# New Value Creation

Mitsubishi Tanabe Pharma Corporation Annual Report 2012



# Becoming a "Company that Can Continue to Provide New Value"

Our vision is to be a global research-driven pharmaceutical company that can be trusted by communities.

Drugs with novel mechanisms of action that give hope to patients with intractable diseases.

Drugs that provide new methods of treatment and improve patients' daily lives.

Drugs that are highly convenient and lessen the burden on health care workers.

The value of a single drug depends on the number of patients.

With a focus on this value, the entire Company will work together to achieve our vision.

To that end, we will continue to implement reforms to become a "company that can continue to create new value," in accordance with the key concept of New Value Creation.

Aiming to be an *inspiring* company that continues to discover and provide drugs that are useful to patients around the world, we will continue to proactively take on the challenges that we face.

OUR PHILOSOPHY

We contribute to the healthier lives of people around the world through the creation of pharmaceuticals.

OUR VISION We strive to be a global research-driven pharmaceutical company that is trusted by communities.



#### Message from the President

# In All of Our Business Activity Processes, We Aim for Sustained Value Creation as a Pharmaceutical Company.

In April 2011, we started the Medium-Term Management Plan 11–15—New Value Creation. This plan is a roadmap to a new growth stage for the Company. It is based on the progress that we made under previous medium-term management plans and covers the five-year period to March 2016.

Mitsubishi Tanabe Pharma was established in October 2007 through the merger of Tanabe Seiyaku and Mitsubishi Pharma. In 2008, we launched the Medium-Term Management Plan 08–10—Dynamic Synergy for 2015 and pushed forward with the creation of an operational base for our growth and development as a new company. Now, we have entered a stage of proactive management as we work to realize Mitsubishi Tanabe Pharma's vision of "being a global research-driven pharmaceutical company that is trusted by communities."

Under Medium-Term Management Plan 11–15, to demonstrate our determination to become a "company that can continue to create new value," we have formulated the key concept of New Value Creation. We will strive to contribute to improving the QOL¹ for large numbers of patients around the world through the discovery and global provision of new drugs that respond to unmet medical needs². I believe that this is our mission: providing a wide-range of value to society.

In the future, we will maintain our focus on this mission in all of our business activity processes, and on that basis we will aim for sustained value creation as a pharmaceutical company.

I would like to ask for the continued support of our shareholders, investors, and other stakeholders.

August 2012

President & Representative Director, Chief Executive Officer

<sup>1.</sup> Abbreviation for Quality of Life. Benchmark that addresses whether patients can enjoy their daily lives with a sense of fulfillment and satisfaction, without a decline in their quality of life.

<sup>2.</sup> Unmet medical needs: Medical needs for which there are no effective treatments or drugs.



#### **Profile**

Mitsubishi Tanabe Pharma Corporation was established in October 2007 through the merger of Tanabe Seiyaku Co., Ltd. and Mitsubishi Pharma Corporation.

Since that time, the Group has worked step by step to establish a strong track record based on the universal values of protecting the health of people around the world and contributing to comfortable lifestyles through the creation of pharmaceuticals.

Through the ongoing creation and provision of new pharmaceuticals in global markets, we will strive to record growth as a pharmaceutical company and contribute to the health of people around the world.

Targeting the realization of this challenging objective, as we move forward we will continue to emphasize working step by step, thereby fulfilling our responsibilities as a company engaged in the life sciences.



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#### Forward-Looking Statements

Statements contained in this annual report that are not historical facts are forward-looking statements that reflect the Company's plans and expectations. These forward-looking statements involve known and unknown risks, uncertainties, and other factors that may cause the Company's actual results, performance, or achievements to differ materially from those anticipated in these statements.

### **Financial Highlights**

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries
Years ended March 31, 2012 (FY 2011), 2011 (FY 2010), 2010 (FY 2009), 2009 (FY 2008) and 2008 (FY2007)

	FY2007 <sup>2</sup>	FY2008	FY2009	FY2010	
Net sales	¥409.4	¥414.7	¥404.7	¥409.5	
Operating income	72.4	71.6	61.4	76.5	
Net income	31.9	26.5	30.2	37.7	
R&D expenses	72.3	73.1	83.0	65.7	
Capital expenditures on an accrual basis	9.9	12.1	8.3	10.1	
Total assets	807.2	810.7	796.8	818.7	
Total net assets	667.8	666.2	676.8	695.9	
Net cash provided by operating activities	46.4	50.5	23.9	59.0	
Net cash used in investing activities	(8.9)	(74.5)	(61.2)	(7.6)	
Net cash used in financing activities	(9.0)	(15.9)	(17.1)	(15.4)	
Financial indicators (%):					
Operating margin	17.7%	17.3%	15.2%	18.7%	
Ratio of R&D expenses to net sales	17.7	17.6	20.5	16.1	
Equity ratio	80.9	80.5	84.1	84.3	
ROE	5.7	4.1	4.6	5.5	
Per share amounts (yen / U.S. dollars¹):					
Net income	¥50.12	¥47.28	¥53.91	¥67.27	
Cash dividends	26.00 <sup>3</sup>	28.00	28.00	28.00	
Number of employees	10,361	10,030	9,266	9,198	

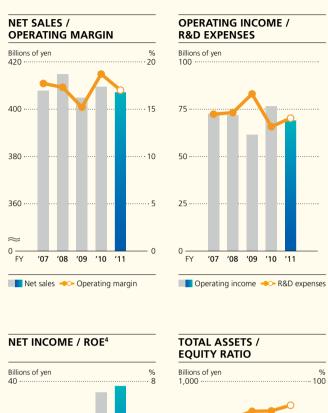
<sup>1.</sup> U.S. dollar amounts are converted from yen, for convenience only, at the rate of ¥82.19 to U.S.\$1, the prevailing exchange rate at March 31, 2012.

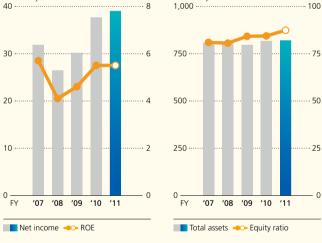
<sup>2.</sup> Figures are based on the simple sum of the results of Tanabe Seiyaku and Mitsubishi Pharma.

<sup>3.</sup> Dividends per share is based on the sum of the interim dividends (¥13) of Tanabe Seiyaku and the year-end dividends (¥13) of Mitsubishi Tanabe Pharma

<sup>4.</sup> The principal reasons for the decline in ROE in fiscal 2007 and fiscal 2008 were an increase in shareholders' equity due to the recording of goodwill, etc., as a result of the merger, and a decline in net income that exceeded amortization of goodwill.

	Billions of yen	Millions of U.S. dollars <sup>1</sup>	% change
	FY2011	FY2011	FY2011/FY2010
	¥407.1	\$4,954	- 0.6%
	69.0	840	- 9.8
	39.0	475	+3.4
······	70.2	855	+6.8
······································	7.0	85	- 30.4
······································	819.9	9,976	+0.1
	721.4	8,778	+3.7
······	37.2	453	- 36.9
······	(63.2)	(769)	+726.4
	(17.1)	(209)	+11.3
	17.0%		_
······	17.3	<u> </u>	<u> </u>
······	87.3	_	<u> </u>
	5.5	_	_
	¥69.54	\$0.85	+3.4%
	35.00	0.43	+25.0
	9,180	_	- 0.2





Note: In general, figures in graphs for fiscal 2007 is the simple sum of the figures for Tanabe Seiyaku and Mitsubishi Pharma.

#### Interview with the President

# Becoming a Global Research-Driven Pharmaceutical Company that can be Trusted by Communities

In October 2011, Mitsubishi Tanabe Pharma publicly announced the Medium-Term Management Plan 11–15—New Value Creation, which outlines the Company's growth strategy roadmap for the five-year period to March 2016. This section presents an interview with President Michihiro Tsuchiya, who discusses the Company's operating environment, results trends, management issues, and the objectives of Medium-Term Management Plan 11–15, as well as the Company's growth strategies over the medium to long term.



#### **OPERATING ENVIRONMENT AND THE COMPANY'S STRATEGIES**

Q. Would you share your thoughts on the operating environment in the pharmaceutical industry and on the Company's strategies?

# To realize sustained growth in a challenging operating environment, we must continually discover and provide new drugs with value for patients around the world.

In the past, many of the mega pharmaceutical companies recorded sustained growth with a business model that is focused on the development and sales of drugs with sales in excess of \$1 billion a year, which are known as blockbuster drugs. In recent years, however, many of these blockbusters have gone off patent, leading to declines in revenues/profits. As a result, this business model is reaching the limit of its usefulness. Looking at markets around the world, growth is sluggish in the industrially developed markets of Japan, the U.S., and Europe. On the other hand, in China and other emerging countries, which are posting rapid economic growth, the markets are growing rapidly as the level of medical care improves. In this setting, pharmaceutical companies are accelerating their restructuring initiatives on a global scale, aiming to speed up new drug development and to enter new markets.

In Japan, which is our core market and the foundation of our revenues/profits, the ethical pharmaceutical market is the second largest in the world. However, with the population aging rapidly, every year the government is strengthening its measures to control health care expenditures, and the rate of growth in the domestic market is slowing. In April 2012, the government implemented a revision of NHI drug prices, which are in principle revised once every two years. Prices were reduced by an industrywide average of 6.00%, with an additional reduction of 0.86% for long-term listed products. Moreover, the government continues to implement measures to promote the use of generic drugs, and the situation remains severe for the producers of innovative ethical drugs, as their revenues/profits come under increasing pressure each year. On the other hand, the system of pricing premiums for newly developed drugs, which was introduced on a trial basis in 2010, has been extended, and the ongoing development of new drugs has become an important part of maintaining and

expanding revenues/profits. However, development costs are rising, and the difficulty of discovering new drugs has increased further. As a result, the hurdles for new drug development are growing higher.

To realize sustained growth in this type of challenging operating environment, we must continually discover and provide new drugs with value for patients around the world. That is, in fact, our vision: to become a global research-driven pharmaceutical company. In this sense, the term "global research-driven pharmaceutical company" does not necessarily mean a company that has production and sales bases throughout the world and develops all of its products in-house. Rather, what is important is that a company provides drugs that are used around the world and works to maximize the value of those drugs, thereby driving its business growth. Accordingly, rather than focus excessively on blockbuster drugs resulting from in-house discovery and development, we must select the method that is most appropriate for maximizing product value, with consideration for the scale of our operations and the distinctive characteristics of each individual product. M&A transactions are one means of expanding business scale, but we believe that there is no point in pursuing scale for its own sake. Our interest in M&A transactions is limited to their use as a tool for achieving other goals. It is important to undertake M&A measures with a clear purpose, such as bolstering technical capabilities, a drug pipeline, or a sales network. Our approach is to complement our own strengths with the use of a variety of frameworks, including cooperative initiatives, and to manage those activities in a manner that is appropriate for the scale of our operations. In the end, this approach is the fastest way to deliver drugs with value to patients, and thereby enhance the Company's results. Moving forward, we will work to become a global research-driven pharmaceutical company with this type of original business model.

#### **VIEW OF EXTERNAL MANAGEMENT ENVIRONMENT**

### Industrially Developed Markets (Japan / U.S. / Europe)

• Markets receptive to innovative medicine

Market scale: Large Growth rate: Low

 Measures to control health care to limit social insurance expenditures (focus on medical cost performance)

#### **Emerging Markets (China, etc.)**

• Markets in which the level of medical treatment is rising rapidly in conjunction with economic growth

Market scale: Rapidly expanding Growth rate: High

 Possible to implement development in a short period of time for products that have been approved in Europe / U.S.

#### Increasing Difficulty in Drug Discovery

- Progress in science and technology; more-complicated, more-advanced disease mechanisms
- Rising development costs, rising approval hurdles

#### **OVERVIEW OF RESULTS IN FISCAL 2011**

#### Q. What is your evaluation of the Company's results in fiscal 2011?

#### We achieved our planned targets in both sales and profits, but we cannot be content with these results. Moving forward, we must continue striving to achieve steady results.

Domestic sales of ethical drugs account for about 90% of our sales of ethical drugs. In the past year, Remicade, an anti-TNF $\alpha$  monoclonal antibody, faced intensifying competition in most of its indications. Nonetheless, with an additional indication for ulcerative colitis and an increased dosage for Crohn's disease, sales of Remicade recorded solid growth. Favorable results were also recorded by Kremezin and Maintate. Sales of Kremezin, a treatment for chronic kidney disease, were transferred from Daiichi Sankyo to the Company, while Maintate, a selective \$1 antagonist, received an additional indication for chronic heart failure. In addition, contributions were made by four new drugs, including Telavic, a treatment agent for chronic hepatitis C that was launched in fiscal 2011. However, the influence of generics increased, and there was also a rebound from a temporary increase in orders that was recorded at the end of the previous fiscal year following the Great East Japan Earthquake. As a result, domestic sales of ethical drugs were down 1.7%, to ¥355.4 billion. On the other hand, royalty revenues from Gilenya (Mitsubishi Tanabe Pharma's brand name: Imusera) a treatment agent for MS that we licensed to Novartis, made a substantial contribution, and sales in fiscal 2011 were down by only a small margin, declining 0.6%, to ¥407.1 billion.

In profits, due to the increase in royalty revenues, gross profit was about the same as in the previous year. However, operating income declined 9.8%, to ¥69.0 billion, due to an increase in R&D expenses and to a rise in sales-related expenses resulting from the launch of new products. Extraordinary items improved by ¥7.6 billion year on year, and as a result net income reached a new record high, increasing 3.4%, to ¥39.0 billion.

In this way, net sales, operating income, and net income all surpassed the planned levels, and considering the difficult operating environment, we recorded solid results. As we strive to achieve our challenging objectives, however, we will not be content with our current situation. Rather, we will continue striving to achieve steady results as we aim for even more challenging objectives.

#### **OVERVIEW OF MEDIUM-TERM MANAGEMENT PLAN 11–15**

Q. Would you discuss the objectives of Medium-Term Management Plan 11–15 (hereafter, the current plan), which was formulated in fiscal 2011?

#### Our objective is to become a "company that can continue to create new value."

Under Medium-Term Management Plan 08–10—Dynamic Synergy for 2015, which was formulated in 2008, the Company successfully generated steady results linked to future growth. We formulated the current plan as a roadmap to turning these results into true strengths and true value, as well as implementing a strong offense in management and achieving dramatic growth. The key concept of the current plan is New Value Creation. This expresses our strong determination to become a "company that can continue to create new value." We will build a management foundation for the discovery and global

provision of new drugs that respond to unmet medical needs, and we will strive to contribute to improving the quality of life for large numbers of patients around the world. I believe that this is our mission: providing a wide-range of value to society. The driving force behind these reforms will be sustained growth spiral. In addition to revenues/profits from existing business, we continually reinvest newly obtained revenues/profits from new products and royalties in R&D and in building a business platform to maximize product value. In this way, we generate the resources needed to continually create new

drugs and achieve sustained growth. Consequently, we will build a revenue/profit structure in which the revenues/profits from priority products and new products accounts for more than half of all profits.

Under the current plan, we have identified four strategic challenges to achieve sustained growth: Bolstering Our Ability to Discover New Drugs; Advancing Domestic Operations, Centered on New Products; Building a Foundation for the Expansion of Overseas Operations; and Accelerating Operational and Structural Reforms. By taking on these challenges, we will become a company with a pipeline of products that address unmet medical needs and the ability to implement stable investment in R&D. In this way, we will be able to implement reforms to become a "company that can continue to create new value."



#### Q. Please explain the four strategic challenges outlined in Medium-Term Management Plan 11-15.

#### We have clarified what we need to do in order to establish a sustained growth spiral.

Our numerical management objectives for fiscal 2015, the final year of the plan, are net sales of ¥500.0 billion and operating income of ¥100.0 billion. Over the five-year period covered by the plan, we will invest a cumulative total of more than ¥100.0 billion. Including the costs of in-licensing, we will maintain an aggressive pace of investment in R&D, at about ¥75.0 billion to ¥80.0 billion a year. For our new drug pipeline, our targets are to launch 10 new products and advance 8 products to late-stage development during the period covered by the plan, as well as to commence clinical trials for 3 development compounds each year. The four strategic challenges that I mentioned are the key measures needed to achieve these objectives.

In bolstering our ability to discover new drugs, we will create new value through the discovery of drugs that address unmet medical needs. Basically, we will conduct development in-house to the acquisition of POC\*, but we will not focus excessively on doing everything in-house. Our policy will be to choose the optimal method for continually launching new drugs and maximizing the product value of the drugs that we provide. As one method of achieving those goals, we will continue to strengthen our alliance strategy, under which we aggressively enter cooperative initiatives and work together with partners to build win—win relationships. We will also take steps to leverage external management resources, such as industry—government—academia tie-ups at the research stage, in-licensing and out-licensing at the development stage, and alliances at the sales stage.

In this way, we will take a flexible, open approach to the development and provision of new drugs.

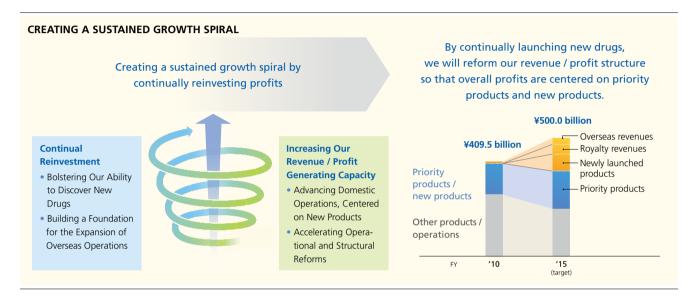
In advancing domestic operations, centered on new products, we will provide drugs with value, together with accurate information. We will strive to implement high-quality information provision activities so that we can provide more patients with Remicade and other priority products as well as with many new drugs that address unmet medical needs.

In building a foundation for the expansion of overseas operations, we will deliver products with value to more customers around the world. In the industrially developed U.S. and Europe, we will use our drugs in the renal disease field as a foothold to establish in-house business development. In addition, we have identified autoimmune disorders as our next field for focused business development activities. In emerging markets, we will work to rapidly launch products that have been approved in industrially developed markets, and we will aggressively promote products that match market characteristics and needs. In particular, in China we will rapidly commence development of diabetes treatment agents and schizophrenia treatment agents after they are approved in Japan or other industrially developed countries. These drugs include Radicut and Telavic. Our objective will be to generate overseas sales that account for 15% or more of our net sales and 40% of our operating income by fiscal 2015.

By accelerating operational and structural reforms, we will strive to become a company that can continually create new value. The Company will accelerate the consolidation and reorganization of the research, production, and head office functions, thereby realizing an organization with both improved productivity and lower costs and establishing an even more streamlined system.

In vaccine operations, we will in-license new technologies and products, centered on our relationship with BIKEN (The Research Foundation for Microbial Diseases of Osaka University). Also, in the generics business, in addition to cooperative initiatives within the Group, we will also consider further strategic alliances, targeting ¥50.0 billion in sales in fiscal 2015.

\* Confirmation that the mechanism is effective and safe in humans



#### MEDIUM-TERM MANAGEMENT PLAN 11-15: RESULTS IN THE FIRST YEAR

Q. Fiscal 2011 was the first year of the Medium-Term Management Plan 11–15. what results did the company achieve?

#### We made considerable progress during the year in preparing the foundation for strong growth in the future, including the launch of new products and steady progress in our development pipeline.

In fiscal 2011, the first year of the plan, we had substantial results in laying the groundwork for strong growth in the years ahead.

In Japan, we launched four new products: Lexapro, an antidepressant; Simponi, a treatment agent for RA; Imusera (Novartis brand name: Gilenya), an oral treatment agent for MS; and Telavic, a treatment agent for chronic hepatitis C. These products have all earned high degrees of satisfaction, and we expect their sales to increase in the future. We have succeeded in launching new drugs that have substantial value, both medically and in terms of their future contribution to our results. In our development pipeline, MP-513 and TP-7284 were advanced to the next development stage. These treatment agents for type 2 diabetes have different mechanisms of action. In August 2011, we filed an NDA for MP-513 (brand name: Tenelia), and manufacturing approval was received in June 2012. In addition,

in December 2011, our joint development partner BIKEN filed an application for BK-4SP, a pertussis-diphtheria-tetanus-inactivated polio combined vaccine. In July 2012, BIKEN received approval of this application. Among our existing products, Remicade plays a central role in our life cycle management strategy. We have acquired approval of an increased dosage for Remicade for Crohn's disease, and we have commenced trials for an additional indication for special types of Behcet's disease. We continue to step up our initiatives to maximize Remicade's product value. For example, we started trials for pediatric Crohn's disease in April 2012 and for severe Kawasaki disease and pediatric ulcerative colitis in May 2012.

Overseas, worldwide sales of Gilenya, which we out-licensed to Novartis, have increased rapidly, and the amount of royalty revenues that we received has started to record substantial growth. Gilenya is the world's only orally administered MS treatment agent, and it has earned a solid reputation in the marketplace as a drug that addresses unmet medical needs in the treatment of MS. With an estimated 2.5 million MS patients worldwide, Gilenya has the potential to grow into a blockbuster product. In addition, overseas, the development of TA-7284, which we licensed to Janssen Pharmaceuticals, has made favorable progress.

We also implemented reorganization measures as a part of our restructuring. In June 2011, we reached a basic agreement with the Japanese Red Cross Society to consider the integration of plasma

fractionation operations. After careful consideration of this integration, the two parties established a new corporation in June 2012, and plans call for operations to start in October. The establishment of this new corporation will contribute to Japan's national self-sufficiency in blood products through the use of economies of scale to reduce costs as well as through the maintenance of sound operations. Moreover, in July 2012 we transferred our fine chemical operations. Moving forward, we will strive to make further progress in focusing our management resources on our pharmaceutical operations.

#### **FISCAL 2012: INITIATIVES AND RESULTS FORECAST**

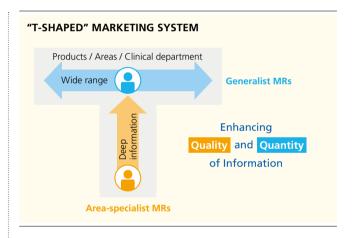
#### Q. Would you discuss the Company's initiatives in fiscal 2012?

## As in fiscal 2011, we will continue to push forward with sales and development of new drugs in fiscal 2012.

To reinforce our foundation for dramatic growth, we will provide "inspiring new drugs" and accurate information to patients.

In Japan, one of our focus products in fiscal 2012 will be Tenelia, a treatment agent for type 2 diabetes that was approved in June 2012. To rapidly enhance its presence in the highly competitive market for diabetes treatment, we reached an agreement on a strategic sales alliance with Daiichi Sankyo, which has sales capabilities that are in the top ranks in Japan. Daiichi Sankyo and Mitsubishi Tanabe Pharma will enter the diabetes market with a combined total of 4,000 MRs. We will move forward with the development of TA-7284, which has a new mechanism of action as a diabetes treatment agent—SGLT2 inhibition. We are aiming to file an application in Japan in 2013. First, it is important that we build a foundation in the diabetes market through sales of Tenelia, because the success of Tenelia will pave the way for the steady market penetration of TA-7284, which we will launch next.

We will also continue working to advance the market penetration of the four new drugs that we launched in fiscal 2011. Imusera and Telavic are innovative new drugs that could bring about a paradigm shift in treatment, but they also have the risk of side effects, and the implementation of an all-patient postmarketing surveillance was a condition of their approval. Accordingly, the provision of high-quality information by MRs will be important in ensuring that the sales of these products get off to a strong start. To accurately provide product information with a limited number of MRs, we will use a T-shaped marketing system (diagram on right), with reinforced links among generalist MRs and area-specialist MRs. In this way, we will rigorously implement



high-quality information provision and appropriate usage. In regard to Lexapro, we will strengthen the cooperation between Mochida Pharmaceutical, our joint sales partner, and Yoshitomiyakuhin, our consolidated subsidiary with strengths in psychiatric medications. We will take advantage of the opportunity presented by the lifting of the ban on long-term prescriptions in August 2012 in order to increase sales. In the year of their launch, the four new drugs—Lexapro, Simponi, Imusera, and Telavic—had combined sales of about ¥3.5 billion, and we are forecasting sales of more than ¥20.0 billion in fiscal 2012.

In addition, in 2012 Remicade, one of our priority products, marked the 10th year since it was launched with an indication of Crohn's disease, and the 9th year since it was launched for RA, its largest market. Over this period, we have steadily expanded indications through life cycle management, and in addition in April 2012 it became possible to shorten the infusion time. As a result,

the burden on patients and medical institutions has been lessened, and consequently further growth is expected. We are forecasting sales of ¥76.0 billion in fiscal 2012, an increase of ¥9.6 billion year on year. In the RA market, competition is expected to intensify due to the launch of drugs with new mechanisms of action, as well as biosimilars\*. Nonetheless, we will continue to strengthen our activities, aiming for combined sales of Remicade and Simponi of ¥100.0 billion.

On the other hand, in addition to continued in-house development, we will aggressively pursue strategic alliances, such as joint development and out-licensing. We licensed TA-1790, a treatment for ED, to Vivus, which filed an NDA in Europe in March 2012 and received approval in the U.S. in April 2012. In South Korea, licensee JW Pharma began sales of TA-1790 in October 2011. In addition,

TA-7284 has been licensed overseas to Janssen Pharmaceuticals, which filed NDAs in the U.S. in May 2012 and in Europe in June 2012. We expect royalty revenues from Gilenya to increase substantially in fiscal 2012. Moving forward, we expect TA-7284, like Gilenya, to become a product that contributes significantly to our results.

Future issues will include laying the foundation for new products, after the conclusion of the current medium-term management plan. To ensure that we can continue to discover new drugs, we will use the revenues from existing drugs as well as new sources of revenues, such as from new drugs and royalty revenues, to invest aggressively to achieve sustained growth.

\* Biopharmaceutical generics

#### Q. In consideration of these initiatives, please discuss the results forecast for fiscal 2012.

# By steadily nurturing new drugs, we will strive to offset the influence of NHI drug price revisions and achieve gains in sales and profits.

Our forecasts for fiscal 2012 are shown on the right. NHI drug prices were revised in April 2012, and we expect the effect on our sales to be about ¥20.0 billion. Ultimately, however, I think that we can achieve growth in sales on account of higher sales of Remicade and increased royalty revenues. On the other hand, we expect only a small increase in profits due to higher R&D expenses and to an increase in SG&A expenses related to new products.

FORECASTS FOR FY2012 (announced on May 8, 2012)					
	FY2011	FY2012 (estimate)	Change		
Net sales	¥407.1 billion	¥429.0 billion	5.4%		
Operating income	69.0 billion	70.0 billion	1.4%		
Net income	39.0 billion	40.5 billion	3.8%		

### Q. Would you discuss cooperative initiatives within the Mitsubishi Chemical Holdings Group (MCHC), of which Mitsubishi Tanabe Pharma is a member?

