: Percentage of shareholding is calculated excluding treasury stock (593,962 shares).

## **Composition of Shareholders**

(As of March 31, 2014)



## **Share Price Range and Trading Volume**



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## Corporate Data

(As of July 31, 2014)

	Sumitomo Dainippon Pharma Co., Ltd.
Establishment	May 14, 1897
Date of Merger	October 1, 2005
Osaka Head Office	6-8 Doshomachi 2-chome, Chuo-ku, Osaka 541-0045, Japan TEL: +81-6-6203-5321 FAX: +81-6-6202-6028
Tokyo Head Office	13-1, Kyobashi 1-chome, Chuo-ku, Tokyo 104-8356, Japan TEL: +81-3-5159-2500 FAX: +81-3-5159-2945
Capital	¥22.4 billion
Employees*	7,015 (consolidated), 4,331 (non-consolidated)
Total Number of Shares Issued	397,900,154
Total Number of Shareholders*	25,672
Stock Exchange Listing	Tokyo Stock Exchange
Securities Code	4506
Independent Public Accountants	KPMG AZSA LLC
Fiscal Year-end	March 31
Ordinary General Meeting of Shareholders	June

Administrator of Shareholders' Register	Sumitomo Mitsui Trust Bank, Limited
Lead Managers	(Main) Daiwa Securities Co., Ltd.; (Sub) SMBC Nikko Securities Inc., Nomura Securities Co., Ltd.
Main Banks	Sumitomo Mitsui Banking Corporation Sumitomo Mitsui Trust Bank, Limited The Bank of Tokyo-Mitsubishi UFJ, Ltd.
Key Facilities	Osaka Head Office (Osaka), Tokyo Head Office (Tokyo), Osaka Center (Osaka), 20 Branches, 4 Plants (Mie, Osaka, Ehime, Oita), 2 Research Laboratories (Osaka), 2 Distribution Centers (Saitama, Hyogo)
Major Consolidated Subsidiaries	DSP Gokyo Food & Chemical Co., Ltd. DS Pharma Animal Health Co., Ltd. DS Pharma Biomedical Co., Ltd. Sunovion Pharmaceuticals Inc. (U.S.) Boston Biomedical, Inc. (U.S.) Boston Biomedical Pharma, Inc. (U.S.) Sumitomo Pharmaceuticals (Suzhou) Co., Ltd. (China)

<sup>\*</sup> As of March 31, 2014