# As the core health care company in the MCHC Group, we will work to contribute to the realization of *KAITEKI* (comfort) society.

The MCHC Group, of which Mitsubishi Tanabe Pharma is a member, is advancing the provision of health care solutions that address unmet medical needs in a wide range of areas, including not just the treatment of disease but also health management, preventive health care, diagnosis, rehabilitation, and other areas. In April 2012, with the objective of promoting the commercialization of health care solutions, the Health Care Solutions Office was established in MCHC. I was appointed as mission coordinator

with responsibility for health care solutions. From this start, we will accelerate cooperation within the MCHC Group and alliances with external entities. As the core health care company in the MCHC Group, Mitsubishi Tanabe Pharma will work to contribute to the realization of *KAITEKI* society\*.

<sup>\*</sup> For further information on *KAITEKI* society, please see the MCHC website http://www.mitsubishichem-hd.co.jp/english/csr/feature/index.html

#### **REFORMING THE CORPORATE CULTURE**

#### Q. What is your approach to reforming the corporate culture?

# Targeting the realization of an "inspiring company," we are working to create a free and open-minded corporate culture.

Since I became president, I have asked the employees to work to make Mitsubishi Tanabe Pharma an "inspiring company," so that we can make dramatic progress toward becoming a global, research-driven pharmaceutical company. When I say "inspiring company," I mean a company in which all employees have confidence and pride and everyone works together to continuously discover and provide "inspiring pharmaceuticals." In October 2012, we will mark five years since the Company was established in 2007. Over that period, we have worked to create a free and open organization, and as a result a new corporate culture has begun to develop. In fiscal 2011, we were able launch several new drugs.

Providing new drugs that are useful around the world contributes to enhancing patients' QOL and improving the Company's results. Moreover, it also plays an important role in invigorating the Company as well as employees. Further, in December 2011 we launched Project NVC (New Value Creation), which aims to invigorate the organization by promoting in-house communication, centered on young and mid-career employees. Moving forward, together with these activities, we will also reform the awareness of all employees based on a solid ethical viewpoint, and we will strive to realize a corporate culture in which employees are proud of their company and inspired by their work.

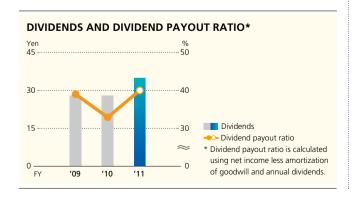
#### **SHAREHOLDER RETURN**

#### Q. Would you explain the Company's basic policy for the return of profits to shareholders?

# We are working to provide a return of profits by raising our target for the dividend payout ratio.

The Company's basic policy for the return of profits calls for providing a stable, ongoing return to shareholders while striving to maximize enterprise value by aggressively investing in future growth.

On that basis, under the medium-term management plan that began in fiscal 2011, we will increase the return of profits to share-holders through growth in profits as well as through an increase in the consolidated dividend payout ratio (prior to amortization of goodwill). Accordingly, we have raised the payout ratio from 35% to 40%.



In consideration of this basic policy and our results, for fiscal 2011 we set the year-end dividend at ¥20 per share. Together with the interim dividend, this resulted in an annual dividend of ¥35 per share, an increase of ¥7 per share year on year. The reason for this increase was our judgment that, in consideration of future results trends, we could provide a stable return of profits. Consequently, the consolidated dividend payout ratio, calculated on the basis of net income (less amortization of goodwill) and annual dividends, increased to 40.0%, from 32.9% in the previous fiscal year. In the future, our policy will be to increase the return to shareholders in line with progress in our performance.

Finally, the Company will take steady action and strive to achieve solid results as we continue working toward the numerical management objectives for fiscal 2015. Moreover, we will endeavor to ensure that all employees share our vision of "becoming a global research-driven pharmaceutical company that can be trusted by communities," and we will do our utmost to contribute to the health of people around the world through the discovery and provision of drugs that meet the expectations of patients in Japan and overseas.

#### **Special Features**



# Value Creation Business Model

Aiming to Become a "Company that Can Continue to Create New Value"

The new drug research and development process extends up to the point where drugs are placed on sale. This process, which includes pre-clinical testing and clinical trials, is known as the "drug discovery" process. After a drug's efficacy and safety are confirmed in these stages, sales of the drug commence after manufacturing and marketing approval is received. All drugs have the potential to cause unexpected side effects if they are not used properly, and there are many cases in which side effects that could not be predicted at the drug discovery stage are revealed after a drug is marketed.

Accordingly, even after a drug is launched, it is important to continually gather information, boost efficacy and safety, improve usage methods, and expand indications. In accordance with that approach, working to enhance the contribution of drugs to medical treatment is known as "post-marketing development."

This section introduces Mitsubishi Tanabe Pharma's business model through the Company's business activities in the two stages of drug discovery and post-marketing development. Our aim is to be a global, research-driven pharmaceutical company that continually creates and provides new drugs that are used around the world. To that end, we are taking steps to effectively utilize limited management resources and rapidly advance new drug development. Then, to ensure that more patients can use newly launched drugs with peace of mind, we are working to create new value through a business model that leverages our distinctive characteristics.



We complement our own strengths by leveraging external technologies and participating in strategic alliances in accordance with product characteristics. In this way, we are working to bolster our drug discovery capabilities and speed up the development process.

P.18 CASE STUDY 1

#### **Establishment of Marketing Franchise Areas**

Through our marketing and R&D activities, we have accumulated evidence and know-how in specific disease areas. In these areas, which we have positioned as marketing franchise areas, we are taking steps to continually strengthen our pipelines. In this way, we are working to utilize the foundation that we have developed as a platform for future profit opportunities as well as to further reinforce our business foundation.

### Strengthening Our Drug Discovery Capabilities, Including Through the Use of Cooperative Initiatives

In the identification of discovery targets, we are moving ahead with cooperative initiatives involving academic institutions in clinical development. In discovery chemistry, which is one of our strengths, we are enhancing the compound optimization function, including through the use of outside technologies. In addition, we have secured new biologics technologies from venture companies. These technologies will facilitate development in such areas as vaccines and orphan diseases.

#### **Speeding up Development Through Strategic Alliances**

We are strengthening our R&D system to facilitate the rapid acquisition of POC\*. Moreover, as an effective means of quickly launching new drugs in global markets, we are aggressively moving ahead with strategic alliances in line with product characteristics, such as out-licensing new drug candidates and concluding sales agreements.

\* Proof of Concept: Confirmation that the mechanism is effective and safe in humans.



We are working to maximize the value of products by advancing appropriate usage through effective information provision and safety management systems and by strengthening life cycle management (LCM).

P.20 CASE STUDY 2

#### **Strengthening Information Provision Systems**

To make the best use of our current MRs and provide accurate information about new products in our various fields of specialty, we are implementing qualitative reforms of our information provision system.

We are taking strategic steps to build a sales system for the careful, rapid provision of information to health care professionals. These include the establishment of a "T-shaped" marketing system as well as joint marketing and joint promotions with other companies.

#### **Bolstering Product Reliability Through Safety Management Systems**

Ethical pharmaceuticals are expected to offer high degrees of efficacy, but they also have the risk of side effects. Accordingly, appropriate usage is of the utmost importance.

For drugs that require special caution in their use, we take a rigorous approach to promotion activities, with a focus on appropriate usage. Through these initiatives, we are working to enhance the trust in our products and to expand our product sales over the medium to long term.

#### **Maximizing Product Value by Stepping Up LCM**

The maximization of product value through LCM initiatives, such as additional indications, is one of the Company's important strategies for the post-marketing development stage.

For example, Remicade, which in 2012 marked the 10th anniversary of its launch, has received additional indications following its launch. Remicade has grown into a drug that is required for patients, and as a result it is making a significant contribution to our revenues and profits.



# **Business Model** at the Drug Discovery Stage

### Development of Imusera, a Treatment Agent for Multiple Sclerosis

In developing new drugs, our approach is to strive to provide the drugs as rapidly as possible to the patients who are waiting for them. However, a lengthy period of time and a substantial amount of financial resources are required to develop a drug and move it forward to the start of sales. Accordingly, our research is focused on specific fields on which we focus our limited management resources. In addition, we are not overly committed to handling everything in-house. Rather, we are taking steps to speed up new drug development through strategic alliances with a wide range of partners. This section introduces our business model through the example of Imusera (Novartis sales name: Gilenya), a treatment agent for multiple sclerosis (MS) that was launched in Japan in November 2011.



#### Imusera, the World's First Innovative New Drug from Japan that respond to the Unmet Medical Needs of MS

MS is an autoimmune disease that results in lesions on nerve cells, such as on the brain, spinal cord, and optical nerves. Its cause is unknown, and it has a range of symptoms, such as numbness and other sensory disturbance, motor disturbance, visual disturbance, and fatigue. It is characterized by cyclical relapse and remission, and the use of a wheelchair may be unavoidable if the disease progresses. Currently, the number of MS patients is estimated to be about 2.5 million worldwide and about 15,000 in Japan. These numbers are increasing each year. The existing treatments are all injections, such as interferon, and the degree of satisfaction with these treatments is not sufficient.

Imusera, which was discovered by the Company, is a once-a-day oral formulation. As a result, in comparison with the existing injection treatments, Imusera has made it possible to significantly lower the burden on patients and health care workers. In addition, with a novel mechanism of action, Imusera's high level of efficacy has been confirmed. In comparison with the existing treatment agent interferon, the annual relapse rate is substantially lower. In this way, Imusera is a new drug that will contribute to improving the QOL of

patients around the world as a first-in-class\* drug that addresses the unmet medical needs of MS.

\* Innovative new drugs that are highly innovative and efficacious and substantially change the existing treatment system

#### Through the Utilization of In-House Discovery and Strategic Alliances, Imusera Has Been Developed with an Eye on Worldwide Markets

As a compound discovered in-house, Imusera was developed with an eye on worldwide markets from an early stage. Overseas, we licensed it to Novartis in September 1997, with Novartis receiving exclusive development and sales rights worldwide, except for Japan. Initially, Novartis began to develop it as a drug to suppress rejection following kidney transplantation, but the clinical trials did not demonstrate benefits that exceeded those of the existing standard treatment, and the trials were halted. Subsequently, Novartis began clinical trials overseas for MS. In August 2010, it was approved in Russia as the world's first oral drug for treating MS. From this start, as of June 2012 it had been approved in more than 60 countries around the world, including the U.S. and countries in Europe, and had been used in the treatment of more than 38,000 patients.

In Japan, the Company and Novartis Pharma, a Japanese subsidiary of Novartis, began clinical trials for MS in October 2007. An NDA was filed in December 2010, and approval was received in September 2011. Sales began in November 2011, with the Company using the name Imusera and Novartis Pharma using the name Gilenya.

In this way, Imusera/Gilenya is an example of success in the rapid provision of a new drug to patients around the world. Specifically, we used a strategic alliance that entailed out-licensing, from an early R&D stage, of a new candidate compound that was discovered in-house. In launching a drug overseas, one method is to develop and sell the drug in-house. However, the costs of developing a drug in fields such as circulatory and metabolism diseases are substantial, and the success rate is not high. With in-house development, this high risk is borne entirely by a single company. However, it is possible to reduce this risk by working together with a partner in a global-scale initiative to develop a new candidate drug that has been discovered in-house. Moreover, a large amount of evidence is acquired in global-scale clinical trials, and as a result it is possible to substantially reduce the time required to obtain approval in domestic and overseas markets.

We have also used this business model with TA-7284, a treatment agent for type 2 diabetes. Clinical trials for diabetes are implemented on an extremely large scale, and conducting them on our own in Europe and the U.S. would entail substantial development costs. Accordingly, we out-licensed TA-7284 to Janssen Pharmaceuticals for overseas markets. Overseas development has made favorable progress, and Janssen Pharmaceuticals filed NDAs in the U.S. in May 2012 and in Europe in June 2012. This drug has a new mechanism of action, SGLT2 inhibition. Favorable data has been obtained in clinical trials, and as a result we expect it to be approved rapidly, in the same way as Imusera and Gilenya.

## Rapidly Recovering Development Costs Through Royalty Revenues

Strategic alliances with other companies, such as the out-licensing of new drug candidates discovered in-house, have a range of merits that extend beyond simply reducing new drug development risks and speeding up the approval process. The royalty revenues that the Company receives by transferring development rights and sales rights make a major contribution to the early recovery of development costs. Our vision of becoming a global research-driven pharmaceutical company means that we will endeavor to become a company that can continually discover and provide pharmaceuticals that contribute to the healthier lives of people around the world. To continually discover and develop promising new drug candidates, a substantial amount of funding is required, and accordingly the royalty revenues obtained through alliances are an important source of funds that ensure the smooth progress of R&D activities.

In fiscal 2011, we recorded rapid growth in technology outlicensing revenues, which rose to ¥9.5 billion, or about four times the previous year's level, due in part to growth in Gilenya royalty revenues. We are forecasting further growth in fiscal 2012, to ¥14.0 billion, due to further growth in Gilenya royalty revenues.

In fiscal 2015, the final year of the medium-term management plan, we expect to receive royalty revenues from TA-7284 as well as Gilenya. We anticipate operating income to reach about ¥40.0 billion, with more than half attributable to royalty revenues.

This series of initiatives at the R&D stage comprises our business model for maximizing the value of drugs that we have discovered. This strategy comprises the cornerstone of the achievement of sustainable growth as an global research-driven pharmaceutical company.

#### **TOPICS**

Imusera Received the Pharmaceutical Society of Japan Award for Drug Research and Development and the Harushige Inoue Award.

In March 2012, Imusera received the Pharmaceutical Society of Japan Award for Drug Research and Development from the Pharmaceutical Society of Japan. Each year, this award is presented to a maximum of two researchers who have achieved research results that are innovative and contributed to medicine, specifically in the discovery of drugs or in the development of applied pharmacology technologies related to drug discovery. As a sphingosine-1-phosphate (S1P1) receptor functional antagonist, Imusera has an innovative method of action. In addition, its development as the world's first oral drug for MS has been highly evaluated. This award, which was established in 1998, was received by calcium antagonist Herbesser (from the former Tanabe Seiyaku) in the first year of the awards and by Radicut (from the former Mitsubishi Pharma) in 2003.

In July 2012, Imusera also received the Harushige Inoue Award from the Japan Science and Technology Agency (JST). Harushige Inoue was the first President of the Research Development Corporation of Japan, one of the predecessors of the JST. He was also the first Director-General of the Agency of Industrial Science and Technology. This award was established in 1976 in consideration of his results in contributing to the progress of science and technology in Japan. In principle, the award is presented to a maximum of two recipients per year, and the recipients are generally researchers or companies with outstanding results in contributing to the progress of science and technology in Japan, as well as to economic growth and social development, specifically with technologies that are based on innovative research results originating in academic settings that are subsequently developed and commercialized by companies. The receipt of the award by Imusera is an indication of the high evaluation of Imusera's innovativeness and its impact on medical treatment.



# **Business Model** at the Post-Marketing Development Stage

# Targeting Steady Market Penetration of New Drugs and Expansion of Remicade

The Company has launched a series of drugs with value, such as Lexapro, Simponi, Imusera, and Telavic, and we are moving into a period in which we will have a large number of new drugs on the market. In fiscal 2012, for example, we plan to launch another new drug for type 2 diabetes. However, to steadily nurture new drugs in the market it is essential that we implement high-quality drug information provision activities and establish safety management systems for each drug. We are strengthening our systems to ensure product safety and reliability through the effective use of our human resources. Also, we are working to maximize the product value of Remicade and other core products by continuing to expand indications.



#### Specialist Units Support MRs in T-Shaped Marketing System

After launching four new drugs in fiscal 2011, we will launch another new drug for diabetes in fiscal 2012. With a large number of new drugs on the market, the role of the MRs, who provide information to health care institutions and doctors about drugs and their appropriate usage, is growing steadily more important. However, increasing the quality and quantity of information that is provided is not an issue that can be resolved simply by increasing the number of MRs. We will work to maximize product value by building systems for the efficient and effective use of our current management resources. To resolve that issue, we built a new information provision system, a T-shaped marketing system.

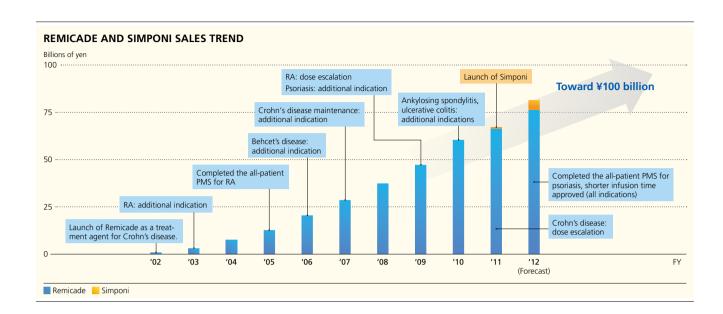
In Japan, the Company has about 1,600 generalist MRs who handle a wide range of clinical departments. However, it will be necessary to provide highly specialized information in the future. The T-shaped marketing system that the Company has built facilitates the provision of support for the generalist MRs by area-specialist MRs who have deep levels of knowledge in specialized fields. Under this system, the generalist MRs will continue to deliver a wide range of products and area-related information to hospitals and other medical facilities,

while the area-specialist MRs will support the activities of the generalist MRs with highly specialized, high-quality information that has been gathered from inside and outside the Company. In addition, through such measures as the use of IT and the establishment of two-way networks, we will strengthen our on-demand information provision system in line with individual needs on the medical front lines.

Furthermore, the entire Group will focus its efforts to promote the market penetration of the anti-depressant Lexapro, such as bolstering cooperative initiatives with Yoshitomiyakuhin, a subsidiary of the Company.

## Telavic: Aiming for Rapid Growth while Maintaining the Highest Priority on Safety

Innovative new drugs that are expected to have high levels of therapeutic efficacy also have risks, such as side effects. If a mistake is made in their use, they will not make a sufficient contribution to patient treatment. In regard to new drugs that require special caution in their use, we take a rigorous approach to promoting appropriate usage by medical institutions and to ensuring safety and reliability through post-marketing surveillance activities. As a result of these initiatives, these drugs can be used by patients for long periods of



time with peace of mind, leading to greater market penetration and sales.

Through sales activities that place the highest priority on safety, Remicade has earned trust on the medical front lines and grown into a major drug. In the same way, we will nurture Telavic, a treatment for chronic hepatitis C that was launched in fiscal 2011. Telavic is Japan's first protease inhibitor that acts directly on the hepatitis C virus and inhibits its proliferation. In clinical trials, it demonstrated high efficacy, even with patients that did not respond to existing treatments. In addition, with Telavic it is possible to shorten the treatment period by half in comparison with existing treatments. In this way, Telavic is an innovative drug that reduces the burden on patients. On the other hand, it has also shown side effects, such as anemia and skin problems. A condition of its approval was the implementation of postmarketing surveillance for all patients (all-patient surveillance). The Company has assigned Telavic specialists to its branches, about 50 in total, and established a system to support MRs in promoting appropriate usage. While maintaining the highest focus on safety, we are providing appropriate usage information to medical institutions. Externally, we have established the Appropriate Usage Committee, which is auditing and providing guidance for the all patient surveillance. As of the end of June 2012, the number of registered patients had surpassed 5,000. By rapidly completing the all-patient surveillance and establishing the safety profile of Telavic, we can obtain the trust of patients and medical institutions.

## Ensuring Remicade Continues to Address Unmet Medical Needs Through Advancement of LCM

Remicade, which has recorded strong growth and become one of our core products, marked the 10th anniversary of its launch in 2012. Remicade is an anti-TNF $\alpha$  monoclonal antibody that targets TNF $\alpha$ , an

inflammatory cytokine. It is a biologic that is effective against inflammatory autoimmue diseases. We in-licensed Remicade from Janssen Pharmaceuticals in 1993 and developed it in Japan. Remicade was launched in 2002 for the treatment of Crohn's disease. Since then, it has steadily received additional indications for the treatment of rheumatoid arthritis (RA), Behcet's disease with refractory uveoretinitis, psoriasis, ankylosing spondylitis, and ulcerative colitis, and sales have recorded substantial growth. Moreover, to address the needs of the medical front lines, certain changes in usages/dosages were approved. In addition, it has become possible to use a shortened infusion time.

Remicade is a biologic that was said to be difficult to handle when it went on sale. As a result, it has taken some time to penetrate the market. However, Remicade has begun to establish a position as an innovative drug that addresses unmet medical needs by offering a dramatic improvement over conventional treatments for a variety of intractable diseases. Since its launch, Remicade has been used to treat more than 50,000 RA patients and more than 80,000 patients for all indications combined, and it has contributed to improving the QOL for large numbers of patients. By steadily accumulating efficacy and safety evidence, we have obtained solid evaluations for Remicade on the medical front lines, and at the same time we have obtained additional indications through LCM. The post-marketing development of Remicade showcases our business model for maximizing product value over the long term. We are currently implementing clinical trials for additional indications for inflammatory autoimmune diseases. The sales of Remicade reached ¥66.3 billion in fiscal 2011, and are expected to reach ¥76.0 billion in fiscal 2012. Moreover, we are aiming to achieve, as rapidly as possible, total combined sales of ¥100.0 billion for Remicade, which is an intravenous injection, and Simponi, an anti-TNF $\alpha$  monoclonal antibody with a different route of administration, subcutaneous injection.

#### Overview of Medium-Term Management Plan 11-15

Under the Medium-Term Management Plan 11–15, the Company is moving forward with initiatives to become a "company that can continue to create new value." To that end, we formulated four strategic challenges. This section introduces those challenges and the progress made in fiscal 2011.

#### **STRATEGIC CHALLENGE 1**

# Bolstering Our Ability to Discover New Drugs

During the period covered by the current plan, our targets are to establish a pipeline and to build discovery capabilities that will enable us to launch 10 new products and advance 8 products to late-stage development by fiscal 2015, as well as to commence clinical trials for 3 development candidates each year. With those objectives, we are striving to strengthen our new drug discovery capabilities.

Our research strengths include compound optimization in the process extending from the discovery of targets to the discovery of development compounds. By utilizing the technologies of academic institutions, venture companies, and others, we will further enhance our in-house strengths and use them to facilitate drug discovery.

Further, through marketing and R&D activities we have accumulated evidence and know-how in specific disease areas, including autoimmune diseases, diabetes, and kidney diseases. We have positioned these areas as marketing franchise areas.

In addition to the areas in which we have special strengths, we will also take on challenges in new disease areas that pose a high level of unmet medical needs. As we strive to continually bolster our pipeline, our initiatives will also include in-licensed products and technologies as well as drugs discovered in-house.

#### **STRATEGIC CHALLENGE 2**

# Advancing Domestic Operations, Centered on New Drugs

During the period covered by the plan, we plan to launch a number of new drugs that will have an impact both medically and economically. Drugs can best demonstrate their true value and contribute to improving the QOL of patients if they are accompanied by accurate information. Accordingly, we will provide a lineup of drugs that address unmet medical needs, together with accurate information based on global evidence, to more patients around the world.



#### SALES POLICIES IN JAPAN

Provide lineup of drugs that respond to unmet medical needs, together with reliable information based on global evidence, to as many patients as possible

#### Remicade

- Further enhance product presence
- High-quality information provision activities as a leading company



#### New Products / Existing Priority Products

- New products: Focus on promoting appropriate usage
- Priority products: Steady promotion
- Post-marketing development of products: Nurturing together with patients, medical professionals

#### **STRATEGIC CHALLENGE 3**

# Building a Foundation for the Expansion of Overseas Operations

We have divided our overseas operations into industrially developed markets, such as the U.S. and Europe, and emerging markets in Asia, centered on China. On that basis, we implement business development activities in



accordance with local market conditions.

In industrially developed markets, we will conduct operations in-house—from development to marketing—for kidney diseases and for critical orphan diseases, including autoimmune diseases. In other disease areas, aiming to maximize product value as rapidly as possible, we will fully utilize a range of measures, such as cooperative initiatives with other companies, and provide drugs to these markets.

In emerging markets, we will work to rapidly launch products that have been approved in Japan, the U.S., or Europe. Furthermore,

in China and other Asian countries we will launch products that match market characteristics and needs, such as hepatitis and infectious disease treatment agents.

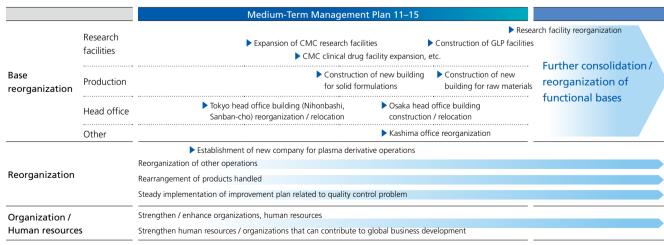
#### **STRATEGIC CHALLENGE 4**

# Accelerating Operational and Structural Reforms

To become a company that can continue to create new value, we must establish a streamlined system and strengthen the organizational and human resources that will support that system.

Since its founding by the merger, the Company has taken steps to consolidate and reorganize its bases and functions. During the period covered by the plan, we will continue these initiatives and accelerate consolidation and reorganization in such areas as research, production, and head office functions, thereby establishing an organization with both improved productivity and lower costs. In addition, aiming to maximize the value of each business and achieve overall optimization of the Mitsubishi Tanabe Pharma Group, we will implement operational and structural reforms as we move forward.

#### SCHEDULE OF WORKSITE, STRUCTURAL, AND ORGANIZATIONAL REFORMS



# Progress during the First Fiscal Year (Fiscal 2012) of the Medium-Term Management Plan

#### Progress in Domestic Pharmaceutical Operations Enhancing Our Lineup of Products with Value

In fiscal 2011, in domestic pharmaceutical operations we made notable progress in such areas as the development and launching of new drugs and the implementation of life cycle management (LCM) for priority products. We achieved considerable success in these endeavors.

For example, we launched four new drugs with value for patients: Lexapro, an antidepressant; Simponi, an anti-TNF $\alpha$  monoclonal antibody; Imusera, a multiple sclerosis treatment agent; and Telavic, a chronic hepatitis C treatment agent. Some of these drugs require special caution in prescription practices. Consequently, we will continue to implement promotion activities, with a focus on appropriate usage, as we strive to steadily increase their market penetration.

Furthermore, we also made progress with two drugs for type 2 diabetes that we have discovered and developed in-house.

One is MP-513, a DPP-4 inhibitor. We filed an NDA for MP-513 in August 2011, and approval was received in June 2012. We plan to begin sales around September, under the brand name Tenelia.

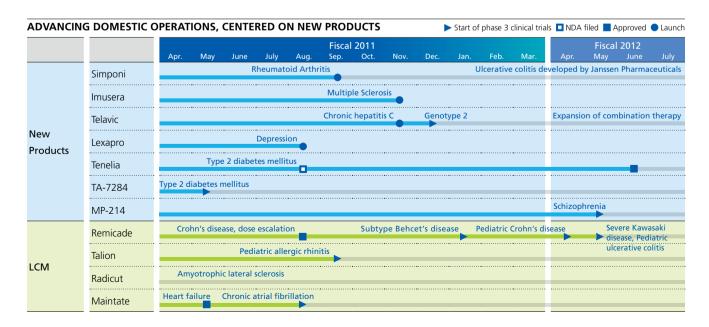


While Tenelia is the fifth DPP-4 inhibitor in Japan, it is the first such drug that was originated in Japan, from discovery to development. With once-a-day administration, Tenelia has potent and sustained action in the improvement of post-prandial high blood glucose levels, from after breakfast to after the evening meal. In addition, it has the advantage of being eliminated via two routes—the liver and the kidneys.

The other is TA-7284, an SGLT2 inhibitor. We started phase 3 clinical trials in May 2011, and we expect to file an NDA in 2013. TA-7284 inhibits SGLT2, a transporter involved in the reabsorption of glucose in the renal tubules, thereby controlling the reabsorption of glucose and promoting its excretion in the urine. In addition to this new mechanism of blood-glucose-lowering, TA-7284 also has a weight loss action. In March 2012, we reached agreement with Daiichi Sankyo on a strategic sales alliance to conduct joint sales activities for these two drugs. Moving forward, we will work to achieve rapid market penetration.

#### **Progress with LCM**

We are making steady progress with LCM initiatives. In August 2011, approval was received for an increased dosage for the use of Remicade in the treatment of Crohn's disease. In addition, we started a number of phase 3 clinical trials, for special types of Behcet's disease, pediatric Crohn's disease, severe Kawasaki disease, and pediatric ulcerative colitis. Moreover, we also launched clinical trials in fiscal 2011 for the purpose of obtaining additional indications for Maintate, Talion, and Telavic. In these ways, we are working to maximize product value in a way that contributes to the treatment of more patients.



#### Progress in Development of Out-Licensed Products Overseas and in Other Overseas Operations

### Contribution from Royalty Revenues and Progress in Development of Out-Licensed Products

Sales of Gilenva, which was discovered by the Company and developed overseas by Novartis, began in 2010. Sales of this drug recorded favorable growth in fiscal 2011, and the resulting royalty revenues have begun to make a contribution to our results. Licensees are also making favorable progress with the development of other drugs that we have out licensed. In April 2012, Vivus received approval in the U.S. for TA-1790, for ED, and Vivus filed an application in Europe in March 2012. In South Korea, JW Pharma began sales of TA-1790 in October 2011. In addition, for TA-7284, a treatment for type 2 diabetes, Janssen Pharmaceuticals filed an NDA in the U.S. in May 2012 and in Europe in June 2012. Data announced at the May 2012 meeting of the American Diabetes Association demonstrates the blood alucose lowering effect and the weight reduction effect of TA-7284. There is a high probability that this drug will become a blockbuster after its launch, and, like Gilenya, we expect it to make a substantial contribution to our results in the future.

#### Progress in Operations in the U.S. and Europe

In the kidney disease area, in August 2011 we filed an application for MCI-196, for hyperphosphatemia, in Europe. In October 2011, we concluded a licensing agreement with Toray for development and sales in North America of MT-9938 (TRK-820), a treatment agent for pruritus. In Japan, Torii Pharmaceutical has sold REMITCH since 2009. In North America, the Company plans to begin clinical trials for its use for pruritus in dialysis patients, the same as in Japan. In the field of autoimmune diseases, which will be our next focus area after the kidney disease field, we are implementing phase I clinical trials in Europe for MT-1303, for multiple sclerosis. Also, in June 2012 we began sales in the U.K. of Argatroban, a selective antithrombin agent (brand names: Exembol in the U.K., and Novastan HI Injection in Japan). This drug, which was discovered by the Company, is currently sold in 11 countries in Europe, including Germany and France, as a treatment agent for heparin-induced thrombocytopenia (HIT) type II.

#### **Progress in China and Other Asian Markets**

In China, our policy is to steadily develop new drugs that have already been approved in Japan. Currently, we are preparing to file an IND for MP-424 (brand name in Japan: Telavic), a treatment agent for hepatitis C. Moreover, we are preparing to rapidly develop MP-513 (brand name in Japan: Tenelia), a treatment agent for type 2 diabetes, after it is launched in Japan.

Furthermore, in May 2011 we started sales of Talion for allergic disorders in China and Indonesia, and in March 2012 we commenced sales of Simponi in Taiwan. In addition, we began sales of pitavastatin calcium (brand name in Japan: Livalo Tablets) for hypercholesterolemia in Indonesia in May 2012 and in Taiwan in June 2012.

## Progress in Operational and Structural Reforms Integration of Plasma Derivative Operations

The Company has been engaged in discussions targeting the integration of the plasma fractionation operations of the Japanese Red Cross Society and Benesis, a consolidated subsidiary of the Company. As a result of these deliberations, the two parties agreed to commence operations from October 2012, following the establishment of the Japan Blood Products Organization in June 2012, and the transfer of each party's plasma fractionation operations to the new organization.

In July 2012, we withdrew from the fine chemical business with the transfer of our pharmaceutical ingredient manufacturing and sales operations to API Corporation and our food chemical operations to TAISHO TECHNOS. Moving forward, we will strive to make further progress in operational and structural reforms.

#### **Bolstering Domestic Foundation in Vaccine Business**

Mitsubishi Tanabe Pharma is also moving forward with the introduction of competitive new vaccine products and technologies based on the sales foundation that the Company has established through its initiatives in the vaccine business. In January 2012, we licensed HibTITER, a Haemophilus influenza type B (Hib) vaccine from Nuron Biotech, of the U.S. Moving forward, we will develop this vaccine in Japan. Moreover, in February 2012 we concluded an agreement with Medi cago, of Canada for joint research into next-generation vaccines.

There have been strong demands from society for an inactivated polio vaccine. In December 2011, BIKEN filed an application, and received its approval in July 2012, for a pertussis-diphtheria-tetanus-inactivated polio combined vaccine. We also participated in the development of this vaccine. Moving forward, we will work aggressively in the field of preventive medicine through the launch of vaccines utilizing new technologies, centered on our cooperative relationship with BIKEN.

#### **Relocation of Tokyo Head Office**

In May 2012, we relocated the Tokyo head office, consolidating bases that had previously been dispersed in the Tokyo area. In addition to the consolidation of bases, the relocation is also intended to increase operational efficiency and communications among organizational units in accordance with the concept of "proposals for new styles of working."

### **State of New Product Development**

As of July 31, 2012

				Stage		
Development code (Generic name)	Category	Indications	Phase 1 2	3	NDA filed	Origin (Remarks)
New Molecular Entities		indications	1 2		NDA IIIed	(Remarks)
		T. 2 P. L				
TA-7284 (Canagliflozin)	SGLT2 inhibitor	Type 2 diabetes mellitus				In-house
MP-214 (Cariprazine)	D3/D2 receptor antagonist	Schizophrenia				Hungary: Gedeon-Richter
MP-435	C5a receptor antagonist	Rheumatoid arthritis				In-house
MT-4666	α7nAChR agonist	Alzheimer's disease				US: EnVivo Pharmaceuticals
MT-3995	Selective mineralocorticoid receptor antagonist	Hypertention				In-house
MT-1303	Sphingosine-1-phosphate receptor functional antagonist	Multiple sclerosis				In-house
				Stage		
Product name (Generic name)	Category	Indications	Phase 1 2	3	NDA filed	Origin (Remarks)
Additional Indications	editegory	indications .			1157 timed	(terraino)
Venoglobulin IH (Polyethylene glycol-treated human normal immunoglobulin)	Human immunoglobulin G	lgG2 deficiency			Dec. 1997	In-house
		Systemic scleroderma				
Radicut (Edaravone)	Free radical scavenger	Amyotrophic lateral sclerosis <sup>1</sup>				In-house
Maintate (Bisoprolol)	Selective β1 blocker	Chronic atrial fibrillation				Switzerland: Merck Serono
Talion (Bepotastine)	Selective histamine H1 receptor antagonist, anti-allergic agent	Pediatric allergic rhinitis				Japan: Ube Industries
Telavic (Telaprevir)	NS3-4A protease inhibitor	Chronic hepatitis C (genotype 2)				US: Vertex Pharmaceuticals
Tenelia (Teneligliptin)	DPP-4 inhibitor	Type 2 diabetes mellitus, additional combination				In-house
Remicade	Anti-TNFα monoclonal antibody	Subtype Behcet's disease				US: Janssen Biotech
(Infliximab [recombinant])		Pediatric Crohn's disease				
		Severe Kawasaki disease				
		Pediatric inflammatory bowel disease				
Cholebine (Colestimide (JAN))	Non-absorbed phosphate binder	Type 2 diabetes mellitus				In-house
(Colestiffice (JAN))	Bile acid signal regulation	Hyperphosphatemia				
		Orphan drug designated				

				Stage	
Development code Generic name)	Category	Indications	Region	Phase 1 2 3 NDA filed	Origin (Remarks)
New Molecular En	tities				
MCI-196 Colestilan (INN))	Non-absorbed phosphate binder	Hyperphosphatemia	EU	Aug. 2011	In-house
ИР-146	Uremic toxin adsorbent	Chronic kidney disease	US, EU		Japan: Kureha
/IP-513 (Feneligliptin)	DPP-4 inhibitor	Type 2 diabetes mellitus	EU		In-house
3 1 7			US —		
GB-1057 Human serum albumin recombinant])	Recombinant human serum albumin	Stabilizing agent	US	_	In-house
A-8995	CETP inhibitor	Dyslipidemia	EU		In-house
ЛР-124	PARP inhibitor	Acute ischemic stroke	US, Canada		In-house
MT-3995	Selective mineral corticoid receptor antagonist	Hypertension	EU	_	In-house
MP-157	Angiotensin type 2 receptor agonist	Hypertension	EU		In-house
ЛТ-1303	Sphingosine-1-phosphate receptor functional antagonist	Multiple sclerosis	EU		In-house
ИТ-7716	NOP receptor agonist	Alcohol-use disorder	US		In-house
LICENSING-OUT					
evelopment code				Stage Phase	
Development code Generic name)	Category	Indications	Region	Phase 1 2 3 NDA filed	Licensee
evelopment code Generic name) A-1790	Category PDE5 inhibitor	Indications Erectile dysfunction	Region EU	Phase 1 2 3 NDA filed	Licensee US: Vivus
evelopment code Generic name) A-1790 Avanafil)				Phase 1 2 3 NDA filed Mar. 2003	US: Vivus US: Janssen
evelopment code Generic name) A-1790 Avanafil)	PDE5 inhibitor	Erectile dysfunction	EU	Phase 1 2 3 NDA filed Mar. 2003	US: Vivus
evelopment code Generic name) A-1790 Avanafil)	PDE5 inhibitor	Erectile dysfunction	EU	Phase           1         2         3         NDA filed           Mar. 2003	US: Vivus US: Janssen
Development code Generic name)  TA-1790 Avanafil)  TA-7284 Canagliflozin)	PDE5 inhibitor	Erectile dysfunction  Type 2 diabetes mellitus	US EU	Phase           1         2         3         NDA filed           Mar. 2003	US: Vivus US: Janssen
Avanafil)	PDE5 inhibitor  SGLT2 inhibitor	Erectile dysfunction  Type 2 diabetes mellitus  Obesity	US EU US, EU	Phase           1         2         3         NDA filed           Mar. 2003	US: Vivus  US: Janssen Pharmaceuticals <sup>2</sup> Korea: Handok Pharmaceuticals
A-1790 Avanafil) A-7284 Canagliflozin) AP-513 Teneligliptin) Te-0047 Firategrast)	PDE5 inhibitor  SGLT2 inhibitor  DPP4 inhibitor  Cell adhesion inhibitor	Type 2 diabetes mellitus  Obesity  Type 2 diabetes mellitus	EU  US  EU  US, EU  Korea	Phase           1         2         3         NDA filed           Mar. 2003	US: Vivus  US: Janssen Pharmaceuticals <sup>2</sup> Korea: Handok
Avanafil) Avanaf	PDE5 inhibitor  SGLT2 inhibitor  DPP4 inhibitor  Cell adhesion inhibitor [α4β7 /α4β1 inhibitor]	Erectile dysfunction  Type 2 diabetes mellitus  Obesity  Type 2 diabetes mellitus  Multiple sclerosis	EU US EU US, EU Korea EU	Phase           1         2         3         NDA filed           Mar. 2003	US: Vivus  US: Janssen Pharmaceuticals <sup>2</sup> Korea: Handok Pharmaceuticals  UK: GlaxoSmithKline
A-1790 Avanafil) A-7284 Canagliflozin) AP-513 Feneligliptin) -0047 Firategrast) AKC-242	PDE5 inhibitor  SGLT2 inhibitor  DPP4 inhibitor  Cell adhesion inhibitor [α4β7 /α4β1 inhibitor]  5-HT1A receptor agonist	Erectile dysfunction  Type 2 diabetes mellitus  Obesity  Type 2 diabetes mellitus  Multiple sclerosis	EU  US  EU  US, EU  Korea  EU	Phase           1         2         3         NDA filed           Mar. 2003	US: Vivus  US: Janssen Pharmaceuticals²  Korea: Handok Pharmaceuticals  UK: GlaxoSmithKline  US: MediciNova  Japan: Senju
evelopment code Generic name)  A-1790 Avanafil)  A-7284 Canagliflozin)  AP-513 Geneligliptin)  -0047 Girategrast)  MKC-242  -39983  MT-210  TU-199	PDE5 inhibitor  SGLT2 inhibitor  DPP4 inhibitor  Cell adhesion inhibitor [α4β7 /α4β1 inhibitor]  5-HT1A receptor agonist  ROCK (rho-kinase) inhibitor	Erectile dysfunction  Type 2 diabetes mellitus  Obesity  Type 2 diabetes mellitus  Multiple sclerosis  Insomnia  Glaucoma	EU  US  EU  US, EU  Korea  EU  US  Japan	Phase           1         2         3         NDA filed           Mar. 2003	US: Vivus  US: Janssen Pharmaceuticals²  Korea: Handok Pharmaceuticals  UK: GlaxoSmithKline  US: MediciNova  Japan: Senju Pharmaceutical
Development code Generic name)  CA-1790 Avanafil)  CA-7284 Canagliflozin)	PDE5 inhibitor  SGLT2 inhibitor  DPP4 inhibitor  Cell adhesion inhibitor [α4β7 /α4β1 inhibitor]  5-HT1A receptor agonist  ROCK (rho-kinase) inhibitor  5-HT2A / Sigma2 receptor antagonist	Erectile dysfunction  Type 2 diabetes mellitus  Obesity  Type 2 diabetes mellitus  Multiple sclerosis  Insomnia  Glaucoma  Schizophrenia  Gastroesophageal reflux	EU  US  EU  US, EU  Korea  EU  US  Japan  EU	Phase           1         2         3         NDA filed           Mar. 2003	US: Vivus  US: Janssen Pharmaceuticals²  Korea: Handok Pharmaceuticals  UK: GlaxoSmithKline  US: MediciNova  Japan: Senju Pharmaceutical  France: Cyrenaic

#### **Overview of Core Ethical Drugs and Sales Trends**

The sales forecasts in this section were announced on May 8, 2012.

#### **Core Products**

#### Remicade Infliximab

Treatment of RA, Crohn's disease, psoriasis, ulcerative colitis, Behcet's disease with refractory uveoretinitis, and ankylosing spondylitis

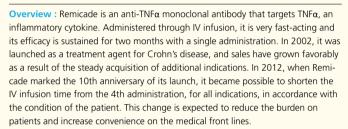
Launch: May 2002

Origin: Janssen Biotech (U.S.)

**Development**: Mitsubishi Tanabe Pharma

Net sales: ¥66.3 billion

domestic : ¥66.3 billion overseas : ¥30 million



Sales trend: Sales in fiscal 2011 were up 9.8%. Under the April 2012 NHI drug price revisions, the price of Remicade was increased due to the addition of a premium for usefulness. In fiscal 2012, we anticipate a contribution to sales from the use of Remicade for ulcerative colitis, for which an additional indication was received in 2010, and for Crohn's disease, for which an increased dosage was approved in 2011. In addition, since May 2012, it is possible to shorten the IV infusion time for patients with no safety problems, which is expected to increase the number of patients to whom the drug is administered due to a reduced burden for patients and reduced space and personnel burdens for medical institutions. The sales forecast for fiscal 2012 is ¥76.0 billion.

#### Radicut Edaravone

#### Cerebral neuroprotectant

Launch: June 2001

Origin: Mitsubishi Tanabe Pharma

**Development:** Mitsubishi Tanabe Pharma

Net sales: ¥22.4 billion

Overview: Radicut, which was developed in Japan, is the world's first cerebral neuroprotectant (free radical scavenger) shown to improve neurological symptoms at the acute stage of cerebral infarction, interference with activities of daily living, and functional disability. It inhibits damage to brain cells



## 2013.4 ## T424

and protects cerebral blood vessels and cells. It is indicated for the treatment of three major types of cerebral infarction (cerebral lacunar, atherothrombotic infarction, and cardiogenic embolism). Administration is started within 24 hours after onset, and it is not administered for more than 14 days. In 2010, we launched an IV infusion bag formulation.

Sales trend: Sales in fiscal 2011 were down 21.6%. In fiscal 2012, we expect conditions to remain difficult due to the influence of the launch of generics and to the influence of reduced prices for long-term listed drugs under the April 2012 NHI drug price revisions. Consequently, we are forecasting sales of ¥14.5 billion in fiscal 2012. Nonetheless, we are conducting special usage research related to treatment within 4.5 hours of cerebral infarction, including combined use with tissue plasminogen activator (t-PA), a thrombolytic agent. Radicut will make a continued contribution to the treatment of cerebral infarction.

#### Maintate Bisoprolol

Treatment of hypertension, angina pectoris, arrhythmia and chronic heart failure

Launch: November 1990

Origin : Merck Serono (Switzerland)

**Development**: Mitsubishi Tanabe Pharma

Net sales: ¥13.9 billion

domestic : ¥13.6 billion overseas : ¥0.2 billion

Overview: Maintate is a representative β blocker used

in more than 100 countries around the world. It exhibits high selectivity for  $\beta 1$  receptor and excellent pharmacokinetics profiles. It has high efficacy and safety, and there is evidence for its cardioprotective action. It has a high share of the domestic  $\beta$  blocker market, about 22%, and it is one of the Company's highest priorities in promotions. In 2011, an additional indication was approved for chronic heart failure.

Sales trend: Domestic sales in fiscal 2011 were up 11.3%. In May 2011, Maintate received an additional indication for chronic heart failure, strengthening its distinctive position as a  $\beta$  blocker with cardioprotective action. As a result, sales substantially increased. In fiscal 2012, we will continue promotional activities using evidence regarding cardioprotective action. The sales forecast for fiscal 2012 is  $\pm 14.5$  billion.

#### **Talion** Bepotastine

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#### Treatment of allergic disorders

Launch: October 2000

Origin: Ube Industries

**Development :** Co-development with Ube

Industries

Net sales: ¥14.0 billion

domestic: ¥13.3 billion overseas: ¥0.6 billion

Overview: Talion has rapid onset of anti-histamine (H1) effects and is effective for allergic

rhinitis, urticaria, and pruritus accompanying dermatitis. It has minimal incidence of sedation. In 2007, an additional formulation, orally disintegrating tablets, was added.

Sales trend: Although in spring 2012, pollen was relatively low throughout the country, domestic sales were down only 0.6% in fiscal 2011 in a substantially contracting market for anti-histamines. In fiscal 2012, we will step up promotion activities for pruritus accompanying dermatitis, which is less susceptible to the influence of pollen trends, and aim for further growth. The sales forecast for fiscal 2012 is ¥16.5 billion.



#### **New Products**

#### Kremezin Spherical carbon adsorbent

Treatment of chronic kidney diseases

Start of sales by the Company : April 2011

Origin : Kureha

Development : Kureha



Overview: Kremezin is an oral absorptive charcoal consisting of porous spherical activated carbon of high purity. Kremezin, which absorbs and excretes uremic toxins out of the body in chronic renal failure, has been highly evaluated on the medical front lines for its ability to improve symptoms of uremia, delay the commencement of dialysis, and control the decline of renal function. It was introduced to the Japanese market in December 1991 as the world's first ethical drug for chronic kidney diseases. In April, 2011, the marketing rights were transferred from Daiichi Sankyo to Mitsubishi Tanabe.

Sales trend: The Company's activities have shown results, and sales recorded favorable growth. We will focus on the ability to control the decline of kidney function, which is highly anticipated, and work to further expand sales in fiscal 2012. The sales forecast for fiscal 2012 is ¥12.5 billion.

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#### Telavic Telaprevir

#### Treatment of chronic hepatitis C

Launch: November 2011

Origin: Vertex Pharmaceuticals (U.S.)

**Development : Mitsubishi Tanabe Pharma** 

Net sales: ¥1.4 billion



Overview: Telavic has been positioned as a first-in-class oral drug for treating chronic hepatitis C. It inhibits hepatitis C virus (HCV) proliferation by inhibiting NS3-4A serine protease, which is involved in HCV replication. For patients with chronic hepatitis C affected by genotype 1 virus, which includes a large number of Japanese patients, it has been shown that combination therapy of three drugs (pegylated interferon + ribavirin + Telavic) improves therapeutic efficacy and shortens the treatment period, compared to the current standard therapy. In addition, it is expected to offer a new treatment opportunity to patients for whom the conventional treatment was not effective.

Sales trend: To conduct the all-patient surveillance that was a condition of its approval, the number of facilities at which it will be available is limited, but registration is making favorable progress, and in fiscal 2012 we will promote this drug while maintaining careful attention to safety. The sales forecast for fiscal 2012 is ¥10.0 billion.

#### Lexapro Escitalopram

#### Treatment of depression

Launch: August 2011

Origin: H. Lundbeck (Denmark)

**Development**: Mochida Pharmaceutical

Net sales: ¥1.2 billion

Overview: Lexapro, a selective serotonin reuptake inhibitor (SSRI) was launched in 2002 and is currently used in 96 countries and regions. Among SSRIs, it has the highest serotonin transporter selectivity. In clinical

settings, its superior efficacy for depression and depressive symptoms and good tolerability have been confirmed. In addition, it has simple administration, and as a result it is expected to contribute to the improvement of medication adherence, which is especially important in patients with depression. We are conducting joint sales activities with Mochida Pharmaceutical.

Sales trend: Growth in the market for depression has begun to slow, and there are many competing products. As a result, Lexapro faced somewhat difficult conditions in the first year after its launch. From April 2012, we have further strengthened the joint promotion conducted by Mochida Pharmaceutical, Mitsubishi Tanabe Pharma, and Yoshitomiyakuhin. In addition, in August the ban on long-term prescriptions will be removed, and we will respond by working to expand prescriptions. The sales forecast for fiscal 2012 is ¥6.0 billion.

#### Simponi Golimumab

#### Treatment of RA

Launch: September 2011

Origin: Janssen Biotech (U.S.)

**Development**: Co-development with Janssen Pharmaceutical

Net sales: ¥0.9 billion

Overview: Simponi is a human TNF $\alpha$  monoclonal antibody that targets TNF $\alpha$ , an inflammatory cytokine. With simple administration—subcutaneous injection once every four weeks—it has superior efficacy that continues for an extended period of time. Its efficacy and safety are higher than other subcutaneous injections, and it is expected to contribute to raising the number of patients who continue treatment. It has an indication for RA (including prevention of articular structural damage), and we are conducting joint sales with Janssen Pharmaceuticals. In addition, Janssen Pharmaceutical is currently conductings clinical trials for ulcerative colitis.

Sales trend: Competition in the RA market is increasing, but since its launch in September 2011, it has recorded favorable sales growth. In fiscal 2012, accompanying the expansion of the market, we will leverage the experience in the RA market that we have accumulated with Remicade to work to expand sales of Simponi. The sales forecast for fiscal 2012 is ¥5.5 billion.

#### **VACCINES**



Net sales: ¥30.3 billion

domestic: ¥28.8 billion overseas: ¥1.5 billion

The Company sells vaccines developed and produced by BIKEN. Due primarily to the launch of vaccines that competed with Mearubik, a live attenuated measles and rubella combination vaccine, and JEBIK V, a freeze-dried, cell-culture derived Japanese encephalitis vaccine, domestic sales of vaccines were down 2.8%, to ¥28.8 billion. In fiscal 2012, the market environment is expected to be challenging, and the sales forecast is ¥28.0 billion. Nonetheless, we will continue working to support educational activities for vaccination and to contribute to increases in the vaccination rate.

#### **Corporate Social Responsibility**

Mitsubishi Tanabe Pharma strives to be a pharmaceutical company that earns the trust of society by demonstrating deep respect for the many types of stakeholders who make up society.



#### **For Patients**

The Company is working to further enhance the reliability of pharmaceuticals in order to be able to continually ensure their effectiveness, quality, and safety throughout the pharmaceutical life cycle (from research to post marketing). In particular, in production and supply we have built a global production system, including Group plants and contract production facilities in Japan and overseas, so that the pharmaceuticals that are produced and supplied can be used with peace of mind by patients. With this system, we are supplying products to a wide variety of people around the world. In the production of pharmaceuticals, we draw on the wide range of technologies and knowhow that we have cultivated over many years to test the raw materials that are procured from Japan and overseas when they are received and to manufacture and test pharmaceutical ingredients and formulations in accordance with GMP. GMP standards in Asia have been made stricter, and in October 2011 Tianjin Tanabe Seiyaku, a manufacturing and sales company in China, became the first company in Tianjin to acquire the new GMP certification. As a means of strengthening our supply chain, we implement "CSR purchasing," under which we confirm the status of the CSR initiatives of our suppliers. Moreover, drawing on the lessons learned from the Great East Japan Earthquake, we are implementing Business Continuity Management (BCM) so that we can provide a stable supply, even in times of large-scale disaster, of emergency-use drugs and of drugs for which an interruption in the supply would have a significant adverse

effect on medical institutions and patients. Furthermore, to realize a more-robust pharmaceutical supply system, we unified the quality policies for all of the Group's plants in fiscal 2011.

In safety measures, we collect safety information after a drug is launched and implement appropriate safety management. In addition, we take steps to minimize the risks to patients. We are also conducting pharmaceutical safety training for executives and for all employees, including employees of Group companies. Moreover, we will continue to implement measures to prevent a recurrence of the Medway problem or quality control problems, as well as business improvement measures. We will continue to strive to provide high-quality pharmaceuticals that can be used by patients with peace of mind.

In R&D, we are conducting discovery research and clinical trials with consideration for bioethics. In research that uses human-derived samples, the ethical and scientific appropriateness of the testing is carefully considered by the Ethics Review Committee. For animal testing, international rules form the basic doctrine, and the testing is conducted after the Animal Experiment Committee investigates the appropriateness of the testing plan. In addition, in clinical testing we comply with the ICH-GCP (standards for the implementation of clinical testing of pharmaceuticals), which were formulated in accordance with the spirit of the Declaration of Helsinki.

#### **For Employees**

We endeavor to develop human resources who maintain high ethical standards, place the highest priority on fairness and integrity, and act in accordance with the standards Pride and Sense of Mission, Challenge and Innovation, Trust and Teamwork, and Harmonious Coexistence with Society. To create a corporate culture in which employees can work toward personal success while channeling their energies toward strengthening the Company, we established the Comprehensive Management System for Human Resources. We are working to develop personnel from a medium- to long-term perspective. From fiscal 2011, we commenced a next-generation leader development program with the objective of systematically developing senior management candidates and a global personnel development program that has a focus on future global development.

Further, in December 2011, with the objective of activating the Group's organization, we launched Project NVC (New Value Creation). We are implementing a range of initiatives, such as interdepartmental exchange programs and the revision of work frameworks and rules.

Furthermore, we continue to implement initiatives in such areas as the introduction of systems that place importance on consideration for the work-life balance of employees, mental health management, and employee diversity, as well as education about human rights.

#### For Local Communities

We are implementing a range of activities for local communities, patients, and their families.

To facilitate interaction among people who are participating in volunteer activities and those who are interested in volunteering, we have been holding the MSC Volunteer Salon, which consists of lectures and mini-concert gatherings, every other month since 1968.

Also, to foster patient-centered medicine, we support the activities of patients' association activities, including sharing information and supporting volunteers. In March 2011, in cooperation with the Japan Spinocerebellar Degeneration & Multiple System Atrophy Society, we sponsored lectures that were open to the public.

From July 2011 to March 2012, the Mitsubishi Chemical Holdings Group (MCHC) provided support for employee volunteer activities in the regions affected by the Great East Japan Earthquake. During this period, about 40 employees of the Group participated in these activities, which included the clearing of rubble.

#### For the Environment

To promote environmental conservation and contribute to the realization of a sustainable society, the Group is working to track the influence of each of its business activities on the environment and to reduce their environmental burden, and to that end we independently and proactively engage in environmentally friendly activities. In addition, we are disclosing environmental information and taking steps to promote environmental communications, such as environmental and social contribution activities.

Energy conservation and the prevention of global warming are positioned as the Group's highest priority environmental objectives. In the environmental medium-term management plan (2011–2015), we have set the goal of reducing CO<sub>2</sub> emissions in fiscal 2015 by more than 30% from the level in fiscal 2005. In addition, we are also working to reduce waste and emissions of chemical substances. In addition, as a member of the MCHC Group, we are striving to realize a *KAITEKI* (comfort) society through reductions in environmental burdens, such as those from greenhouse gases.

In the summer of fiscal 2011, the influence of the Great East Japan Earthquake was another factor affecting energy consumption, and we took steps to save electricity at all of our domestic worksites. In addition, we worked to raise employee awareness. As a result, the quantity of electricity consumed from July to September was down 20% year on year at the Toda office and 27% in the Tokyo head office area. In addition, Choseido Pharmaceutical has taken advantage of long sunlight hours by installing photovoltaic power generation equipment on the roof of the Kawauchi Plant (Tokushima City, Tokushima Prefecture).

In regard to vehicles used in sales activities, we have reduced the number of vehicles in comparison with the previous year. Moreover, we have increased the number of environmentally friendly vehicles, such as electric vehicles and hybrid vehicles, to about 50% of our total business vehicles. In these ways, we are working to reduce CO<sub>2</sub> emissions.

In May 2012, we consolidated the operations in the Nihonbashi building and the Sanban-cho building of our Tokyo head office, into the Nihonbashi Koamicho district. The new Nihonbashi building is leased, but environmental initiatives were implemented through cooperation between the owner of the building and the Company. This building, which includes photovoltaic power generation and LED lighting, received an S ranking under the Comprehensive Assessment System for Building Environmental Efficiency (CASBEE). The building reflects appropriate consideration for both the work environment and the natural environment.

In addition, our environmental and social contribution activities include employees and their families. In October 2011, the head office and the Kashima office participated in simultaneous cleanup activities that were implemented prior to the Osaka marathon. Participants in these activities included residents, companies, and the Osaka City government.



The Company issues a CSR Report, which provides information about specific CSR initiatives.

#### **TOPICS**

#### Selection for FTSE4Good Index Series

Mitsubishi Tanabe Pharma has been included in the FTSE4Good Index Series, a leading index for responsible investing (RI), for nine consecutive years.



FTSE4Good

#### FTSE4Good Index Series

FTSE4Good is an RI index created by the FTSE Group. Based on FTSE Group original standards, companies that fulfill a certain level of CSR activities are selected for inclusion in the index. As of the end of March 2012, the index included 975 companies, including 181 Japanese companies, out of a total of about 2,700 companies from 25 countries.

#### **Corporate Governance and Internal Control**

### Strengthening Corporate Governance and Internal Controls

The Mitsubishi Tanabe Pharma corporate philosophy is "to contribute to the healthier lives of people around the world through the creation of pharmaceuticals," and our vision is "to be a global research-driven pharmaceutical company that is trusted by communities." To realize the corporate philosophy, fundamental policies for the maintenance of internal control systems have been established by the Board of Directors. We are implementing a range of initiatives to strengthen our corporate governance and internal controls. Also, once a year reports are made to the Board of Directors on the current status of the fundamental policies, and revisions are made if necessary.

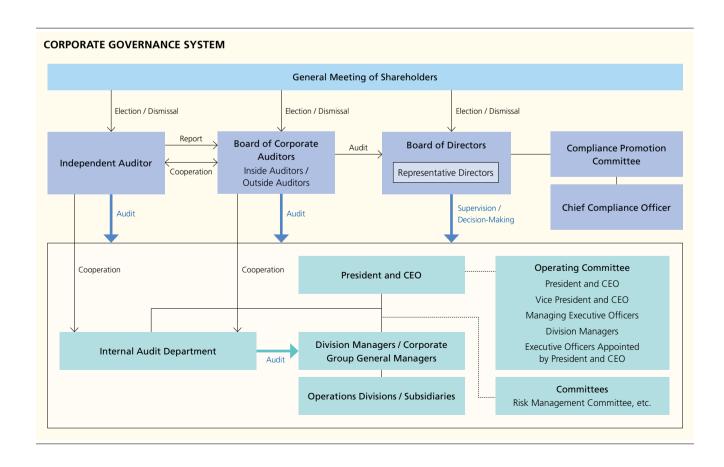
#### **Corporate Governance System**

The Company has adopted the corporate auditor system. In addition to the General Meeting of Shareholders and the Directors, the Company has established the Board of Directors, Corporate Auditors, and the Board of Corporate Auditors and employs an independent auditor. In June 2011, the Company began to utilize outside directors, and two outside directors with high levels of independence were appointed. These directors have abundant experience as corporate managers and wide-ranging knowledge

in science, technology, and corporate governance. Under this management system and auditing system, the Company has identified its most important issues as fulfilling its responsibilities to shareholders and all other stakeholders and working to maximize enterprise value. To that end, the Company works to ensure efficiency and speed in management decision-making and to ensure transparency and objectivity in management by enhancing the supervision and auditing conducted by the outside directors and by enhancing the auditing system, centered on the corporate auditors. In these ways, the Company is working to establish a corporate governance system that can earn the trust of society.

#### **Management System**

The Board of Directors has eight members, two of whom are outside directors. Regular meetings of the Board of Directors are held once a month, and in addition are held flexibly as needed. The Board makes decisions about business execution and supervises operational execution. The Company has adopted the corporate officer system for the execution of Company business and clarified the distinction between the decision-making / auditing function and the executive function. The Operating Committee, which includes the President and CEO, Senior Managing Executive Officers, Managing Executive Officers,



and executive officers who are appointed by the President and CEO, meets two or more times per month as a general rule. The committee discusses issues of importance to the overall execution of Company business, and important matters are brought up for discussion in the Board of Directors. In this way, the Company works to enhance the speed and effectiveness of decision-making.

#### **Auditing System**

The Board of Corporate Auditors has four members, two of whom are outside corporate auditors. The Board of Corporate Auditors receives reports on the progress of audits by all corporate auditors and the independent auditor. Lawyers, who are legal specialists, and people with experience in banks or securities companies are nominated to be outside corporate auditors. At the same time, people with considerable knowledge in finance, accounting, or law are nominated to be standing corporate auditors. In this way, the Company has established an auditing system with high levels of independence and specialized skills.

Corporate auditors attend important meetings, such as meetings of the Board of Directors and the Operating Committee. In addition, they conduct interviews on the execution of duties with the Board of Directors, executive officers, and members of each Company division, review documents relating to major decisions, and investigate the operations and assets of principal worksites and subsidiaries (including internal control systems, such as those for compliance and risk management). In these ways, the corporate auditors audit the execution of Company business.

The Board of Corporate Auditors works to maintain close ties with the independent auditor and the internal auditing divisions and to strengthen the auditing function. The corporate auditors also receive explanations of audit plans and policies and quarterly reports on audit implementation and results from the independent auditor, as well as regularly exchange opinions with the independent auditor. When necessary, the corporate auditors witness on-site work and review work by the independent auditor. At the end of each period the corporate auditors receive reports on the execution of audits by the independent auditor. Also, in regard to audit plans, progress, and results, the corporate auditors exchange opinions with the internal auditing divisions on a regular monthly basis. At the same time, the corporate auditors receive reports on the results of the evaluation of internal control systems for financial reporting.

To provide support for the corporate auditors in the execution of their duties, including the duties of the outside corporate auditors, the Company has established the Corporate Auditors' Office, which is independent from business execution. The Corporate Auditors' Office has three full-time staff.

For internal auditing, the Company has established the Internal Audit Department, which is independent from the executive divisions

and audits the internal control systems in operations divisions. The Internal Audit Department has 13 employees.

The Company has taken steps to facilitate proper audits, appointing Ernst & Young ShinNihon LLC as its independent auditor and providing accurate management information.

#### **Nomination of Outside Officers**

To enhance management transparency and objectivity and to strengthen the Board of Directors' supervisory function, two outside directors have been nominated. Furthermore, two outside corporate auditors have been nominated. From an independent perspective, these outside corporate auditors implement audits regarding the legality and soundness of management.

In nominating outside officers, the Company has not established standards, etc., regarding independence. The outside officers have been nominated in consideration of the reason for nomination and relationships with the Company, as described on the following page. The four people meet the requirements of the Tokyo Stock Exchange and the Osaka Securities Exchange for independent officers, and the Company has reported them as independent officers to both exchanges.

#### **Compensation of Directors and Corporate Auditors**

The Company has adopted a method of calculating director compensation that reflects the Company's results. The compensation amount is determined by the Board of Directors within a range fixed at the General Meeting of Shareholders and as provided for by the basic formula for the calculation of compensation for the Board of Directors. This is to ensure the transparency of compensation-related decision-making.

In the year ended March 31, 2012, directors' compensation (for six directors; excluding outside directors) amounted to ¥263 million and corporate auditors' compensation (for three corporate auditors\*; excluding outside corporate auditors) totaled ¥66 million. Compensation for outside officers (for four officers) was ¥37 million. The Company and consolidated subsidiaries paid ¥75 million and ¥19 million, respectively, to Ernst & Young ShinNihon LLC as compensation for auditing and verification.

\* Includes 1 corporate auditor who retired at the 4th Ordinary General Meeting of Shareholders held on June 22, 2011.

### Other Special Matters that May Have a Significant Impact on Corporate Governance

In regard to the independence of the Company from its parent company, Mitsubishi Chemical Holdings (MCHC), both companies have agreed that, in principle, for 10 years from October 1, 2007, the Company will remain listed and Mitsubishi Chemical Holdings will maintain its shareholding ratio in the Company. Both companies have also agreed that the Company will be operated based on the

principle of independent decisions and judgment as a publicly listed company. The Company believes that it has secured its independence from its parent company.

MCHC is a pure holding company that does not conduct its own operating activities. Accordingly, between MCHC and the Company, there are no transactions that have the potential to significantly influence the results of the Company, and there are no plans to engage in such transactions in the future. The Company has concluded a contract with MCHC under which the Company provides payment to MCHC for Group management expenses in an amount equivalent to the benefits received based on the brand value and comprehensive strengths of MCHC. However, the amount of those payments is not significant.

In regard to transactions between the Company and other companies in the MCHC Group, in making decisions the highest priority is given to increasing the enterprise value of the Group in order to maximize the benefit to all of the Company's shareholders.

The Company received administrative actions in April 2010 for the Medway problem and in July 2011 for the quality control problem. The Company has reflected deeply on these problems. To recover the trust of society, the Company is working earnestly to rigorously implement recurrence prevention as well as business improvement measures. To further advance these measures, the Company established the Outside Committee for Recovering Trust Following the Medway and Quality Control Problems. The committee is conducting investigations and providing advice. Matters such as progress with the business improvement plan are reported in this committee as needed. The committee had met 15 times by the end of May 2012. In September 2011, the committee offered a report regarding advice on quality control and quality assurance operations. Subsequently, in accordance with that advice, the Company took steps to facilitate progress in business improvement and to restore trust, such as holding lectures by doctors and pharmacists.

#### NAME OF OUTSIDE OFFICER, RELATIONSHIPS BETWEEN OUTSIDE OFFICERS AND THE COMPANY, AND REASON FOR NOMINATION

	Relationships between outside officers and the Company	Reason for nomination
Shigehiko Hattori Outside director	Shigehiko Hattori is Representative Director, Chairman of the Board of Shimadzu and an outside director of Sapporo Holdings and Brother Industries. There are no special conflicts of interest between the Company and Shimadzu, Sapporo Holdings, or Brother Industries.	Shigehiko Hattori was nominated as outside director on account of the Company's judgment that his abundant experience as a corporate manager and his wide-ranging knowledge in science and technology would be useful in the Company's management. In addition, in the Company's judgment there is no cause for concern about a conflict of interest between Shigehiko Hattori and public shareholders, and he has been designated as an independent officer.
Seishiro Yoshioka Outside director	Seishiro Yoshioka is a Corporate Advisor at Osaka Gas. There are no special conflicts of interest between the Company and Osaka Gas.	Seishiro Yoshioka was nominated as outside director on account of the Company's judgment that his abundant experience as a corporate manager and his wide-ranging knowledge in corporate governance would be useful in the Company's management. In addition, in the Company's judgment there is no cause for concern about a conflict of interest between Seishiro Yoshioka and public shareholders, and he has been designated as an independent officer.
Masanao lechika Outside corporate auditor	Masanao lechika is Executive Partner at Daiichi Law Office. There are no special conflicts of interest between the Company and Daiichi Law Office.	Masanao lechika was nominated as outside corporate auditor in the anticipation that he would conduct appropriate audits based on his abundant experience as an attorney and his high level of knowledge in regard to social responsibility. In addition, in the Company's judgment there is no cause for concern about a conflict of interest between Masanao lechika and public shareholders, and he has been designated as an independent officer.
Takashi Nishida Outside corporate auditor	Takashi Nishida holds a concurrent post as a corporate auditor at MCHC, which is the parent company of the Company. Due to the importance of Group auditing, he is serving concurrently as an outside corporate auditor of the Company. There are no special conflicts of interest between Takashi Nishida and the Company. In addition, Takashi Nishida previously worked at The Bank of Tokyo-Mitsubishi UFJ, with which the Company engaged in banking transactions. However, he has already retired from that bank, and there are no special conflicts of interest between that bank and the Company.	Takashi Nishida was nominated as outside corporate auditor in the anticipation that he would conduct appropriate audits based on his abundant financial institution experience and wide-ranging knowledge in finance. In addition, in the Company's judgment there is no cause for concern about a conflict of interest between Takashi Nishida and public shareholders, and he has been designated as an independent officer.

#### **Risk Management System**

Mitsubishi Tanabe Pharma has established risk management regulations with the objective of implementing appropriate management for the risks that accompany the Company's business activities, and the Company has established and operates a system based on those regulations. In accordance with these regulations, the Company has established the Risk Management Committee, which is led by the president. The Group regularly identifies, analyses, and evaluates the risks that it faces. In implementing these measures, we ascertain the areas and types of risks that we face in our business activities, including the risks faced by Group companies, and ensure that the necessary countermeasures for each risk are implemented by the relevant department. In preparations for times when it appears that risk events that could give rise to serious damage, such as disasters, accidents, or the emergence of new diseases, might occur, we have established a Companywide system for minimizing damage while continuing business activities, such as providing important pharmaceuticals and meeting customer needs.

#### **Compliance System**

To ensure sound business activities, Mitsubishi Tanabe Pharma has formulated the Corporate Behavior Charter, which identifies the top priorities for directors and employees in the implementation of business activities, and the Mitsubishi Tanabe Pharma Group Code of Conduct, which provides specific behavioral guidelines. In accordance with the code, members of the Board of Directors and Board of Corporate Auditors take the lead in strictly adhering to laws, regulations, and the Company's Articles of Incorporation. Also, the Company is taking steps to create a Companywide compliance system, including the establishment of the Compliance Promotion Committee and the Internal Controls & Compliance Department,

both of which are led by the Chief Compliance Officer. The provision of gains and any other relationships with groups that act in an antisocial manner are forbidden. Furthermore, we have formulated guidelines for checking suppliers for any possible affiliations with such antisocial elements. In this way, we have established a system for eliminating transactions with antisocial elements.

Furthermore, we have established an internal notification system managed according to internal regulations, which operates as an internal system for reporting on legal violations and other compliance issues. We have established internal and external hotlines for reports and consultations, and are working to respond to a wide variety of needs for consultation, including for the employees of Group subsidiaries.

To ensure a solid compliance foundation, the Company is conducting a range of training. These include top seminars for directors and officers, Companywide training for all employees, and human rights training, as well as department-level training that deals with issues specific to the operations of each department. For Group subsidiaries, we are taking steps to build a system to ensure appropriate operational activities are implemented in a seamless manner with the Company, such as building a system for the application of the Company's Compliance Program.

Furthermore, we conduct compliance progress checks once a year, and implement monitoring of such factors as compliance awareness and workplace environments.

### **Accountability to Stakeholders**

In order to promote understanding of the Company and to obtain fair evaluations of the Company, Mitsubishi Tanabe Pharma strives to disclose in a fair, timely, and appropriate manner important Company information related to its activities, such as its management policies, management objectives, and financial

#### **CORPORATE BEHAVIOR CHARTER**

We will maintain high ethical standards, place priority on fairness and integrity in all activities, and act in accordance with the following guidelines.

PRIDE AND SENSE OF MISSION

As people involved in the creation of pharmaceuticals, we will work with pride and a sense of mission as we endeavor to research and develop pharmaceuticals that are needed by society and to ensure product safety and quality.

CHALLENGE AND INNOVATION

With acute sensitivity and a broad perspective, we will focus on our future direction, decisively take on the challenge of meeting higher goals, and strive to create innovative value.

TRUST AND TEAMWORK

Through free and open communication, we will promote mutual understanding and respect, and we will emphasize teamwork as we strive to maximize our results based on strong relationships of trust.

HARMONIOUS COEXISTENCE WITH SOCIETY

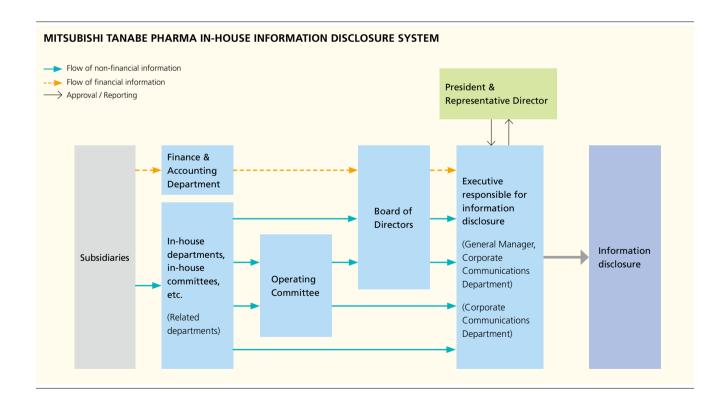
We will work to achieve harmonious coexistence with society by acting with consideration for local communities and the environment.

situation, to all of its stakeholders, including shareholders, investors, patients and healthcare workers, and local communities. We adhere to the Financial Instruments and Exchange Law and other Japanese laws and regulations relating to information disclosure and stock exchange regulations for listed securities. Also, based on our information disclosure regulations, and in accordance with the relevant internal systems, we ensure that both the content and timing of our information disclosure is fair to all stakeholders. Moreover, as a member of society, we take feedback from all stakeholders seriously, strive to share information with stakeholders, and work to deepen mutual understanding.

We give a range of presentations to explain the Company's financial situation, describe the development of new products, and explain important management policies and business developments. These presentations include results briefings for institutional investors, R&D presentations, and business presentations. To enable individual and overseas investors to access presentations, the audio and video for presentations, as well as for the Q&A sessions, can be viewed on the Company's website. We also report on our CSR initiatives in our CSR Report.

#### **In-House Information Disclosure System**

The Company has established an in-house system to implement Companywide disclosure of company information in a timely and appropriate manner—the Mitsubishi Tanabe Pharma In-House Information Disclosure System. The executive responsible for information disclosure will control the in-house system, which was established in accordance with information disclosure regulations; will determine whether or not disclosure of company information is appropriate; and will implement disclosure.



# Messages to Shareholders and Investors from the Outside Directors

To ensure management transparency and objectivity and to strengthen the Board of Directors' oversight function, Shigehiko Hattori and Seishiro Yoshioka were appointed as outside directors in June 2011.

A message from each of the outside directors is presented below.

Looking at the Mitsubishi Tanabe Pharma Group from an outside perspective, there is a clear commitment to the proper fulfillment of the Group's responsibility to provide explanatory information, both inside and outside the Group, and an awareness that the Group is heading in the right direction. Meetings of the Board of Directors are also conducted in a manner that makes it easy for outside directors to state their views. To help ensure that business execution is handled in an appropriate manner, as an outside director I offer necessary opinions from an outside viewpoint.

Pharmaceuticals is an important business that is entrusted with people's lives and does not permit even the smallest mistake. It is also a business that simultaneously requires solid defense and strong offense. The only companies that will survive are those that take on the challenge of drug discovery, starting at zero and creating results that lead to the development of new drugs.

In defense, I make judgments based on common sense and generally accepted ideas and state my views at meetings of the Board of Directors. In offense, on the other hand, it is necessary to have a specific strategy for overseas markets, especially in the premium market segment. In implementing the Medium-Term Management Plan 11–15, a key strategy will be to develop overseas markets. To that end, the next step will be to focus on our position in global markets as and identify regions and fields where needs are high. One fundamental duty of outside directors is to offer opinions from an outside viewpoint in order to facilitate appropriate business execution. In addition to that duty, I will also strive to provide opinions about the expansion of overseas business, based on my overseas experience at Shimadzu.

In the future, I will continue to do my utmost to fulfill my duties as an outside director and to meet the expectations of the Company's stakeholders in a manner that fosters the realization of a management system that can support simultaneous progress in both solid defense and strong offense.



Shigehiko Hattori Director, Mitsubishi Tanabe Pharma Chairman of the Board and Representative Director, Shimadzu Corporation

As a member of the Board of Directors, the duties of an outside director are to participate in the decision-making of the Board of Directors and to supervise business execution from an independent viewpoint. In making decisions, key points of focus include whether a policy contributes to the sound development of the Company over the long term and whether appropriate risk evaluation and management is being implemented. In addition to these two points, I am continually aware of the responsibility to provide explanatory information to shareholders and other stakeholders.

Previously, I worked in energy business management at Osaka Gas. Pharmaceuticals and energy are certainly different industries, but I believe that the fundamental elements of business decision-making are the same. There is no change to the essential nature of an operating company, which works to achieve sustained growth while fulfilling its social responsibilities by effectively and soundly creating and providing goods and services that are useful in society.

At meetings of the Board of Directors, points of discussion regarding resolutions, including the nature of the risks involved, are presented without omission, and discussions are held from a diverse range of viewpoints. Also, in regard to risk management, I believe that the recognition, evaluation, and handling of risks is being conducted in an appropriate manner, in accordance with the basic policies for internal control. In my judgment, the various organizations that support the Group's corporate governance are functioning in a sound and appropriate manner.

The Medium-Term Management Plan 11–15, which deals with the Group's comprehensive strengths and true value, will determine the Group's future. In these initiatives, I believe it is extremely important to create a free and open-minded corporate culture with a greater sense of unity. Based on that type of awareness, Project NVC was launched in December 2011, and I look forward to its success. Moving forward, I will strive to advance the medium-term management plan from that viewpoint and to provide advice as needed.



Seishiro Yoshioka Director, Mitsubishi Tanabe Pharma Corporate Advisor, Osaka Gas Co., Ltd.

# **Board of Directors and Auditors**

As of July 1, 2012



# Directors

#### Michihiro Tsuchiya

President & Representative Director, Chief Executive Officer

#### Kuniaki Kaga

### Representative Director,

#### Senior Managing Executive Officer

Division Manager of Research Division, General Manager of International Business Unit, International Strategy & Operation, Internal Controls & Compliance Department Chief Compliance Officer

#### Kenichi Yanagisawa

#### Board Director,

# Senior Managing Executive Officer

Division Manager of Sales & Marketing Division, Tokyo Head Office,

Medical Intelligence Department

#### Kenkichi Kosakai

#### Board Director,

#### Managing Executive Officer

Corporate Management

Corporate Management Department, Finance & Accounting Department,

Corporate Communications Department,

Human Resources Department,

Human Resources Development Department

#### Masayuki Mitsuka

# Board Director,

# Managing Executive Officer

Division Manager of Development Division, General Manager of Medical Science Department

#### Takashi Kobayashi

#### Board Director,

# Managing Executive Officer

Business Unit,

Responsible for Special Assignments from the President, Products Quality Issue Management Office,

Products Quality issue Management Office,

Business Coordination Office,

OTC Business Department,

Generics Business Department,

Plasma Products Business Office

### Shigehiko Hattori

Board Director (outside)

#### Seishiro Yoshioka

Board Director (outside)

#### **Auditors**

#### Junji Hamaoka

Corporate Auditor (standing)

# Koichi Fujisawa

Corporate Auditor (standing)

#### Masanao lechika

Corporate Auditor (outside)

#### Takashi Nishida

Corporate Auditor (outside)



# **Financial Section**

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# **Six-Year Financial Summary**

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries

	2012/3	2011/3	2010/3	2009/3	2008/3 <sup>1</sup>	2007/3
Financial figures (billions of yen):						
Net sales						
Tanabe Seiyaku	¥407.1	¥409.5	¥404.7	¥414.7	¥ 315.6	¥177.5
Mitsubishi Pharma					[409.4]	227.5
Cost of sales						
Tanabe Seiyaku	152.2	154.5	147.8	158.1	113.4	69.0
Mitsubishi Pharma					[150.5]	79.9
Selling, general and administrative expenses						
Tanabe Seiyaku	185.8	178.3	195.4	184.8	148.2	78.1
Mitsubishi Pharma					[186.4]	107.5
Operating income						
Tanabe Seiyaku	69.0	76.5	61.4	71.6	54.0	30.4
Mitsubishi Pharma					[72.4]	39.9
Net income						
Tanabe Seiyaku	39.0	37.7	30.2	26.5	21.9	20.1
Mitsubishi Pharma					[31.9]	24.3
R&D expenses						
Tanabe Seiyaku	70.2	65.7	83.0	73.1	59.8	28.5
Mitsubishi Pharma				•••••	[72.3]	47.2
Capital expenditures on an accrual basis						
Tanabe Seiyaku	7.0	10.1	8.3	12.1	5.9	4.3
Mitsubishi Pharma		•••••••••••••••••••••••••••••••••••••••			[9.9]	5.4
Depreciation and amortization						
Tanabe Seiyaku	12.4	12.4	13.2	15.6	12.5	6.7
Mitsubishi Pharma					[15.0]	10.6
Total assets						
Tanabe Seiyaku	819.9	818.7	796.8	810.7	807.2	297.0
Mitsubishi Pharma		······································	······································			323.3
Total net assets						
Tanabe Seiyaku	721.4	695.9	676.8	666.2	667.8	233.5
Mitsubishi Pharma		······································	······································			253.2
Interest-bearing debt						
Tanabe Seiyaku	2.1	2.8	2.4	7.4	8.1	0.1
Mitsubishi Pharma						8.4
Net cash provided by operating activities						
Tanabe Seiyaku	37.2	59.0	23.9	50.5	38.0	21.4
Mitsubishi Pharma					[46.4]	28.0
Net cash provided by (used in) investing activities						
Tanabe Seiyaku	(63.2)	(7.6)	(61.2)	(74.5)	(4.8)	(8.5)
Mitsubishi Pharma	(03.2)	(70)	(01.2)	(74.3)	[(8.9)]	4.3
Net cash used in financing activities					[(0.5/]	4.5
Tanabe Seiyaku	(17.1)	(15.4)	(17.1)	(15.9)	(6.0)	(6.0)
Mitsubishi Pharma	(17.1)	(13.4)	(17.1)	(13.3)	[(9.0)]	(11.2)
Cash and cash equivalents at end of the year					[(3.0)]	(11.2)
Tanabe Seiyaku	54.3	97.8	62.9	116.9	160.0	46.1
•	J4.J	J7.0	UZ.3	110.3	100.0	85.1
Mitsubishi Pharma						

	2012/3	2011/3	2010/3	2009/3	2008/31	2007/3
Per share amounts (yen):						
Net income—basic						
Tanabe Seiyaku	¥ 69.54	¥ 67.27	¥ 53.91	¥ 47.28	¥ 50.12	¥ 82.36
Mitsubishi Pharma	***************************************	•	•••••••••••••••••••••••••••••••••••••••		•••••••••••••••••••••••••••••••••••••••	53.02
Net assets						
Tanabe Seiyaku	1,275.85	1,230.16	1,194.79	1,162.69	1,163.96	948.30
Mitsubishi Pharma	•••••••••••••••••••••••••••••••••••••••	······································	······································	••••	•••	531.95
Cash dividends						
Tanabe Seiyaku	35.00	28.00	28.00	28.00	26.00 <sup>2</sup>	24.00
Mitsubishi Pharma						14.15
Financial indicators (%):						
Ratio of cost of sales						
Tanabe Seiyaku	37.4%	37.7%	36.5%	38.1%	35.9%	38.9%
Mitsubishi Pharma		······································	······································		[36.8]	35.2
Ratio of SG&A expenses						
Tanabe Seiyaku	45.6	43.6	48.3	44.6	47.0	44.0
Mitsubishi Pharma					[45.5]	47.2
Operating margin						
Tanabe Seiyaku	17.0	18.7	15.2	17.3	17.1	17.2
Mitsubishi Pharma					[17.7]	17.6
Ratio of R&D expenses to net sales						
Tanabe Seiyaku	17.3	16.1	20.5	17.6	18.9	16.1
Mitsubishi Pharma					[17.7]	20.8
Equity ratio						
Tanabe Seiyaku	87.3	84.3	84.1	80.5	80.9	78.2
Mitsubishi Pharma						75.4
DE ratio						
Tanabe Seiyaku	0.3	0.4	0.4	1.1	1.2	0.1
Mitsubishi Pharma						3.4
ROA						
Tanabe Seiyaku	4.8	4.7	3.8	3.3	4.0	7.0
Mitsubishi Pharma					[4.5]	7.7
ROE						
Tanabe Seiyaku	5.5	5.5	4.6	4.1	4.9	9.0
Mitsubishi Pharma					[5.7]	10.2
Dividend payout ratio						
Tanabe Seiyaku	40.0 <sup>3</sup>	32.9³	39.0³	43.0³	44.04	29.1
Mitsubishi Pharma						30.0
Others:						
Number of employees						
Tanabe Seiyaku	9,180	9,198	9,266	10,030	10,361	4,554
Mitsubishi Pharma						5,907
Number of common stock issued (thousands)						
Tanabe Seiyaku	561,417	561,417	561,417	561,417	561,417	267,598
Mitsubishi Pharma						458,435

<sup>1.</sup> Figures in brackets are based on the simple sum of the results of Tanabe Seiyaku and Mitsubishi Pharma.
2. Dividends per share is based on the sum of the interim dividends (¥13) of Tanabe Seiyaku and the year-end dividends (¥13) of Mitsubishi Tanabe Pharma.

<sup>3.</sup> Dividend payout ratio is calculated using net income less amortization of goodwill.

<sup>4.</sup> Dividend payout ratio is calculated using Mitsubishi Tanabe Pharma's net income for the second half of the fiscal year (less amortization of goodwill) and Mitsubishi Tanabe Pharma's year-end dividends.

# **Management's Discussion and Analysis**

(Amounts less than ¥100 million are omitted)

#### **Results of Operations**

#### **Net Sales**

In fiscal 2011, net sales declined ¥2.3 billion, to ¥407.1 billion.

The Group's pharmaceutical operations consist of ethical drugs and OTC products. These operations are conducted in Japan and overseas, but domestic sales of ethical drugs account for the majority of the Group's sales.

In the domestic ethical drug market, the government continued to implement measures to promote the use of generic drugs and to control health care expenditures, and competition among companies intensified. Consequently, market conditions remained challenging.

In this setting, net sales of ethical drugs in the domestic market were down ¥6.2 billion year on year in fiscal 2011, to ¥355.4 billion. Factors contributing to higher sales included Remicade, an anti-TNF $\alpha$  monoclonal antibody, and Maintate, a selective  $\beta1$  antagonist. In addition, Telavic, for the treatment of chronic hepatitis C, and other new drugs gradually began to contribute to the Company's results. Sales of Remicade were up ¥5.9 billion year on year, to ¥66.3 billion, and sales of Maintate rose ¥1.3 billion, to ¥13.6 billion. However, these positive factors were offset by negative factors, such as an increase in the influence of competing generics and a rebound from a temporary increase in orders that was recorded at the end of the previous year following the Great East Japan Earthquake, which occurred on March 11, 2011. Furthermore, overall sales of vaccines were down ¥0.8 billion, to ¥28.8 billion, while sales of products handled by the Company's sales subsidiary, Tanabe Seiyaku Hanbai (including generic drugs and long-time listed drugs transferred from the Company) rose ¥3.4 billion, to ¥17.4 billion.

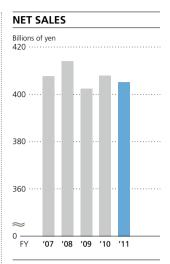
Overseas sales of ethical drugs were down ¥2.8 billion, to ¥18.4 billion, and sales of OTC drugs were flat year on year, at ¥5.4 billion. In Others, sales were up ¥6.4 billion, to ¥18.2 billion, due in part to royalties from Gilenya, an MS treatment agent that was licensed to Novartis.

Overall, sales of pharmaceuticals declined ¥2.6 billion, to ¥397.5 billion, and accounted for 97.6% of net sales. Overseas sales rose ¥2.5 billion, to ¥28.3 billion, and the overseas sales ratio was 7.0%, an increase of 0.7 percentage point.

Billions of ye
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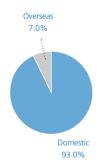
		2012/3		2011/3	Change
Net sales	¥407.1	(100.0%)	¥409.5	(100.0%)	¥- 2.3
Sales by business segment:					
Pharmaceuticals	397.5	(97.6)	400.2	(97.7 )	- 2.6
Domestic ethical drugs	355.4	(87.3 )	361.6	(88.3 )	- 6.2
Overseas ethical drugs	18.4	(4.5 )	21.3	(5.2 )	- 2.8
OTC drugs	5.4	(1.3 )	5.4	(1.3 )	- 0.0
Others	18.2	(4.5 )	11.8	(2.9 )	+6.4
Other business	9.5	(2.4 )	9.3	(2.3 )	+2.0
Sales by region:					
Domestic	378.8	(93.0)	383.7	(93.7 )	- 4.9
Overseas	28.3	(7.0 )	25.7	(6.3 )	+2.5

Note: Figures in parentheses are percentages of net sales.



Note: In general, figures in graphs for fiscal 2007 are the simple sum of the figures for Tanabe Seiyaku and Mitsubishi Pharma.

#### **SALES BY REGION**



#### SALES OF MAJOR PRODUCTS IN THE DOMESTIC MARKET

Bil	lions	of	V

	2012/3	2011/3	Change
Remicade	¥66.3	¥60.4	¥ +5.9
Radicut	22.4	28.7	- 6.2
Ceredist	18.0	18.0	- 0.0
Anplag	15.2	16.4	- 1.1
Talion	13.3	13.4	- 0.0
Urso	14.4	15.3	- 0.8
Maintate	13.6	12.3	+1.3
Kremezin*	11.6	_	+11.6
Depas	10.9	11.4	- 0.4
Venoglobulin IH	10.6	9.6	+1.0
Vaccines	28.8	29.6	- 0.8
Mearubik	9.5	12.2	- 2.7
Influenza	9.0	7.1	+1.8
JEBIK V	7.1	6.9	+0.1

<sup>\*</sup> In fiscal 2010, sales of Kremezin were transferred from Daiichi Sankyo to the Company, but the amount of sales to Daiichi Sankyo are not disclosed.

#### **Operating Income**

Operating income declined ¥7.5 billion, to ¥69.0 billion.

Net sales were down ¥2.3 billion, but due to such factors as the influence of exchange rates and increase in royalty income, gross profit was flat year on year, at ¥254.8 billion. The cost of sales ratio improved 0.3 percentage point, to 37.4%.

SG&A expenses increased ¥7.4 billion, to ¥185.8 billion. Due in part to one-time licensing payments, R&D expenses were up ¥4.4 billion, to ¥70.2 billion. In addition, selling expenses rose due to the launch of new drugs.

The R&D expense ratio increased 1.2 percentage points, to 17.3%.

Billions of yen

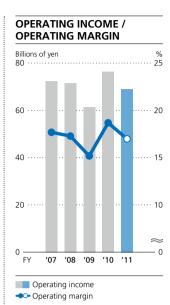
		2012/3		2011/3	Change
Cost of sales	¥152.2	(37.4%)	¥154.5	(37.7%)	¥- 2.2
SG&A expenses	185.8	(45.6 )	178.3	(43.6 )	+7.4
R&D expenses	70.2	(17.3 )	65.7	(16.1 )	+4.4
Non-R&D expenses	115.5	(28.4 )	112.6	(27.5 )	+2.9
Labor costs	51.9	(12.8 )	52.5	(12.8 )	- 0.5
Amortization of goodwill	10.1	(2.5 )	10.1	(2.5 )	- 0.0
Other	53.4	(13.1 )	49.9	(12.2 )	+3.5
Operating income	69.0	(17.0 )	76.5	(18.7 )	- 7.5

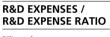
Note: Figures in parentheses are percentages of net sales.

### Net Income

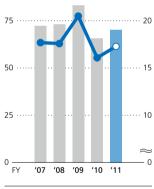
Operating income declined, but the net balance of extraordinary items improved ¥7.6 billion, and consequently net income rose ¥1.2 billion year on year, to ¥39.0 billion.

Extraordinary income was up ¥0.5 billion, to ¥1.1 billion, due primarily to gain on sales of property, plant and equipment of ¥0.7 billion and reversal of reserve for loss on disaster of ¥0.4 billion. Extraordinary losses were down ¥7.0 billion, to ¥6.1 billion. Loss on impairment of fixed assets was ¥3.3 billion, and loss on valuation of investments in securities was ¥2.1 billion. In the previous fiscal year, the Company recorded extraordinary losses of ¥13.2 billion, including loss on valuation of investments in securities of ¥8.0 billion, loss on disaster accompanying the Great East Japan Earthquake of ¥2.1 billion, and loss on impairment of fixed assets ¥0.8 billion.



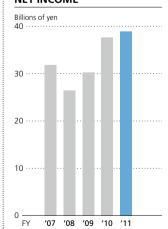








## NET INCOME



#### **Financial Position**

#### Assets, Liabilities, and Net Assets

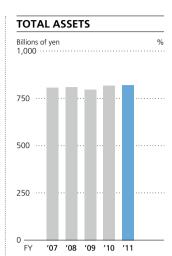
Total assets at the end of the fiscal year were ¥819.9 billion, an increase of ¥1.2 billion from the previous fiscal year-end. Marketable securities and cash and time deposits declined, but deposits and other items increased, and total current assets rose ¥28.0 billion year on year, to ¥419.6 billion. Fixed assets decreased ¥26.8 billion, to ¥400.2 billion. Investments in securities decreased due in part to redemptions, and property, and plant and equipment and goodwill were down as a result of depreciation and amortization and impairment of fixed assets.

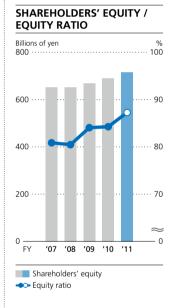
Total liabilities were down ¥24.3 billion from the end of the previous fiscal year, to ¥98.4 billion. Declines were also recorded in income taxes payable, accounts payable–other, deferred income taxes, and reserve for HCV litigation.

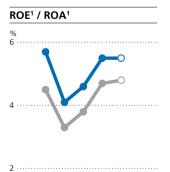
Total net assets at the end of the period were up ¥25.5 billion from the end of the previous fiscal year, to ¥721.4 billion. Net income was ¥39.0 billion, and cash dividends paid were ¥16.2 billion. As a result, retained earnings increased by ¥22.7 billion. Total accumulated other comprehensive loss decreased by ¥2.8 billion. As a result, the equity ratio was 87.3%, an increase of 3.0 percentage points from the end of the previous fiscal year.

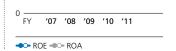
					Billions of yen
		2012/3		2011/3	Change
Total assets	¥819.9	(100.0%)	¥818.7	(100.0%)	¥ +1.2
Total current assets	419.6	(51.2 )	391.5	(47.8 )	+28.0
Fixed assets	400.2	(48.8 )	427.1	(52.2 )	- 26.8
Total liabilities	98.4	(12.0 )	122.7	(15.0 )	- 24.3
Total current liabilities	69.5	(8.5 )	87.7	(10.7 )	- 18.1
Total long-term liabilities	28.8	(3.5 )	35.0	(4.3 )	- 6.1
Total net assets	721.4	(88.0)	695.9	(85.0 )	+25.5

Note: Figures in parentheses are percentages of total assets or percentages of the total of liabilities and net assets.









<sup>1.</sup> The principal reasons for the decline in ROE and ROA in fiscal 2007 and fiscal 2008 were an increase in shareholders' equity due to the recording of goodwill etc., as a result of the merger, and a decline in net income that exceeded amortization of goodwill. Extraordinary losses were ¥20.3 billion in fiscal 2007, ¥25.7 billion in fiscal 2008, ¥10.7 billion in fiscal 2009, ¥13.2 billion in fiscal 2010, and ¥6.1 billion in fiscal 2011.

#### **Cash Flows**

Net cash provided by operating activities was ¥37.2 billion, an decrease of ¥21.8 billion. Major inflows included income before income taxes and minority interests of ¥63.7 billion, depreciation and amortization of ¥12.4 billion, and amortization of goodwill of ¥10.1 billion. Major outflows included income taxes paid of ¥28.3 billion and increase in inventories of ¥8.6 billion.

Net cash used in investing activities was ¥63.2 billion, an increase of ¥55.5 billion from the previous year. Purchases of marketable securities and proceeds from sales, etc., netted out to an inflow of ¥43.1 billion. However, increase in deposits, used as working capital, was ¥110.7 billion, and purchases of property, plant and equipment and proceeds from sales of property, plant and equipment netted out to an outflow of ¥7.3 billion, resulting in the substantial year-on-year increase in net cash used in investing activities.

Net cash used in financing activities was ¥17.1 billion, an increase of ¥1.7 billion. Major items included cash dividends paid of ¥16.2 billion.

As a result, net cash outflows for the year were ¥43.5 billion, and the balance of cash and cash equivalents at the end of fiscal 2011 was ¥54.3 billion, a decrease of ¥43.5 billion.

Billions of ven

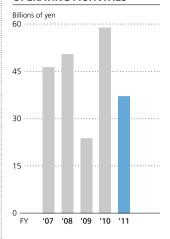
	2012/3	2011/3	Change
Net cash provided by operating activities	¥37.2	¥ 59.0	¥- 21.8
Net cash used in investing activities	(63.2)	(7.6)	- 55.5
Net cash used in financing activities	(17.1)	(15.4)	- 1.7
Cash and cash equivalents at end of the year	54.3	97.8	- 43.5

#### **Dividends**

The Company's basic policy calls for providing a stable and continuous return to shareholders while striving to maximize enterprise value by aggressively investing in future growth. Under the Medium-Term Management Plan 11–15, the basic objective for the dividend payout ratio, prior to amortization of goodwill, is 40% (the basic objective for the dividend payout ratio after amortization of goodwill is 50%), and the Company will work to provide an enhanced return to shareholders.

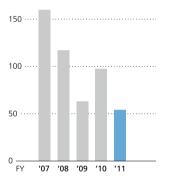
In accordance with its basic policy on the distribution of earnings, the Company set annual dividends at ¥35.0 per share, an increase of ¥7.0 per share. The dividend payout ratio, calculated on the basis of net income less amortization of goodwill and annual dividends, was 40.0%.

# NET CASH PROVIDED BY OPERATING ACTIVITIES

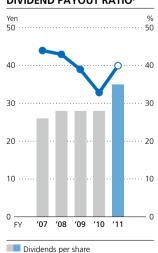


# CASH AND CASH EQUIVALENTS

Billions of yen



# DIVIDENDS PER SHARE<sup>2</sup> / DIVIDEND PAYOUT RATIO<sup>3</sup>



Dividend payout ratio

Dividends per share are presented as follows: For fiscal 2007, the interim dividends of the former Tanabe Seiyaku are used for the interim dividends (¥13) and the year-end dividends of Mitsubishi Tanabe Pharma are used for the year-end dividends (¥13).

<sup>3.</sup> The dividend payout ratio is presented as follows: For fiscal 2007, the dividend payout ratio is calculated using Mitsubishi Tanabe Pharma's net income for the second half of the fiscal year (less amortization of goodwill) and Mitsubishi Tanabe Pharma's year-end dividends. For fiscal 2008 and subsequent years, the dividend payout ratio is calculated using Mitsubishi Tanabe Pharma's net income for the fiscal year (less amortization of goodwill) and annual dividends.

# **Operational Risks**

The following are major risks that have the potential to significantly influence the financial position or performance of the Mitsubishi Tanabe Pharma Group. In recognition of the possibility that these events could occur, the Group works to prevent their occurrence and to implement countermeasures in the event of their occurrence. Items in this document relating to the future are based on the judgment of the Group as of the end of fiscal 2011 (ended March 31, 2012).

#### 1. Risks related to new drug R&D

The R&D of new drugs requires lengthy investment and the commitment of substantial resources, but there is no guarantee that this process will result in the creation of new products or new technologies. In addition, pharmaceuticals cannot be sold if approval is not obtained under the legal and regulatory system of each country, and it is difficult to accurately predict whether or not products will be sold and the timing of those sales. The development of current development compounds might be halted in the event that problems with effectiveness or safety are found in nonclinical trials, clinical trials, etc., or in the event that they are determined to lack economic value due to innovation in medical treatment techniques, the launch of other drugs, etc. In the event that R&D investment does not lead to the sales of new drugs, there could be a significant influence on the Group's financial position or results.

#### 2. Risks related to adverse drug reactions

Clinical trials conducted prior to the receipt of approval for a new drug are implemented with a limited number of test subjects, even in the event that approval is acquired following a rigorous safety evaluation, it is not possible to predict everything about safety in post-marketing use. Under the post-marketing use for the patients with various backgrounds, it is possible that there will be reports of new adverse drug reactions that had not been experienced previously. In the event that sales are suspended or that a large amount of compensation to victims arises, depending on such factors as the severity and frequency of those side effects, the Group's financial position and results of operations could be significantly affected.

# 3. Risks related to the national health insurance system (NHI) and the reduction of drug price standards

The sale of ethical drugs is significantly impacted by the various health insurance systems that relate to drug price standards as well as medical and other fees. Revisions to the drug price standard system that sets the official price of pharmaceuticals; various health insurance systems, encompassing medical and other fees, that influence trends in the use of pharmaceuticals by medical institutions, and; similar revisions to the standards and systems employed overseas could substantially impact the Group's financial position and results.

### 4. Risks related to product sales

In the future, in the event of the emergence of factors—such as the launch of competing new products or generic products due to the termination of the patent, the launch of innovative new drugs or new technologies that lead to new methods of treatment, or the announcement of new evidence—that lead to a relative change in the position of the Company's pharmaceutical products in clinical treatment and to a decline in sales, the Group's financial position or results could be significantly affected.

#### 5. Risks related to intellectual property

If the Group's business activities conflict with the patents or other intellectual property rights of other parties, it is possible that activities could be suspended or that there could be a legal dispute. Also, in the event that the Group believes that its patents or other intellectual property rights have been infringed upon by another party, the Group might file lawsuits. As a result of these actions, there could be an influence on the Group's financial position or results.

#### 6. Risks related to alliance with other companies

The Group works with other companies in joint research, joint development, product licensing and introduction, commissioned production, commissioned sales, joint promotion, and joint marketing in each business field, such as research, development, production, and marketing. However, in the future if contracts are changed or alliances dissolved, if the management environment of alliance partners worsens, if the management policies of alliance partners changes substantially, or if the supply of products suspend or delay substantially, there could be an adverse influence on the Group's financial position or results.

#### 7. Risks related to production and stable supply

In the event of the emergence of technical or legal / regulatory problems in the Group's production and distribution facilities, or in the event of operational stoppages or disorder due to fires or other disasters, a suspension of or substantial delay in the supply of products, there could be an influence on the Group's financial position or results.

#### 8. Risks related to legal issues

In the research, development, and production of pharmaceuticals, there is a trend toward stricter regulations regarding product quality and the environment. In the event that these regulations are further tightened, there is a possibility that corresponding additional expenses will arise, which could have an adverse influence on the Group's financial position or results.

#### 9. Risks related to product liability

It is possible that the Group will be responsible for potential product liability stemming from product research, development, manufacturing, or sales activities. The Group is covered by product liability insurance, but in the event that claims exceeding the limits of this insurance coverage are approved, there could be a significant influence on the Group's financial position or results.

#### 10. Risks related to financial market fluctuations

- a) In the year ended March 31, 2012, overseas sales accounted for 7.0% of the Group's consolidated net sales. Certain raw materials for products and finished goods handled by the Company are directly imported from overseas. Substantial fluctuations in exchange rates could lead to declines in sales, increases in procurement costs, the generation of foreign exchange losses, etc., as well as declines in the assets of overseas consolidated subsidiaries, etc., and the Group's financial position and results of operations could be significantly affected.
- b) As of the end of March 2012, the Group held marketable securities of ¥46.3 billion and investments in securities of ¥116.5 billion, certain of which are liquid stocks and bonds, etc. Accordingly, events such as the recording of a loss on valuation due to declines in market prices could have a significant influence on the Group's financial position or results.

### 11. Risks related to environmental safety

In the event that hazardous and serious damage to the environment is caused by chemical substances that are used in operating activities, it is possible that the Group could incur expenses needed for environmental improvement, face a decline in societal trust, bear responsibility for the payment of compensation, etc. In the event that one or more of these situations occurs, the Group's financial position or results could be significantly affected.

#### 12. Risks related to lawsuits

a) In regard to operational activities, in addition to adverse drug reactions, it is possible that the Group could face lawsuits regarding product liability, labor problems, fair trade, etc. As a result, there could be a significant influence on the Group's financial position or results.

b) The Japanese government, the Company, its subsidiary Benesis Corporation, and another party were defendants in lawsuits in which the plaintiffs sought compensation for damages allegedly suffered through HCV (hepatitis C virus) infection following use of a fibrinogen product or a blood-coagulation factor IX product (Christmassin). However, to resolve this litigation, in January 2008 the Japanese government promulgated and put into effect "the Special Relief Law Concerning the Payment of Benefits to Relieve the Patients of Hepatitis C Infected through Specified Fibrinogen Preparations and Specified Blood-Coagulation Factor IX Preparations Contaminated by Hepatitis C Virus" ("the Relief Law"). In regard to the expenses associated with the relief payments under the Relief Law, the standards for the method and the allocation of the burden of the expenses were announced on April 10, 2009. In accordance with those standards, the Company has made provisions for those expenses. For this expense burden, the cumulative total of the provisions for reserve for HCV litigation was ¥23.0 billion, of which ¥20.4 billion had already been paid out as of the end of March 2012. However, due to changes in the expected number of benefits recipients, the Group's financial position or results could be significantly affected.

The standards determining the Company's portion of the expense burden are shown below:

#### 1. Portion of expense burden

	The Company's portion of the burden
People infected with HCV, as stipulated in Article 2, Paragraph 3, of the Relief Law, through use of specific fibrinogen products from August 21, 1985 to April 21, 1987	100%
People infected with HCV, as stipulated in Article 2, Paragraph 3, of the Relief Law, through use of specific fibrinogen products from April 22, 1987 to June 23, 1988	Two-thirds
People infected with HCV, as stipulated in Article 2, Paragraph 3, of the Relief Law, through the use of specific blood-coagulation factor IX products on or after January 1, 1984	100%

2. Lump-sum payment of ¥5.1 billion in addition to payments made in accordance with the portions in (1) above.

#### 13. Risks related to information management

The Group possesses large amounts of non-public information, including personal information, and in the event that information is leaked outside the Group due to inappropriate system access, system damage, or accidents, etc., there could be an influence on the Group's financial position or results, such as a decline in reputation.

# 14. Risks related to substantial upfront investment for the purpose of expanding overseas operations

Substantial upfront investment is necessary to expand and advance overseas operations, and it is possible that, due to changes in the laws and systems of each country, the worsening of diplomatic relations, or natural disaster, etc., the opportunity to recover that investment might be lost and operations under development might be affected. As a result of these actions, there could be an influence on the Group's financial position or results.

# 15. Major assumptions regarding operational activities

Pharmaceutical manufacturing and sales are the Group's principal business operations. In accordance with the Pharmaceutical Affairs Law, the Group has obtained licenses for pharmaceutical manufacturing and sales, pharmaceutical manufacturing and wholesale pharmaceutical sales, and conducts manufacturing and sales of ethical pharmaceutical and OTC products. The products handled include narcotics, psychotropic agents, and raw materials for stimulants, etc., and the Group is subject to laws and regulations related to the Narcotics and Psychotropic Substances Control Law and the Stimulant Drugs Control Law.

Since the Group also handles veterinary drugs as well as poisonous and toxic substances, the Group is subject to laws and regulations covering the wholesale of veterinary drug sales, and general sales of poisonous and toxic substances. In manufacturing drugs that are exported overseas, the Group is subject to the regulations of the Pharmaceutical Affairs Law.

In addition, the Group is required to register a raw materials master file, etc., with the authorities in the importing countries and acquire import permission, local manufacturing permission, etc. Moreover, the Group is subject to the rules and regulations relating to the control of exports and international transportation of hazardous materials in each importing country, as well as the laws and regulations related to customs clearance. These rules and regulations are revised and subject to additional stipulations on an individual country basis. Certain terms and conditions are also reinforced annually. Taking the aforementioned into consideration, Group operations may be affected.

In regard to these permissions, etc., they must be extended periodically, as determined by laws / regulations. Also, in the event of a violation of laws / regulations, it is possible that permissions, etc., of the Group could be cancelled or the Group could be ordered to suspend all or a portion of operations for a specified period of time. The Group is currently unaware of any reasons for the validity of its permissions, etc., to come into question. In the event that cancellation, etc., of permissions, etc., is ordered, because of the damage to the societal trust or the termination of contracts, there could be a significant influence on the Group's financial position or results.

Major permissions, etc., received are as follows:

Date received	Permission, etc.	Approving authority	Details of permission, etc.	Expiry of permission, etc.	Grounds for legal violation or primary reason for revocation of permission, etc.
Jan. 1, 2012	Pharmaceutical manufacturing and sales	Osaka Prefecture	Permission to manufac- ture and sell pharma- ceutical products, etc.	Dec. 31, 2016 (5-year renewable)	Disqualification as per Article 12.2 of the Pharmaceutical Affairs Law
Jan. 1, 2011	Manufacturing of narcotics <sup>1</sup>	Ministry of Health, Labour and Welfare	License to manufacture narcotic drugs	Dec. 31, 2012 (2-year renewable)	Disqualification as per Article 3.2 of the Narcotics and Psychotropic Control Act
Oct. 1, 2009	Manufacturing of psychotropic drugs <sup>1</sup>	Ministry of Health, Labour and Welfare	License to manufacture psychotropic drugs	Sep. 30, 2014 (5-year renewable)	Disqualification as per Article 50.2 of the Narcotics and Psychotropic Control Act
Oct. 19, 2009	Handling of raw materials for stimulants <sup>2</sup>	Local governments	Permission to sell raw materials for stimulants	Dec. 31, 2013 (4-year renewable)	Disqualification as per Article 30.3 of the Stimulant Drugs Control Law
Oct. 13, 2009	Wholesale pharmaceutical sales <sup>3</sup>	Local governments	Permission to sell or offer pharmaceutical products	Oct. 12, 2015 (6-year renewable)	Disqualification as per Article 34.2 of the Pharmaceutical Affairs Law
Oct. 1, 2009	Pharmaceutical manufacturing <sup>4</sup>	Local governments	Permission to manu- facture or import phar- maceutical products	Sep. 30, 2014 (5-year renewable)	Disqualification as per Article 13.4 of the Pharmaceutical Affairs Law
Oct. 19, 2009	Wholesale veterinary drug sales <sup>5</sup>	Local governments	Permission to sell or offer pharmaceutical products for animals	Oct. 18, 2015 (6-year renewable)	Disqualification as per Article 34.2 of the Pharmaceutical Affairs Law
Oct. 19, 2009	General sales of poisonous and toxic substances <sup>6</sup>	Local governments	Registration to sell, etc., poisonous and toxic substances	Oct. 18, 2015 (6-year renewable)	Disqualification as per Article 5, or 19 of the Poisonous and Dele- terious Substances Control Act

Permission information for narcotic manufacturing at Osaka Plant of Mitsubishi Tanabe Pharma Factory Ltd. that primarily handles drugs covered by these regulations is shown.

<sup>2.</sup> Permission information for handling of raw materials for stimulants at Head Office (Production Division) that primarily handles them covered by these regulations is shown.

<sup>3.</sup> Permission has been obtained by multiple places of operations, therefore permission information for Head Office (Sales and Marketing Division) is shown.

<sup>4.</sup> Permission has been obtained by multiple places of operations, therefore permission information for Osaka Plant of Mitsubishi Tanabe Pharma Factory Ltd. is shown.

<sup>5.</sup> Permission has been obtained by multiple places of operations, therefore permission information for Head Office (Production Division) is shown.

<sup>6.</sup> Permission has been obtained by multiple places of operations, therefore permission information for Head Office (Production Division) is shown.

# 16. Problems related to certain deficiencies in quality testing (hereinafter, quality control problems) at consolidated subsidiary

On July 19, 2011, the Company received a business improvement order from the Minister of Health, Labour and Welfare related to a violation of the Pharmaceutical Affairs Law. On the same day, the Ashikaga Plant of consolidated subsidiary Mitsubishi Tanabe Pharma Factory Ltd. received a business suspension order from the Governor of Tochigi Prefecture. The administrative action related to a violation of the Pharmaceutical Affairs Law regarding "Medway Injection" in 2010, and the administrative actions described above, have damaged the Group's reputation among patients and health care professionals and adversely affected the Group's image. If such incidents continue, it is possible that the Group's financial position and results of operations could be significantly affected.

#### 17. Risks related to major disasters and other events

In the event of a major or secondary disaster that results in stoppages at the production or distribution bases of the Group or supplier, or damages and / or interruptions to the operations of raw material suppliers or outsourced manufacturers, the Group may be forced to suspend or incur significant delays in the supply of products. In each case, the potential exists for the Group's financial position and operating results to be substantially affected. In addition, the implementation of research and development plans may be impacted by damages to the Group's research facilities, medical and other institutions at which testing is conducted, or secondary disaster such as blackouts. In addition, problems with communications with the Group's production and distribution bases or with the Group's research bases, or problems with the Group's computer bases, could have a similar impact.

#### 18. Relationship with parent company and other Group companies

#### Position in the Group centered on Mitsubishi Chemical Holdings Corporation (MCHC)

The Company belongs to the MCHC Group, which is centered on MCHC, the Company's parent company. The ownership of MCHC in Mitsubishi Tanabe Pharma Corporation reached 56.34%.

The MCHC Group has three business domains: Performance Products, Health Care, and Industrial Materials, and operates businesses with four core business companies—Mitsubishi Tanabe Pharma Corporation, Mitsubishi Chemical Corporation, Mitsubishi Plastics, Inc., and Mitsubishi Rayon Co., Ltd. The Company has integrated systems for the research, development, manufacturing, and sales of ethical pharmaceuticals, and the Company plays a central role in the MCHC Group's health care operations.

#### **Transactions with MCHC Group**

The Company's relationship with its parent company, MCHC, and MCHC's corporate group, includes the following transactions:

- $\boldsymbol{\cdot}$  procurement of raw materials, etc., and sales of chemical products, etc.
- conclusion of leases and consignment contracts for the sites of research facilities and plants and the buildings, etc., thereon, in Yokohama City, Kanagawa Prefecture; Kamisu City, Ibaraki Prefecture.
- payment as consideration for exclusive rights to intellectual property held by the corporate group of the parent company.
- conclusion of contracts for research outsourcing and information disclosure.
- consignment contracts with overseas subsidiaries.

Fundamentally, these transactions involve rational transaction terms decided upon following two-way negotiations conducted with reference to general market prices.

The Company leases buildings used for the research laboratory in Yokohama, Kanagawa. Construction of a laboratory building, the Pharma Research Building 2, of its own on that site was completed in February 2011. As a result, the Company returned a part of the research laboratory which the Company rented from the MCHC Group. In the future, the lease on the buildings used for the research laboratory will be cancelled in stages. Also, plans call for the outsourcing of work by overseas subsidiaries to be gradually eliminated as the Company's international operations progress.

In addition, a contract has been concluded with MCHC regarding the burden of operational expenses, and for enjoyment of benefits based on the brand value and comprehensive strengths of MCHC in the development of operations in Japan and overseas, the Company is responsible for certain expenses arising in regard to the operation of MCHC. Operational expenses are calculated in accordance with operating profit as well as the amount of resources injection, ratio derived from number of shares, and total assets, with an upper limit of 0.5% of consolidated sales.

In the year ended March 31, 2012, the Company's expenses, included the following: procurement of raw materials, etc., of ¥0.4 billion, conclusion of leases and consignment contracts for the sites of research facilities and plants and the buildings, etc., thereon, in Yokohama City, Kanagawa Prefecture, and Kamisu City, Ibaraki Prefecture, of ¥1.7 billion, payment as consideration for exclusive rights to intellectual property held by the corporate group including the parent company of ¥0.7 billion and operating expenses of ¥0.7 billion. In all of the above cases, the expenses are an insignificant percentage of the Company's total expenses. In the event of changes in the contracts or details of the transactions with the MCHC Group, there could be a significant influence on the Mitsubishi Tanabe Pharma Group's results or financial position. API Corporation, a group company of the MCHC Group, is an associated company of the Mitsubishi Tanabe Pharma Group, and the above amounts do not include transactions between the Company and API Corporation (purchases of raw materials, etc.: ¥8.6 billion, etc.).

#### **Personnel relationships with MCHC Group**

a) Concurrent service of directors and corporate auditors

As of June 22, 2012, the directors, corporate auditors, and employees of MCHC and its Group companies include one person who is concurrently serving as a corporate auditor (non-full time) of the Company. The Company's Board of Corporate Auditors has four members.

Position at the Company	Name	Position in Group company	Reason for position
Corporate auditor (outside)			Concurrent service from the viewpoint of Group auditing
		Mitsubishi Chemical Corporation Corporate auditor (outside)	

Michihiro Tsuchiya, who is a representative director of the Company, serves concurrently as a director (non-full time) of MCHC and a director (non-full time) of The KAITEKI Institute, Inc.

b) Acceptance of reassigned personnel

The Group has accepted the reassignment of 8 people from the MCHC Group for limited periods of time with such objectives as enhancing links among information systems and logistic departments.

#### **Capital relationship with MCHC**

Currently, MCHC holds 56.34% of the Company's issued shares. In regard to management decision-making, there are no matters that require the prior approval of MCHC, the Company's parent company. Also, the percentage of the Company's stock held by MCHC will, in principle, be maintained for 10 years from October 1, 2007. At this time, the Company believes that the ownership ratio remains unchanged.

However, in the future, in the event that there is a change in the management policies of the MCHC Group, the Company's financial position and results of operations could be affected.

There are risks other than those described above, and the risks listed here do not include all of the risks faced by the Group.

# **Consolidated Balance Sheets**

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries March 31, 2012 and 2011

		Millions of yen	Thousands of U.S. dollars (Note 1)
	2012	2011	2012
Assets			
Current assets:			
Cash and deposits (Notes 3 and 5)	¥ 15,466	¥ 27,409	\$ 188,174
Notes and accounts receivable, trade (Notes 4 and 5):			
Notes	902	1,100	10,975
Accounts	126,305	127,275	1,536,744
Less allowance for doubtful receivables	(41)	(45)	(499
	127,166	128,330	1,547,220
Marketable securities (Notes 5 and 6)	46,345	84,788	563,876
Inventories (Note 7)	86,190	77,702	1,048,668
Deferred income taxes (Note 11)	9,343	12,551	113,676
Deposits (Note 5)	130,791	56,356	1,591,325
Other current assets	4,350	4,445	52,926
Total current assets	419,651	391,581	5,105,865
Property, plant and equipment (Note 16):			
Land	46,359	50,009	564,047
Buildings and structures	130,998	132,555	1,593,843
Machinery and vehicles	111,968	108,976	1,362,307
Tools, furniture and fixtures	38,391	38,306	467,101
Leased equipment	99	49	1,205
Construction in progress	594	2,299	7,227
	328,409	332,194	3,995,730
Less accumulated depreciation	(224,480)	(218,682)	(2,731,233
Property, plant and equipment, net	103,929	113,512	1,264,497
Investments, goodwill and other assets: Investments in securities (Notes 5 and 6):			
Unconsolidated subsidiaries and affiliates	7,332	7,307	89,208
Others	109,264	120,295	1,329,407
Goodwill	105,549	115,682	1,284,207
Software	2,619	2,555	31,865
Long-term prepaid expenses	14,350	7,393	174,595
Prepaid pension expenses (Note 10)	42,101	40,449	512,240
Deferred income taxes (Note 11)	7,898	13,789	96,095
Long-term deposits	1,866	1,956	22,704
Other assets	5,368	4,225	65,312
Less allowance for doubtful receivables	(2)	(39)	(24
Total investments, goodwill and other assets	296,345	313,612	3,605,609
Total assets	¥ 819,925	¥ 818,705	\$ 9,975,971

	_	Millions of yen	Thousands of U.S. dollars (Note
	2012	2011	2012
iabilities and Net Assets			
Current liabilities:			
Short-term debt (Notes 5 and 8)	¥ 2,170	¥ 2,891	\$ 26,402
Accounts payable, trade (Note 5)	28,878	29,617	351,35
Accounts payable, other	15,723	20,373	191,30
Income taxes payable (Note 11)	6,254	14,649	76,09
Consumption taxes payable	2,030	2,336	24,69
Reserve for employees' bonuses	11,121	11,467	135,30
Reserve for sales returns	167	163	2,03
Reserve for loss on disaster (Note 17)	40	1,531	48
Other current liabilities (Note 9)	3,201	4,695	38,94
Total current liabilities	69,584	87,722	846,62
ong-term liabilities:			
Accrued retirement benefits for employees (Note 10)	10,584	11,853	128,77
Accrued retirement benefits for directors and corporate auditors	6	5	7.
Deferred income taxes (Note 11)	9,338	11,450	113,61
Reserve for health management allowances for HIV compensation (Note 24)	1,461	1,513	17,77
Reserve for health management allowances for SMON compensation	3,622	3,835	44,06
Reserve for HCV litigation (Note 24)	2,520	4,627	30,66
Other liabilities (Note 9)	1,325	1,741	16,12
Total long-term liabilities	28,856	35,024	351,089
Net assets:			
Shareholders' equity (Note 12):			
Common stock:			
Authorized – 2,000,000,000 shares			
Issued – 561,417,916 shares at March 31, 2012 and 2011	50,000	50,000	608,34
Capital surplus	451,186	451,186	5,489,54
Retained earnings	224,168	201,424	2,727,43
Treasury stock, at cost	(486)	(407)	(5,91
Total shareholders' equity	724,868	702,203	8,819,41
Accumulated other comprehensive loss			
Unrealized holding loss on securities	(82)	(2,712)	(99
Deferred gain (loss) on hodges	93	(1,010)	1,13
Deferred gain (loss) on hedges	(9,134)	(8,280)	(111,13
Translation adjustments		(12,002)	(110,99
	(9,123)		
Translation adjustments	5,740	5,758	69,83
Translation adjustments  Total accumulated other comprehensive loss	<del>-</del>	5,758 695,959	69,839 8,778,258

# **Consolidated Statements of Income**

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries Years ended March 31, 2012 and 2011

		Millions of yen	Thousands of U.S. dollars (Note 1)
	2012	2011	2012
Net sales (Note 23)	¥407,156	¥409,540	\$4,953,839
Cost of sales	152,284	154,564	1,852,829
Gross profit	254,872	254,976	3,101,010
Selling, general and administrative expenses (Note 14)	185,829	178,392	2,260,969
Operating income	69,043	76,584	840,041
Other income (expenses):			
Interest and dividend income	2,352	2,342	28,617
Interest expense	(18)	(15)	(219)
Foreign exchange loss, net	(1,507)	(1,422)	(18,336)
Donations	(383)	(361)	(4,660)
Gain (loss) on sales or disposal of fixed assets, net	305	(451)	3,711
Gain on sales of investments in securities	_	144	_
Loss on disaster (Note 17)	(108)	(2,140)	(1,314)
Loss related to business suspension (Note 15)	_	(737)	_
Loss on impairment of investments in securities (Note 6)	(2,197)	(8,005)	(26,731)
Special retirement benefits (Note 10)	(109)	(482)	(1,325)
Loss on impairment of fixed assets (Note 16)	(3,334)	(807)	(40,565)
Restructuring loss	_	(149)	_
Other, net	(256)	(400)	(3,115)
	(5,255)	(12,483)	(63,937)
Income before income taxes and minority interests	63,788	64,101	776,104
Income taxes (Note 11):			
Current	20,031	26,988	243,716
Deferred	4,497	(485)	54,714
	24,528	26,503	298,430
Income before minority interests	39,260	37,598	477,674
Minority interests	246	(149)	2,993
Net income	¥ 39,014	¥ 37,747	\$ 474,681

# **Consolidated Statements of Comprehensive Income**

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries Years ended March 31, 2012 and 2011

		Millions of yen	Thousands of U.S. dollars (Note 1)
	2012	2011	2012
Income before minority interests	¥39,260	¥37,598	\$477,674
Other comprehensive income (loss) (Note 18)			
Unrealized holding gain on securities	2,635	500	32,060
Deferred gain (loss) on hedges	1,104	(633)	13,432
Translation adjustments	(1,042)	(2,418)	(12,678)
Other comprehensive loss of equity-method companies attributable to the Company	(11)	(40)	(134)
Total other comprehensive income (loss)	2,686	(2,591)	32,680
Comprehensive income	¥41,946	¥35,007	\$510,354
Comprehensive income (loss) attributable to:			
Shareholders of the Company	¥41,893	¥35,592	\$509,709
Minority interests	¥ 53	¥ (585)	\$ 645

# **Consolidated Statements of Changes in Net Assets**

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries Years ended March 31, 2012 and 2011

	Number of shares of				Treasury	Unrealized	Deferred			Millions of yen
	common stock (Thousands)	Common stock	Capital surplus	Retained earnings	stock, at cost	holding loss on securities	gain (loss) on hedges	Translation adjustments	Minority interests	Total net assets
Balance at April 1, 2010	561,417	¥50,000	¥451,185	¥179,409	¥(277)	¥(3,218)	¥ (378)	¥(6,251)	¥6,343	¥676,813
Net income for the year				37,747						37,747
Cash dividends	_	_	_	(15,711)	_	_	_	_	_	(15,711)
Increase in treasury stock	_	_	_	_	(135)	_	_	_	_	(135)
Change in scope of equity method	-	_	-	(21)	-	_	-	-	_	(21)
Gain on sales of treasury stock	-	-	1	-	5	-	-	-	-	6
Net changes in items other than shareholders' equity	-	-	-	_	-	506	(632)	(2,029)	(585)	(2,740)
Balance at April 1, 2011	561,417	¥50,000	¥451,186	¥201,424	¥(407)	¥(2,712)	¥(1,010)	¥(8,280)	¥5,758	¥695,959
Net income for the year		_	_	39,014	_	_	_	_	_	39,014
Cash dividends	_	_	_	(16,270)	_	_	_	_	_	(16,270)
Increase in treasury stock	_	_	_	_	(79)	_	_	_	_	(79)
Gain on sales of treasury stock	_	_	_	_	0	_	_	_	_	0
Net changes in items other than shareholders' equity	_	_	_	_	_	2,630	1,103	(854)	(18)	2,861
Balance at March 31, 2012	561,417	¥50,000	¥451,186	¥224,168	¥(486)	¥ (82)	¥ 93	¥(9,134)	¥5,740	¥721,485
									Thousands of U	J.S. dollars (Note 1)
		Common	Capital surplus	Retained earnings	Treasury stock, at cost	Unrealized holding loss on securities	Deferred gain (loss) on hedges	Translation adjustments	Minority interests	Total net assets
Balance at April 1, 2011		\$608,346	\$5,489,549	\$2,450,711	\$(4,952)	\$(32,997)	\$(12,288)	\$(100,742)	\$70,058	\$8,467,685
Net income for the year			_	474,681		_	_		_	474,681
Cash dividends		_	_	(197,956)	_	_	_	_	_	(197,956)
Increase in treasury stock		_	_	_	(961)	_	_	_	_	(961)
Gain on sales of treasury stock		_	-	-	0	_	_	_	_	0
Net changes in items other than shareholders' equity						31,999	13,420	(10,391)	(219)	34,809
Balance at March 31, 2012		\$608,346	\$5,489,549	\$2,727,436	\$(5,913)	\$ (998)	\$ 1,132	\$(111,133)	\$69,839	\$8,778,258

# **Consolidated Statements of Cash Flows**

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries Years ended March 31, 2012 and 2011

		Millions of yen	Thousands of U.S. dollars (Note 1)
	2012	2011	2012
Cash flows from operating activities:			
Income before income taxes and minority interests  Adjustments for:	¥ 63,788	¥ 64,101	\$ 776,104
Depreciation and amortization	12,468	12,432	151,697
Loss on impairment of fixed assets	3,334	807	40,565
Amortization of goodwill	10,133	10,149	123,288
Decrease in accrued retirement benefits for employees	(1,257)	(1,285)	(15,294)
Increase in prepaid pension expenses	(1,652)	(3,719)	(20,100)
(Decrease) increase in allowance for doubtful receivables	(40)	4	(487)
Decrease in reserve for HCV litigation	(2,106)	(6,062)	(25,624)
(Decrease) increase in reserve for loss on disaster	(1,491)	1,531	(18,141)
Interest and dividend income	(2,352)	(2,342)	(28,617)
Interest expense	18	15	219
(Gain) loss on sales or disposal of fixed assets, net	(530)	309	(6,448)
Gain on sales of investments in securities	(550)	(144)	(0,440)
Loss on impairment of investments in securities	2,197	8,005	26,731
Equity in earnings of affiliates	(162)	(259)	(1,971)
Decrease (increase) in notes and accounts receivable, trade	981	(2,566)	11,936
Increase in inventories	(8,601)	(4,772)	(104,648)
(Decrease) increase in accounts payable, trade	(564)	2,489	(6,862)
Decrease in accounts payable, other	(2,142)	(2,123)	(26,061)
Other, net	(8,918)	2,151	(108,505)
Subtotal	63,104	78,721	767,782
Interest and dividends received	2,520	2,577	30,661
Interest and dividends received	(9)	(14)	(110)
Income taxes paid	(28,368)	(22,217)	(345,151)
Net cash provided by operating activities	37,247	59,067	453,182
Cash flows from investing activities:	37,217	33,007	133,102
Purchases of marketable securities	(34,898)	(74,834)	(424,602)
Proceeds from sales and redemption of marketable securities	78,065	100,605	949,811
Increase in time deposits	(1,940)	(18,674)	(23,604)
Decrease in time deposits	11,256	17,739	136,951
Increase in deposits	(110,752)	-	(1,347,512)
Increase in long-term deposits	(406)	(548)	(4,940)
Decrease in long-term deposits		569	(1,5 10)
Purchases of property, plant and equipment	(9,502)	(7,954)	(115,610)
Proceeds from sales of property, plant and equipment	2,172	894	26,427
Purchases of intangible fixed assets	(1,249)	(754)	(15,196)
Purchases of investments in securities	(1,407)	(29,767)	(17,119)
Proceeds from sales and redemption of investments in securities	5,449	5,002	66,298
Other, net	(13)	71	(158)
Net cash used in investing activities	(63,225)	(7,651)	(769,254)
Cash flows from financing activities:	(03,223)	(7,031)	(703,231)
(Decrease) increase in short-term debt, net	(718)	482	(8,736)
Repayments of long-term debt	-	(29)	(0).50
Cash dividends paid	(16,270)	(15,711)	(197,956)
Other, net	(172)	(161)	(2,093)
Net cash used in financing activities	(17,160)	(15,419)	(208,785)
Effect of exchange rate changes on cash and cash equivalents	(398)	(1,139)	(4,842)
Net (decrease) increase in cash and cash equivalents	(43,536)	34,858	(529,699)
Cash and cash equivalents at beginning of the year	97,880	62,958	1,190,899
Increase in cash and cash equivalents resulting from merger with an unconsoli-	2.,000	02,330	.,.50,055
dated subsidiary	_	5	_
Increase in cash and cash equivalents resulting from inclusion of a consolidated			
subsidiary	<u> </u>	59	_
Cash and cash equivalents at end of the year (Note 3)	¥ 54,344	¥ 97,880	\$ 661,200

# Notes to Consolidated Financial Statements

Mitsubishi Tanabe Pharma Corporation and Consolidated Subsidiaries

#### 1. BASIS OF PREPARATION OF CONSOLIDATED FINANCIAL STATEMENTS

The accompanying consolidated financial statements of Mitsubishi Tanabe Pharma Corporation (the "Company") and its consolidated subsidiaries (collectively, the "Group") have been prepared in accordance with the provisions set forth in the Corporation Law of Japan and the Financial Instruments and Exchange Law of Japan and its related accounting regulations, and in conformity with accounting principles generally accepted in Japan ("Japanese GAAP"), which are different in certain respects as to the application and disclosure requirements of International Financial Reporting Standards.

The accompanying consolidated financial statements have been compiled from the consolidated financial statements prepared by the Company as required by the Financial Instruments and Exchange Law of Japan. In preparing the accompanying consolidated financial statements, certain reclassifications and rearrangements have been made to present

them in a form which is familiar to readers outside Japan. In addition, the notes to the accompanying consolidated financial statements include information which is not required under accounting principles generally accepted in Japan but is presented herein as additional information.

Certain reclassifications of previously reported amounts have been made to conform the consolidated financial statements for the year ended March 31, 2011 to the 2012 presentation. Such reclassifications had no effect on consolidated net income or net assets.

The translation of the Japanese yen amounts into U.S. dollars is included solely for the convenience of readers outside Japan, using the prevailing exchange rate at March 31, 2012, which was ¥82.19 to U.S.\$1. This translation of convenience should not be construed as a representation that the Japanese yen amounts have been, could have been, or could in the future be, converted into U.S. dollars at this or any other rate of exchange.

#### 2. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

#### (1) Principles of Consolidation

The accompanying consolidated financial statements include the accounts of the Company and its 28 significant consolidated subsidiaries for the year ended March 31, 2012.

For the year ended March 31, 2012, the Company applied the equity method to 2 unconsolidated subsidiaries, including Choseido Pharmaceutical Co., Ltd., and 2 affiliates, including API Corporation.

Tanabe Seiyaku Malaysia, an unconsolidated subsidiary, and Arkema Yoshitomi, Ltd., an affiliated company, are not accounted for by the equity method because the net income and retained earnings of these companies are insignificant.

Nineteen overseas consolidated subsidiaries have fiscal years ending on December 31 for the year ended March 31, 2012. Since the difference between that date and the end of the Company's fiscal year is not greater than three months, the accounts of these subsidiaries as of December 31 have been used in preparing the Company's consolidated financial statements, with adjustments made as necessary to account for significant transactions occurring between December 31 and March 31.

Goodwill resulting from the difference between the cost and underlying net equity of investments in consolidated subsidiaries and affiliates accounted for by the equity method is deferred and amortized using the straight-line method over a period of fifteen years.

#### (2) Foreign Currency Transactions

All monetary receivables and payables denominated in foreign currencies are translated into yen at the rates of exchange in effect at the balance sheet date and gain or loss on each translation is credited or charged to income.

The balance sheet accounts of the overseas consolidated subsidiaries are translated into yen at the rates of exchange in effect at the balance sheet date, except that the components of net assets excluding minority interests are translated at their historical exchange rates. Revenue and expense accounts are translated at the average rates of exchange in effect during the year. Adjustments resulting from translating foreign currency financial statements are not included in the determination of net income and are presented as translation adjustments and minority interests in the accompanying consolidated balance sheets.

#### (3) Cash and Cash Equivalents

In preparing the consolidated statements of cash flows, cash on hand, readily-available deposits and short-term highly liquid investments with maturities not exceeding three months at the time of purchase are considered to be cash and cash equivalents.

#### (4) Allowance for Doubtful Receivables

The allowance for doubtful receivables is provided to cover possible losses on collection. With respect to normal trade accounts receivable, it is stated at an amount based on the actual rate of historical bad debts, and for certain doubtful receivables, the uncollectible amount has been individually estimated.

#### (5) Marketable Securities and Investments in Securities

Marketable securities and investments in securities are classified into one of the following categories based on the intent of holding, resulting in different measurements of and method of accounting for changes in fair value. Held-to-maturity debt securities are stated at amortized cost. Available-for-sale securities with available market value are stated at market value. Unrealized holding gains and unrealized holding losses on these securities are reported, net of applicable income taxes, as a separate component of accumulated other comprehensive income (loss). Other available-for-sale securities with no available market value are stated at cost determined by the moving average method. Cost of securities sold is determined by the moving average method. Investments in investment business limited liability partnerships and other similar partnerships, which are deemed to be securities under Article 2, Clause 2 of the Financial Instruments and Exchange Law of Japan, are valued at the amount of the underlying equity in their net assets based on the latest financial statements available as of the closing date stipulated in the partnership agreement.

Significant declines in market value or the net asset value of held-to-maturity debt securities, equity securities issued by unconsolidated subsidiaries and affiliated companies not accounted for by the equity method, and available-for-sale securities, judged to be other than temporary, are charged to income.

#### (6) Inventories

Inventories are stated at the lower of cost or net selling value, cost being determined primarily by the weighted average method.

# (7) Property, Plant and Equipment and Depreciation (excluding leased equipment)

Property, plant and equipment are stated at cost. Depreciation of property, plant and equipment is calculated primarily by the declining-balance method using rates based on the estimated useful lives of the respective assets. Buildings (excluding structures attached to the buildings) acquired on or after April 1, 1998 are depreciated using the straight-line method. The principal estimated useful lives are as follows:

Buildings and structures 10 to 50 years Machinery and equipment 4 to 8 years

#### (8) Intangible Fixed Assets (excluding leased assets)

Intangible fixed assets are amortized by the straight-line method. Amortization of software utilized internally is calculated by the straight-line method over an estimated useful life of primarily 5 years.

#### (9) Leased Equipment

Leased equipment arising from finance lease transactions which do not transfer ownership to the lessee are depreciated to a residual value of zero by the straight-line method using the contract term as the useful life.

Among finance lease transactions which do not transfer ownership to lessee, those that started on or before March 31, 2008 are accounted for as operating leases.

#### (10) Reserve for Employees' Bonuses

Reserve for employees' bonuses is provided at the estimated amount of bonuses to be paid to the employees in the following year which has been allocated to the current fiscal year.

#### (11) Reserve for Sales Returns

Reserve for sales returns is estimated and recorded to provide for future losses on the return of products.

#### (12) Reserve for Loss on Disaster

The Company and certain of consolidated subsidiaries have recorded amounts estimated to be necessary for expenditures related to the Great East Japan Earthquake, such as restoration of fixed assets.

# (13) Accrued Retirement Benefits for Employees

Accrued retirement benefits for employees are provided based on the estimated retirement benefit obligation and the pension assets.

Prior service cost is amortized by the straight-line method over a period of 10 years, which is within the estimated average remaining years of service of the eligible employees.

Actuarial gain or loss is amortized in the year following the year in which the gain or loss is recognized by the straight-line method over a period of 10 years, which is within the estimated average remaining years of service of the eligible employees.

On April 1, 2009, the Company integrated the retirement benefit system used by the former Tanabe Seiyaku Co., Ltd. with the retirement benefit system used by the former Mitsubishi Pharma Corporation.

Actuarial gain or loss incurred up to the year ended March 31, 2009, on

the former Tanabe Seiyaku Co., Ltd. and the former Mitsubishi Pharma Corporation pensions is being amortized beginning in the year following the year in which the gain or loss was recognized by the straight-line method over periods of 13 years for the former Tanabe Seiyaku Co., Ltd. and 5 years for the former Mitsubishi Pharma Corporation, respectively.

#### (14) Accrued Retirement Benefits for Directors and Corporate Auditors

Certain of consolidated subsidiaries have retirement benefit plans for their officers which are stated at 100 percent of the estimated amount calculated in accordance with each company's internal rules.

#### (15) Reserve for Health Management Allowances for HIV Compensation

To provide for future payments of health management allowances and settlement payments (including attorney fees) in connection with a lawsuit for damages filed by plaintiffs infected with HIV, the Company has set aside an estimated amount for such future payments.

In accordance with the settlement reached in March 1996, for health management allowances, the Company has set aside the present value of the estimated amount of future payments to be made calculated with reference to the amounts actually paid to patients with AIDS who have already reached settlements; and, for settlement payments, the Company has set aside the estimated amount of payments to be made to existing plaintiffs of HIV lawsuits as of March 31, 2012 and to future plaintiffs, as patients infected with HIV through the use of antihemophilic preparations (non-heat-treated concentrated preparations), calculated with reference to settlement outcomes up to March 31, 2012.

# (16) Reserve for Health Management Allowances for SMON (Sub-acute Myelo-Optical-Neuropathy) Compensation

The Company pays health management allowances and nursing expenses for plaintiffs covered under the compromise settlement reached in the SMON litigation.

The Company has made a provision in the accompanying consolidated financial statements for the estimated future medical treatment payments to be made over the remaining lives of the parties entitled to such payments under the compromise settlement.

#### (17) Reserve for HCV Litigation

To provide for losses that may arise in the future in accordance with "the Special Relief Law Concerning the Payment of Benefits to Relieve the Patients of Hepatitis C Infected through Specified Fibrinogen Preparations and Specified Blood-Coagulation Factor IX Preparations Contaminated by Hepatitis C Virus" ("Relief Law"), which was promulgated and enacted to facilitate the settlement of damage recovery lawsuits filed on behalf of people infected with HCV (hepatitis C virus), the Company has set aside the estimated amount of payments based on estimates of the people receiving relief and the amount of relief payments required under the Relief Law.

#### (18) Derivatives and Hedging Transactions

Derivatives positions are carried at fair value with any changes in unrealized gain or loss charged or credited to income, except for those which meet the criteria for deferral hedge accounting under which unrealized gain or loss is deferred and reported as deferred gains or losses on hedges in a separate component of accumulated other comprehensive income (loss).

#### (19) Income Taxes

Deferred income taxes are recognized with respect to the differences between financial reporting and the tax bases of the assets and liabilities. Deferred taxes are measured at the rates which are expected to apply to the period when each asset or liability is realized, based on the tax rates which have been enacted as of the balance sheet date or are subsequently enacted.

The Company and certain consolidated subsidiaries adopt the consolidated taxation system.

(Supplementary information)

(Application of Accounting Standard for Accounting Changes and Error Corrections)

Effective the year ended March 31, 2012, the Company and its domestic consolidated subsidiaries have applied "Accounting Standard for Accounting Changes and Error Corrections" (Accounting Standards Board of Japan ("ASBJ") Statement No.24 issued on December 4, 2009) and "Guidance on Accounting Standard for Accounting Changes and Error Corrections" (ASBJ Guidance No.24 issued on December 4, 2009).

Millions of yen Thousands of LLS dollars

### 3. CASH AND TIME DEPOSITS

A reconciliation of cash and deposits in the accompanying consolidated balance sheets at March 31, 2012 and 2011 and cash and cash equivalents in the accompanying consolidated statements of cash flows for the years then ended is as follows:

		Thousands of O.S. dollars	
	2012	2011	2012
Cash and deposits	¥15,466	¥ 27,409	\$188,174
Time deposits maturing after three months	(2,498)	(11,540)	(30,393)
Marketable securities maturing within three months	21,196	25,497	257,890
Cash equivalents included in other current assets	142	159	1,728
Cash equivalents included in deposits	20,038	56,355	243,801
Cash and cash equivalents	¥54,344	¥ 97,880	\$661,200

#### 4. NOTES RECEIVABLE

The balance sheet date for the year ended March 31, 2012 fell on a bank holiday. Consequently, notes receivable, trade of ¥109 million (\$1,236 thousand) with due dates on March 31, 2012 were included in the balance and settled on the next business day.

#### **5. FINANCIAL INSTRUMENTS**

#### Overview

#### (1) Policy for Financial Instruments

The Group manages its funds by investing in both short-term and long-term, highly stable, financial assets.

The Group has introduced a cash management system ("CMS") to efficiently use capital and reduce financing costs, and enable Group companies to internally borrow and lend among themselves.

The policy with regard to derivative transactions is to limit the amount to the actual demand, and transactions are not carried out for speculative purposes.

#### (2) Types of Financial Instruments and Related Risk

Notes and accounts receivable, trade, are amounts owed to the Group, and are subject to the credit risk of customers. Marketable securities and investments in securities are mainly Japanese government bonds, bonds to be held to maturity, or shares of counterparty companies in operational or capital alliances, and are subject to risk from market price fluctuations. The deposits are funds to the parent company primarily. The deposits are exposed to its credit risks.

Accounts payable, trade, are operating obligations to be paid by the Group and most are payable within one year. A portion of these are for purchases of raw materials and are denominated in foreign currencies, and are subject to risk from exchange rate fluctuations. As necessary, however, these are netted against operating claims and forward foreign

exchange contracts are used to hedge the net position.

Derivative transactions involve forward foreign exchange contracts and currency option contracts entered into in order to manage the risk arising from adverse fluctuation in foreign currency exchange rates related to operating claims and obligations denominated in foreign currencies.

#### (3) Risk Management for Financial Instruments

## (a) Monitoring of credit risk

As to the management of credit risk (risk of nonperformance by counterparty), the Group regularly monitors the status of major counterparties with regard to operating claims and manages maturity dates and outstanding amounts by transaction counterparty in accordance with its claims management regulations, while at the same time working to quickly identify and reduce concerns of repayment resulting from the weakening of a counterparty's financial position.

Japanese government bonds, bonds to be held to maturity and deposits are deemed to have minimal credit risk because the Group primarily invests only in bonds with high ratings.

To strictly minimize the credit risk related to counterparty nonperformance when entering into derivative transactions, counterparties are limited to financial institutions with high credit ratings.

The maximum amount of credit risk as of the end of the fiscal year is reflected in the amounts recorded for financial assets in the consolidated balance sheets that are subject to credit risk.

#### (b) Monitoring of market risks

As to the management of market risks (risks from exchange rate or interest rate fluctuations), foreign currency-denominated operating claims and obligations are hedged as necessary using forward foreign exchange contracts and foreign exchange options.

The market value of marketable securities and investments in securities are regularly determined and the financial position of the issuer (counterparty company) is monitored, and for securities other than Japanese government bonds and bonds to be held to maturity, the decision of whether to continue to hold the security or not is regularly reviewed taking into account for the relationship with the counterparty companies.

For derivative transactions, the authority to enter into transactions and the maximum amounts of those transactions are determined based on internal regulations, and outstanding contract amounts, market values are regularly reported to the responsible director.

#### (c) Monitoring of liquidity risk

As to the management of liquidity risk associated with fund procurement (risk of being unable to make payment on payment date), based on

reports submitted by each department, the Finance & Accounting Department prepares and updates funding plans in a timely manner, while at the same time the Group manages liquidity risk by means of maintaining sufficient liquidity on hand.

# (4) Supplementary Explanation of the Estimated Fair Value of Financial Instruments

The market value of financial instruments is based on the market price, and when no market price exists, a rationally calculated amount is used. These calculations include variable factors, so the resulting amount may fluctuate if different underlying assumptions are applied. The notional amounts shown in Note 21 "Derivative and Hedging Transactions" do not represent the amounts of their market risk.

The carrying value of financial instruments on the accompanying consolidated balance sheets as of March 31, 2012 and 2011, and their estimated market value are shown in the following table. The following table does not include financial instruments for which it is extremely difficult to determine the market value.

Mill	lions	of	yer

			2012
	Carrying value	Market value	Difference
Assets:			
Cash and deposits	¥ 15,466	¥ 15,466	¥ –
Notes and accounts receivable, trade	127,207	127,207	_
Marketable securities and investments in securities	150,717	149,168	(1,549)
Deposits	130,791	130,791	_
Total assets	¥424,181	¥422,632	¥(1,549)
Liabilities:			
Accounts payable, trade	28,878	28,878	_
Short-term debt	2,170	2,170	_
Total liabilities	¥ 31,048	¥ 31,048	¥ –
Derivative transactions in other current assets or other assets	¥ 150	¥ 150	¥ –

Millions of yen

			2011
	Carrying value	Market value	Difference
Assets:			
Cash and deposits	¥ 27,409	¥ 27,409	¥ -
Notes and accounts receivable, trade	128,375	128,375	_
Marketable securities and investments in securities	199,005	196,896	(2,109)
Deposits	56,356	56,356	_
Total assets	¥411,145	¥409,036	¥(2,109)
Liabilities:			
Accounts payable, trade	29,617	29,617	_
Short-term debt	2,891	2,891	-
Total liabilities	¥ 32,508	¥ 32,508	¥ –
Derivative transactions in other current liabilities or other liabilities	¥ (1,702)	¥ (1,702)	¥ –

Thousands of U.S. dollars

			2012
	Carrying value	Market value	Difference
Assets:			
Cash and deposits	\$ 188,174	\$ 188,174	\$ -
Notes and accounts receivable, trade	1,547,719	1,547,719	_
Marketable securities and investments in securities	1,833,763	1,814,916	(18,847)
Deposits	1,591,325	1,591,325	_
Total assets	\$5,160,981	\$5,142,134	\$(18,847)
Liabilities:			
Accounts payable, trade	351,357	351,357	_
Short-term debt	26,402	26,402	_
Total liabilities	\$ 377,759	\$ 377,759	\$ -
Derivative transactions in other current assets or other assets	\$ 1,825	\$ 1,825	\$ -

The value of assets and liabilities arising from derivative transactions are shown as the net amount, with total net obligations shown in parentheses.

The financial instruments such as cash and deposits; notes and accounts receivable, trade; deposits; accounts payable, trade; and short-term debt are settled within a short period of time and the market value is therefore nearly equal to the book value, so the book value is used.

As to the market value of marketable securities and investment in securities, the exchange price prevailing in the applicable stock exchange is used for equities, and the exchange price prevailing in the applicable stock exchange or price provided by financial institutions is used for bonds. Negotiable certificates of deposit and commercial paper are settled within a short period of time and the market value is therefore nearly equal to the book value, so the book value is used.

Financial instruments for which it is deemed extremely difficult to determine the market value at March 31, 2012 and 2011 are as follows:

		Thousands of U.S. dollars	
	2012	2011	2012
			Carrying value
Unlisted and unquoted stocks	¥11,263	¥12,477	\$137,036
Investments in investment business limited liability partnerships	961	908	11,692

Scheduled redemption amounts after the end of the fiscal years ended March 31, 2012 and 2011 for monetary claims and marketable securities with maturities are as follows:

				Millions of yen
				2012
	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Current and time deposits	¥ 15,454	¥ –	¥ –	¥ –
Notes and accounts receivable, trade	127,207	_	_	_
Marketable securities and investments in securities: Held-to-maturity debt securities:				
Bonds	_	_	1,897	_
Other	2,077	3,500	500	10,000
Available-for-sale securities with maturities:		•••••••••••••••••••••••••••••••••••••••	•••••••••••••••••••••••••••••••••••••••	
Bonds	9,000	52,300	_	_
Other	37,200	_	_	_
Deposits	130,791	_	_	_
Total	¥321,729	¥55,800	¥2,397	¥10,000

N/III	llions	$\cap$ t	Ven

				ivillions of yen
				2011
	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Current and time deposits	¥ 27,399	¥ –	¥ –	¥ -
Notes and accounts receivable, trade	128,375	_	_	_
Marketable securities and investments in securities:		••••	••••	
Held-to-maturity debt securities:				
Bonds	490	_	2,018	_
Other	4,582	4,509	2,518	10,000
Available-for-sale securities with maturities:		••••		
Bonds	28,585	61,841	_	_
Other	55,547	_		_
Deposits	56,356	_	_	_
Total	¥301,334	¥66,350	¥4,536	¥10,000
			-	Thousands of U.S. dollars
				2012
	Due in one year or less	Due after one year through five years	Due after five years through ten years	Due after ten years
Current and time deposits	\$ 188,028	\$ -	\$ -	\$ -
Notes and accounts receivable, trade	1,547,719	_	_	_
Marketable securities and investments in securities:				
Held-to-maturity debt securities:				
Bonds	_	_	23,081	_
Other	25,271	42,584	6,083	121,669
Available-for-sale securities with maturities:		•••	••••	
Bonds	109,502	636,330	_	_
Other	452,609	_	_	_
Deposits	1,591,325	_	_	_
Total	\$3,914,454	\$678.914	\$29,164	\$121,669

# 6. MARKETABLE SECURITIES AND INVESTMENTS IN SECURITIES

Held-to-maturity debt securities with available market value at March 31, 2012 and 2011 are as follows:

Treat to matarity debt securities with available market value at						Millions of yen
					Held-to-matur	ity debt securities
			2012			2011
	Carrying value	Market value	Unrealized gain (loss)	Carrying value	Market value	Unrealized gain (loss)
Securities with market value exceeding carrying value:						
Bonds	¥ 3,922	¥ 4,286	¥ 364	¥ 6,935	¥ 7,179	¥ 244
Securities with market value not exceeding carrying value:						
Bonds	14,084	12,171	(1,913)	17,182	14,829	(2,353)
Total	¥18,006	¥16,457	¥(1,549)	¥24,117	¥22,008	¥(2,109)

	Thousands of U.S. dollars			
		Held-to-matu	rity debt securities	
			2012	
	Carrying value	Market value	Unrealized gain (loss)	
Securities with market value exceeding carrying value:				
Bonds	\$ 47,719	\$ 52,147	\$ 4,428	
Securities with market value not exceeding carrying value:		·		
Bonds	171,359	148,084	(23,275)	
Total	\$219,078	\$200,231	\$(18,847)	

Available-for-sale securities with available market value at March 31, 2012 and 2011 are as follows:

Available-101-sale securities with available market value at iv	iaicii 51, 2012 a	110 2011 ale as 1	OllOVV3.			Millions of yen
				Available-for-sa	ale securities with avail	lable market value
			2012			2011
	Acquisition cost	Carrying value	Unrealized gain (loss)	Acquisition cost	Carrying value	Unrealized gain (loss)
Securities with carrying value exceeding acquisition cost:						
Stocks	¥ 10,502	¥ 15,506	¥ 5,004	¥ 3,023	¥ 5,097	¥ 2,074
Bonds	61,319	61,948	629	70,345	70,915	570
Subtotal	71,821	77,454	5,633	73,368	76,012	2,644
Securities with carrying value not exceeding acquisition cost:		•••••••••••••••••••••••••••••••••••••••			•••••••••••••••••••••••••••••••••••••••	•••••••••••••••••••••••••••••••••••••••
Stocks	23,396	18,061	(5,335)	30,165	23,818	(6,347)
Bonds	_	_	_	19,517	19,511	(6)
Other	37,196	37,196	_	55,547	55,547	_
Subtotal	60,592	55,257	(5,335)	105,229	98,876	(6,353)
Total	¥132,413	¥132,711	¥ 298	¥178,597	¥174,888	¥(3,709)

Thousands of U.S. dollars				
	Available-for-sale securities with available market value			
			2012	
	Acquisition cost	Carrying value	Unrealized gain (loss)	
Securities with carrying value exceeding acquisition cost:				
Stocks	\$ 127,777	\$ 188,660	\$ 60,883	
Bonds	746,064	753,717	7,653	
Subtotal	873,841	942,377	68,536	
Securities with carrying value not exceeding acquisition cost:				
Stocks	284,658	219,747	(64,911)	
Bonds	_	_	_	
Other	452,561	452,561	_	
Subtotal	737,219	672,308	(64,911)	
Total	\$1,611,060	\$1,614,685	\$ 3,625	

Impairment losses on available-for-sale securities amounting to ¥2,197 million (\$26,731 thousand), and ¥8,005 million were recorded for the years ended March 31, 2012 and 2011, respectively.

Available-for-sale secur	ities sold during the years end	ed March 31, 2012 a	nd 2011 are as follow	S:		
						Millions of yen
					Available-f	or-sale securities sold
			2012			2011
	Proceeds	Gain on sale	Loss on sale	Proceeds	Gain on sale	Loss on sale
Stocks	¥19	¥5	¥–	¥452	¥135	¥64
Other	_	_	_	50	9	_
Total	¥19	¥5	¥–	¥502	¥144	¥64
		Thou	isands of U.S. dollars			
		Available-f	or-sale securities sold			
			2012			
	Proceeds	Gain on sale	Loss on sale			
Stocks	\$231	\$61	\$-			
Other	_	_	_			
Total	\$231	\$61	<u>\$</u>			

### 7. INVENTORIES

Inventories at March 31, 2012 and 2011 are as follows:

		ivillions of yen	Thousands of U.S. dollars
	2012	2011	2012
Finished goods and merchandise	¥64,259	¥57,173	\$ 781,835
Semi-finished products and work-in-process	897	1,417	10,914
Raw materials and supplies	21,034	19,112	255,919
Total	¥86,190	¥77,702	\$1,048,668

### 8. SHORT-TERM DEBT

The annual weighted average interest rates on short-term debt at March 31, 2012 and 2011 are as follows:

	2012	2011
Short-term debt	1.31%	0.41%

#### 9. LEASE OBLIGATIONS

The aggregate annual maturities of lease obligations recorded as other current liabilities and other liabilities subsequent to March 31, 2012 are summarized as follows:

Years ending March 31,	Millions of yen	Thousands of U.S. dollars
2013	¥20	\$243
2014	19	231
2015	13	158
2016	12	146
2017	9	110
Total	¥73	\$888

#### **10. ACCRUED RETIREMENT BENEFITS**

The Company and certain consolidated subsidiaries offer a choice between a defined contribution pension plan and a prepaid plan; a choice between a cash balance plan and a prepaid plan; a contract-type defined-benefit corporate pension plan; or a system of lump-sum payments at retirement.

There are also cases in which additional retirement allowances not included in the actuarial calculation as per retirement benefit accounting are paid when an employee retires.

Certain consolidated subsidiaries have joined comprehensive multiple employer welfare pension plans. In addition, the Company has established a retirement benefit trust.

On April 1, 2011, the Company transferred a qualified pension system (closed-type) to a contract-type defined-benefit corporate pension plan in accordance with the Defined Benefit Corporate Pension Act.

The following table sets forth the funded and accrued status of the retirement benefit plans and the amounts recognized in the accompanying consolidated balance sheets at March 31, 2012 and 2011 for the Group's defined benefit pension plans:

Millions of yen		Thousands of U.S. dollars
2012	2011	2012
¥(150,320)	¥(142,177)	\$(1,828,933)
143,895	138,610	1,750,760
(6,425)	(3,567)	(78,173)
39,387	33,817	479,219
(1,445)	(1,654)	(17,581)
31,517	28,596	383,465
42,101	40,449	512,240
¥ (10,584)	¥ (11,853)	\$ (128,775)
	¥(150,320) 143,895 (6,425) 39,387 (1,445) 31,517 42,101	2012         2011           ¥(150,320)         ¥(142,177)           143,895         138,610           (6,425)         (3,567)           39,387         33,817           (1,445)         (1,654)           31,517         28,596           42,101         40,449

The components of retirement benefit expenses for the years ended March 31, 2012 and 2011 are outlined as follows:

		Millions of yen		
	2012	2011	2012	
Service cost	¥ 2,497	¥ 2,235	\$ 30,381	
Interest cost	3,549	3,567	43,180	
Expected return on plan assets	(3,461)	(3,475)	(42,110)	
Amortization of actuarial loss	6,417	4,039	78,075	
Amortization of prior service cost	(210)	(217)	(2,555)	
Contributions to multiple employer welfare pension plans	8	8	97	
Retirement benefit expenses	¥ 8,800	¥ 6,157	\$107,069	
Other	912	870	11,096	
Total retirement benefit expenses	¥ 9,712	¥ 7,027	\$118,165	

In addition to the retirement benefit expenses listed above, additional retirement allowances totaling ¥109 million (\$1,325 thousand) and ¥482 million were recognized and accounted for as special retirement benefits for the years ended March 31, 2012 and 2011, respectively.

"Other" in the above table represents contributions to defined contribution pension plans.

The assumptions used in accounting for the above defined benefit pension plans for the years ended March 31, 2012 and 2011 are as follows:

	2012	2011
Discount rates	1.8%	2.5%
Expected rate of return on plan assets	2.5%	2.5%

The funded status related to the multiple employer welfare pension plans for the years ended March 31, 2012 and 2011 is as follows:

		Thousands of U.S. dollars	
	2012	2011	2012
Pension assets	¥ 239,856	¥ 254,274	\$ 2,918,311
Benefit obligations calculated under pension financing	363,315	365,248	4,420,428
Unfunded obligations	¥(123,459)	¥(110,974)	\$(1,502,117)

The Group's overall contributions to the plan were 0.14% and 0.15% as of March 31, 2012 and 2011, respectively.

These percentages are not the same as the Group's actual percentage of obligations.

The above information on the funded status and the Group's contribution percentage were as of March 31, 2011 and 2010, the most recent valuation dates.

## 11. INCOME TAXES

The Company and certain domestic consolidated subsidiaries are subject to a number of different income taxes, which, in the aggregate, indicate a statutory tax rate in Japan of approximately 40.6% for the years ended March 31, 2012 and 2011.

Overseas consolidated subsidiaries are subject to the income taxes of the respective countries in which they operate.

The effective tax rates reflected in the accompanying consolidated statements of income for the years ended March 31, 2012 and 2011 differ from the above statutory tax rate for the following reasons:

	2012	2011
Statutory tax rate	40.6%	40.6%
Adjustments:		
Amortization of goodwill	6.4	6.3
Non-deductible expenses	2.8	2.7
Non-taxable dividend income, etc.	(1.9)	(2.0)
Elimination of dividends upon consolidation	1.6	1.7
Adjustment for per capita inhabitant taxes	0.2	0.2
Special deduction for R&D expenses	(9.2)	(7.7)
Valuation allowance	(0.2)	0.1
Effect of changes in corporation tax rates	(1.3)	_
Other	(0.5)	(0.6)
Effective tax rates	38.5%	41.3%

Adjustment of deferred tax assets and liabilities due to change in the corporate tax rate

Due to the promulgation on December 2, 2011, of the "Act for Partial Revision of the Income Tax Act, etc., for the Purpose of Creating a Taxation System Responding to Changes in Economic and Social Structures" (Act No.114 of 2011) and the "Act on Special Measures for Securing Financial Resources Necessary to Implement Measures for Reconstruction following the Great East Japan Earthquake" (Act No.117 of 2011), the effective statutory tax rate used to measure deferred tax assets and liabilities in the fiscal year ended March 31, 2012 has been changed from

40.6% used in the previous fiscal year to 37.9% for items expected to be realized from fiscal years during the period beginning April 1, 2012 to March 31, 2015, and to 35.5% for items expected to be realized in fiscal years beginning April 1, 2015.

As a result of this change, the net amount of deferred tax assets increased by ¥828 million (\$10,074 thousand), deferred gain on hedges increased by ¥4 million (\$49 thousand), income taxes-deferred decreased by ¥839 million (\$10,208 thousand), and unrealized holding loss on securities decreased by ¥15 million (\$183 thousand) as of and for the year ended March 31, 2012.

The significant components of deferred tax assets and liabilities of the Company and its consolidated subsidiaries at March 31, 2012 and 2011 are summarized as follows:

		Millions of yen	
	2012	2011	2012
Deferred tax assets:			
Reserve for employees' bonuses	¥ 4,089	¥ 4,539	\$ 49,751
Enterprise taxes	808	1,382	9,831
Loss on devaluation of inventories	2,007	2,121	24,419
Unrealized gain on inventories	1,980	2,220	24,090
Accrued retirement benefits for employees	228	201	2,774
Reserve for health management allowances for SMON compensation	478	500	5,816
Reserve for health management allowances for HIV compensation	522	614	6,351
Reserve for HCV litigation	955	1,878	11,619
Loss on devaluation of investments in securities	96	110	1,168
Excess amortization of long-term prepaid expenses	4,480	4,726	54,508
Prepaid research expenses	9,796	12,718	119,187
Net operating loss carryforward	16,833	17,943	204,806
Excess depreciation	1,364	1,697	16,596
Loss on impairment of fixed assets	1,425	1,464	17,338
Other	1,163	3,360	14,150
Gross deferred tax assets	46,224	55,473	562,404
Valuation allowance	(17,056)	(18,320)	(207,519)
Total deferred tax assets	29,168	37,153	354,885
Deferred tax liabilities:			
Prepaid pension expenses	(4,690)	(4,295)	(57,063)
Unrealized holding gains on securities	(6,103)	(5,057)	(74,255)
Deferred capital gain on property	(1,510)	(1,834)	(18,372)
Reserve for special depreciation	-	(1)	_
Unrealized holding gain on land	(8,618)	(10,888)	(104,855
Other	(355)	(188)	(4,319)
Total deferred tax liabilities	(21,276)	(22,263)	(258,864)
Net deferred tax assets	¥ 7,892	¥ 14,890	\$ 96,021

The net deferred tax assets of ¥7,892 million (\$96,021 thousand) and ¥14,890 million as of March 31, 2012 and 2011 in the above table are analyzed as follows:

	Millions of yen		of yen Thousands of U.S. dollars	
	2012	2011	2012	
Deferred income taxes – current assets	¥ 9,343	¥ 12,551	\$ 113,676	
Deferred income taxes – non-current assets	7,898	13,789	96,095	
Deferred income taxes included in other current liabilities	(11)	_	(135)	
Deferred income taxes – non-current liabilities	(9,338)	(11,450)	(113,615)	
	¥ 7,892	¥ 14,890	\$ 96,021	

### 12. SHAREHOLDERS' EQUITY

The Corporation Law of Japan (the "Law") provides that an amount equal to 10% of the amount to be disbursed as distributions of capital surplus (other than the capital reserve) and retained earnings (other than the legal reserve) be transferred to the capital reserve and the legal reserve, respectively, until the sum of the capital reserve and the legal reserve equals 25% of the capital stock account. Such distributions can be made at any time by resolution of the shareholders, or by the Board of Directors if certain conditions are met.

Under the Law, upon the issuance and sale of new shares of common stock, the entire amount of the proceeds is required to be accounted for as common stock, although a company may, by resolution of the Board of Directors, account for an amount not exceeding one-half of the proceeds of the sale of new shares as additional paid-in capital.

#### Common stock and treasury stock

Movements in common stock in issue and treasury stock for the years ended March 31, 2012 and 2011 are summarized as follows:

				Thousands of shares
				2012
	Number of shares at beginning of the fiscal year	Increase during the fiscal year	Decrease during the fiscal year	Number of shares at end of the fiscal year
Common stock	561,417	_	-	561,417
Treasury stock	353	70	0	423
				Thousands of shares
				2011
	Number of		•	Number of shares

				2011
	Number of shares at beginning of the fiscal year	Increase during the fiscal year	Decrease during the fiscal year	Number of shares at end of the fiscal year
Common stock	561,417	_	_	561,417
Treasury stock	256	101	4	353

### 13. CONTINGENT LIABILITIES

The Group had the following contingent liabilities at March 31, 2012 and 2011:

	Millions of yen		ren Thousands of U.S. dollars	
	2012	2011	2012	
Debt guaranteed:				
Employees' housing loans from banks	¥ 80	¥ 97	\$ 973	
Bank loans to Choseido Pharmaceutical Co., Ltd.	¥2,577	¥ 3,174	\$31,354	

#### 14. RESEARCH AND DEVELOPMENT EXPENSES

Research and development expenses for improvement of existing products and development of new products, including basic research and fundamental development costs, are charged to income as incurred.

Research and development expenses included in selling, general and administrative expenses for the years ended March 31, 2012 and 2011 were ¥70,241 million (\$854,617 thousand) and ¥65,784 million, respectively.

#### 15. LOSS RELATED TO BUSINESS SUSPENSION

Loss related to business suspension was recorded mainly in relation to the suspension of manufacturing for recombinant human serum albumin preparation, "Medway Injection."

#### **16. LOSS ON IMPAIRMENT OF FIXED ASSETS**

The Company and its consolidated subsidiaries group their assets in association with their business and production process. Idle assets which are not anticipated to be utilized in the future and leased property are classified as individual cash-generating units. Assets, which are not definitely linked to a specific business, such as the head-office building, the facilities for research and development and the facilities for welfare, are classified as corporate assets.

For the year ended March 31, 2012, the book value of the impaired fixed assets, which primarily includes idle assets, was reduced to the recoverable amount, and the amount of the reduction of ¥3,334 million (\$40,565 thousand) was recorded as loss on impairment of fixed assets. The impairment loss on primary fixed assets is summarized as follows:

Location	Major use	Classification	Millions of yen	Thousands of U.S. dollars
Mitsubishi Tanabe Pharma Sanban-cho Building (Chiyoda-ku, Tokyo)	•	Land, buildings and structures	¥2,923	\$35,564
Mitsubishi Tanabe Pharma Kashima Building for Raw Materials (Kamisu City, Ibaragi)	Research facility	Buildings and structures	206	2,506
Mitsubishi Tanabe Pharma No. 3 Hirano-machi Building (Chuo-ku, Osaka City)	Administrative and sales operations	Land	141	1,716

In connection with the relocation of the Company's Tokyo Branch, the Sanban-cho Building will become an idle asset. In addition, the Company decided to sell the Kashima Building used for the development of raw materials and the No.3 Hirano-machi Building. The book values of the above assets were reduced to its recoverable amounts accordingly. The recoverable amounts are measured at their net selling values. The net selling values are based on reasonable estimates made with reference to the officially published prices or estimated selling amounts.

For the year ended March 31, 2011, the book value of the impaired fixed assets, which primarily includes idle assets, was reduced to the recoverable amount, and the amount of the reduction of ¥807 million was recorded as loss on impairment of fixed assets. The impairment loss on primary fixed assets is summarized as follows:

Location	Major use	Classification	Millions of yen
Mitsubishi Tanabe Pharma Kyushu Branch	Sales operations	Land and buildings	
(Hakata-ku, Fukuoka City)			¥227
Mitsubishi Tanabe Pharma Yokohama Office	Research facility	Buildings and structures	
(Aoba-ku, Yokohama City)			131
Mitsubishi Tanabe Pharma Toyonaka Parking Lot	Leasing	Land	
(Toyonaka City, Osaka)	_		256

In connection with the relocation of the Company's Kyushu Branch, the former building became an idle asset. In addition, in connection with the completion of the new building for the Medicinal Chemistry Laboratory, the former research laboratory on the premises of the Yokohama Office became an idle asset. The future cash flow of the Toyonaka Parking Lot is

below its book value due to the decline of its profitability. The book values of the above assets were reduced to their recoverable amounts accordingly. The recoverable amounts of these assets are measured at their net selling values. The net selling values are based on reasonable estimates made with reference to the officially published prices.

### 17. LOSS ON DISASTER

For the year ended March 31, 2012, the Group recorded a loss on disaster consisting of fixed costs during the period in which operations of certain consolidated subsidiaries were shut down in connection with the impact of the Great East Japan Earthquake.

For the year ended March 31, 2011, in connection with the impact of the Great East Japan Earthquake, the Group recorded a loss on disaster consisting of losses on inventories, expenses for supporting the restoration of third-party wholesalers, fixed costs during the period in which operations of certain consolidated subsidiaries were shut down, and a reserve for loss on disaster.

# 18. OTHER COMPREHENSIVE INCOME

The following table presents reclassification adjustments and tax effects of other comprehensive income for the year ended March 31, 2012:

	Millions of yen	Thousands of U.S. dollars
	2012	2012
Unrealized holding gains on securities:		
Amount arising during the year	¥ 4,932	\$ 60,007
Reclassification adjustments	(491)	(5,974)
Before tax effects	4,441	54,033
Tax effects	(1,806)	(21,973)
Unrealized holding gains on securities	2,635	32,060
Deferred gain on hedges:		
Amount arising during the year	217	2,640
Reclassification adjustments	1,635	19,893
Before tax effects	1,852	22,533
Tax effects	(748)	(9,101)
Deferred gain on hedges	1,104	13,432
Translation adjustments:		
Amount arising during the year	(1,042)	(12,678)
Other comprehensive income of equity method companies attributable to the Company:		
Amount arising during the year	(11)	(134)
Other comprehensive income	¥ 2,686	\$ 32,680

### 19. RELATED PARTY TRANSACTIONS

Principal transactions between the Company and related parties for the years ended March 31, 2012 and 2011 are summarized as follows: [Transactions with Mitsubishi Chemical Holdings Corporation ("MCHC")]

	Millions of yen	Thousands of U.S. dollars
	2012	2012
Deposits	¥130,789	\$1,591,301
Interest income	496	6,035
[Transactions with MCFA Inc.]		
	Millions of yen	
	2011	
Deposits	¥17,384	
Interest income	184	

MCHC is the parent company.

MCFA Inc. is a fellow subsidiary of the Company whose parent company is MCHC.

The balances due to MCHC or MCFA Inc. at March 31, 2012 and 2011 are as follows:

		Millions of yen	Thousands of U.S. dollars
	2012	2011	2012
Due to MCHC	¥130,789	¥ -	\$1,591,301
Due to MCFA Inc.	_	56,355	_

#### 20. LEASES

The following pro forma amounts represent the acquisition cost, accumulated depreciation and net book value of property leased to the Company and its consolidated subsidiaries at March 31, 2012 and 2011, which would have been reflected in the accompanying consolidated balance

sheets if finance leases, other than those which transfer the ownership of the leased property to the Company or its consolidated subsidiaries, that started on or before March 31, 2008 (which are currently accounted for as operating leases) had been capitalized:

Mil	lions	of	ye
-----	-------	----	----

			2012			2011
	Acquisition cost	Accumulated depreciation	Net book value	Acquisition cost	Accumulated depreciation	Net book value
Category of leased property:						
Machinery	¥ –	¥ –	¥ -	¥ 80	¥ 72	¥ 8
Tools and equipment	233	193	40	657	540	117
Total	¥233	¥193	¥40	¥737	¥612	¥125

Thousands of U.S. dollars

			2012
	Acquisition cost	Accumulated depreciation	Net book value
Category of leased property:			
Machinery	\$ -	\$ -	\$ -
Tools and equipment	2,835	2,348	487
Total	\$2,835	\$2,348	\$487

Lease payments of the Company and its consolidated subsidiaries relating to finance leases accounted for as operating leases amounted to ¥95 million (\$1,156 thousand) and ¥177 million for the years ended March 31, 2012 and 2011, respectively. Depreciation on these leased assets calculated by the straight-line method would have amounted to ¥95 million (\$1,156 thousand) and ¥177 million for the years ended March 31, 2012 and 2011, respectively, if it had been reflected in the accompanying consolidated balance sheets.

Future minimum lease payments (including the interest portion thereon) subsequent to March 31, 2012 under finance leases, other than those which transfer the ownership of the leased property to the Company or its consolidated subsidiaries, that started on or before March 31, 2008 are summarized as follows:

Years ending March 31,	Millions of yen	Thousands of U.S. dollars
2013	¥26	\$317
2014 and thereafter	14	170
	¥40	\$487

Future minimum payments subsequent to March 31, 2012 under non-cancelable operating leases are summarized as follows:

Years ending March 31,	Millions of yen	Thousands of U.S. dollars
2013	¥1,034	
2014 and thereafter	634	7,714
	¥1,668	\$20,294

#### 21. DERIVATIVE AND HEDGING TRANSACTIONS

Derivative financial instruments are utilized by the Company principally in order to manage the risk arising from adverse fluctuation in foreign currency exchange rates. The Company has established a control environment which includes policies and procedures for risk assessment, including an assessment of the effectiveness of hedging, and for the approval, reporting and monitoring of transactions involving derivatives. The Company does not hold or issue derivatives for speculative trading purposes.

The Company is exposed to certain market risk arising from forward foreign exchange contracts and currency option contracts. The Company is also exposed to the risk of credit loss in the event of non-performance by any of the counterparties to the forward foreign exchange contracts and currency option contracts; however, the Company does not anticipate non-performance by any of these counterparties, all of whom are financial institutions with high credit ratings.

The Company does not carry out an assessment of hedge effectiveness because of a high correlation between the hedging instruments and hedged items. The notional amounts and estimated fair value on the outstanding derivatives positions for which hedge accounting has been applied at March 31,

2012 and 2011 are as follows:			Millions of yen
			2012
	Notional amounts	Over one year	Estimated fair value
Forward foreign exchange contracts:			
Buying:			
USD, accounts payable–trade	¥28,240	¥13,775	¥157
Currency option contracts:			
Selling:			
USD, accounts payable–trade	1,837	_	(5)
GBP, accounts payable–trade	420		(2)
Buying:			(=)
USD, accounts payable–trade	1,837		(1)
GBP, accounts payable–trade	420		1
	420		¥150
Total	<del></del>		<b>‡130</b>
			Millions of yen
			2011
	Notional amounts	Over one year	Estimated fair value
Forward foreign exchange contracts:			
Buying:			
USD, accounts payable–trade	¥28,146	¥13,454	¥(1,656)
EUR, accounts payable—other	106	+15,454	
GBP, accounts payable—other	603		2 10
Currency option contracts:			
Selling:	0.072	0.072	2
USD, accounts payable–trade	8,972	8,972	2
Buying:	0.070		(50)
USD, accounts payable–trade	8,972	8,972	(60)
<u>Total</u>			¥(1,702)
			Thousands of U.S. dollars
			2012
	Notional amounts	Over one year	Estimated fair value
Forward foreign analysis and some sections of	- INOtional amounts	Over one year	Estilliated fall value
Forward foreign exchange contracts:			
Buying:	£242 F04	£467 F00	£1.010
USD, accounts payable–trade	\$343,594	\$167,599	\$1,910
Currency option contracts:			
Selling:			(5.1)
USD, accounts payable–trade	22,351		(61)
GBP, accounts payable–trade	5,110		(24)
Buying:			
USD, accounts payable–trade	22,351		(12)
GBP, accounts payable–trade	5,110		12
Total			\$1,825
22. AMOUNTS PER SHARE			
Amounts per share as of and for the years ended March 31, 2012 and 2011 are as follows:			
,		Yen	U.S. dollars
	2012	2011	2012

69.54

35.00

¥1,275.85

¥ 67.27

¥1,230.16

28.00

\$ 0.85

\$15.52

0.43

Net income

Net assets

Cash dividends

Diluted net income per share has not been presented since no potentially dilutive securities have been issued.

Net income per share is computed based on the net income available for distribution to shareholders of common stock and the weighted average number of shares of common stock outstanding during each year. The amounts per share of net assets are computed based on the number of shares of common stock outstanding at the year end.

Cash dividends per share represent the cash dividends proposed by the Board of Directors as applicable to the respective fiscal years together with the interim cash dividends paid.

#### 23. SEGMENT INFORMATION

The Company and consolidated subsidiaries are primarily engaged in the research and development, manufacturing, procurement, and sales of pharmaceuticals, and "Pharmaceuticals" is therefore the only reportable segment.

In the Pharmaceuticals segment, the Company and consolidated subsidiaries operate business activities related to ethical drugs and overthe-counter ("OTC") drugs in Japan and overseas.

As the Pharmaceuticals segment is the only reportable segment, the disclosure of segment information, such as calculation method of net sales, profit or loss, assets, liabilities and other items by reportable segment; information regarding amounts of net sales, profit or loss, assets, liabilities and other items by reportable segment; differences between totals for reportable segments and amounts presented in consolidated financial statements and major details about such differences; information regarding impairment losses on fixed assets by reportable

segment; and information regarding amount of amortization of goodwill and unamortized balance by reportable segment, for the year ended March 31, 2012 and 2011 has been omitted.

As sales of products and services to external customers in a single segment account for more than 90% of net sales in the consolidated statements of income, the disclosure of the information by product and service for the years ended March 31, 2012 and 2011 has been omitted.

As sales of products and services to external customers in Japan account for more than 90% of net sales in the consolidated statements of income, the disclosure of net sales by region for the years ended March 31, 2012 and 2011 has been omitted.

As the amount of property, plant and equipment located in Japan accounts for more than 90% of property, plant and equipment in the consolidated balance sheets, the disclosure of property, plant and equipment by region for the years ended March 31, 2012 and 2011 has been omitted.

The following table summarizes the information by major customers for the years ended March 31, 2012 and 2011:

	Millions of yen		Thousands of U.S. dollars	
	2012	2011	2012	
Customer name			Net sales	Related segment
SUZUKEN CO., LTD.	¥74,484	¥72,453	\$906,242	Pharmaceuticals
Toho Pharmaceutical Co., Ltd.	68,837	67,643	837,535	Pharmaceuticals
Alfresa Corporation	58,305	56,377	709,393	Pharmaceuticals
MEDICEO CORPORATION	57,092	58,570	694,634	Pharmaceuticals

#### 24. LITIGATION

# Court action for damages relating to HIV (human immunodeficiency virus) infection

The former Green Cross Corporation, one of the predecessors of the Company, together with the Japanese government and four other pharmaceutical manufacturers were named as defendants in a number of lawsuits for compensation filed by the plaintiffs claiming to have been infected with HIV (human immunodeficiency virus) through use of non-heat-treated concentrated preparations.

During the period from the first settlement relating to the lawsuits, which was agreed to on March 29, 1996, to March 31, 2011, settlements were reached with 1,379 plaintiffs. Subsequently, on April 15, 2011, settlements were reached with three additional plaintiffs, and, on May 16, 2011, a settlement was reached with one additional plaintiff. As a result, settlements have been reached with 1,383 plaintiffs in total.

The court action has essentially terminated.

# U.S. court action for damages relating to HIV (human immunodeficiency virus) infection

A wholly-owned U.S. subsidiary of the Company, Alpha Therapeutic Corporation, together with three other U.S. manufacturers of blood products, are defendants in a U.S. class action lawsuit filed chiefly by

non-U.S. residents (residents of Europe, etc.) claiming to have been infected with HIV or other viruses by non-heat-treated concentrated preparations sold in the 1980s. In September 2010, a settlement was reached with more than 95% of over 2,650 plaintiffs, and as a result the majority of this lawsuit has been concluded.

In regard to this lawsuit, Alpha Therapeutic Corporation has product liability insurance, and negotiations for insurance coverage with the insurance companies are underway.

# Court action for compensation by patients infected with HCV (hepatitis C virus)

Since 2002, the Company and its subsidiary Benesis Corporation, together with the Japanese government and other parties, have been defendants in lawsuits in which the plaintiffs seek compensation for damages allegedly suffered through HCV (hepatitis C virus) infection following use of a fibrinogen product or a blood coagulant factor IX product (Christmassin) sold by the former Green Cross Corporation, one of the predecessors of the Company. However, to resolve these lawsuits, on January 16, 2008, Japan's government promulgated and put into effect "the Special Relief Law Concerning the Payment of Benefits to Relieve the Patients of Hepatitis C Infected through Specified Fibrinogen Preparations and

Specified Blood-Coagulation Factor IX Preparations Contaminated by Hepatitis C Virus" ("the Relief Law"). Subsequently, on September 28, 2008, a "basic agreement" for the conclusion of the court action was signed with the nationwide plaintiff group.

After the Relief Law was put into effect, in accordance with the procedures determined by the law, patients filed a lawsuit against the government and established their eligibility for relief. Subsequently, a settlement with the government was reached, and the relief for the patients was provided through the payment of benefits.

In regard to the expense of relief payments under the Relief Law, the burden of that expense and the method of sharing that burden were the subject of discussions with the Minister of Health, Labour and Welfare, and those standards were announced by the Minister of Health, Labour and Welfare on April 10, 2009.

In order to reach a full resolution of the issue of HCV infection through use of specific fibrinogen products or specific coagulation factor IX products, the Company is committed to continued earnest engagement in the future.

#### Court action regarding average wholesale prices

In the United States, the federal government and certain state governments, etc., have filed claims for damages against multiple pharmaceutical companies including the Company's wholly owned subsidiary Alpha Therapeutic Corporation, alleging that the reported average wholesale prices ("AWP") higher than actual sales prices resulted in overpayment as compared to the amounts which would have been paid under public reimbursement systems. These suits are currently pending. In certain of the AWP lawsuits, settlements have been reached with the plaintiffs.

#### **25. SUBSEQUENT EVENTS**

1. The Japanese Red Cross Society and the Company, in accordance with a basic agreement reached on June 17, 2011, have carefully considered the integration of the plasma fractionation operations of the Japanese Red Cross Society and Benesis Corporation, a wholly owned subsidiary of the Company that is engaged in the production and sale of fractionation products. The two parties entered into a contract on the integration of the plasma fractionation operations on May 7, 2012.

The two parties have agreed to establish the "Japan Blood Products Organization" and to transfer their plasma fractionation operations to the new organization, with operations scheduled to commence on October 1, 2012. The organization will secure sound operations by leveraging economics of scale to reduce costs at the production and supply stages.

The Japanese Red Cross Society and Mitsubishi Tanabe Pharma Corporation believe that the Japan Blood Products Organization will make a broad contribution to enhance the health of people in Japan in the years ahead by contributing to the achievement of national self-sufficiency in plasma fractionation products on securing a stable supply of safe blood products.

The amount of assets related to the plasma fractionation products operations for Benesis Corporation expected to be transferred to the new operations will be determined at a later date. The total assets, net sales, and number of employees of Benesis Corporation as of and for the fiscal year ended March 31, 2012 are as follows:

	Millions of yen	Inousands of U.S. dollars
Total assets as of March 31, 2012	¥32,000	\$389,342
Net sales for the year ended March 31, 2012	¥19,500	\$237,255
Number of employees as of March 31, 2012	565	

2. The following distribution of retained earnings of the Company, which has not been reflected in the accompanying consolidated financial statements for the year ended March 31, 2012, was approved at the annual general shareholders' meeting held on June 22, 2012:

	Millions of yen	Thousands of U.S. dollars
Year-end cash dividends (¥20.0 (U.S.\$0.24) per share)	¥11,219	\$136,501

# **Report of Independent Auditors**

The Board of Directors Mitsubishi Tanabe Pharma Corporation

We have audited the accompanying consolidated financial statements of Mitsubishi Tanabe Pharma Corporation and its consolidated subsidiaries, which comprise the consolidated balance sheet as at March 31, 2012, and the consolidated statements of income, comprehensive income, changes in net assets, and cash flows for the year then ended and a summary of significant accounting policies and other explanatory information, all expressed in Japanese year.

#### 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 designing and operating such internal control as management determines is necessary to enable the preparation and fair presentation of the consolidated financial statements that are free from material misstatement, whether due to fraud or error.

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

Our responsibility is to express an opinion on these consolidated financial statements based on our audit. We conducted our audit in accordance with auditing standards generally accepted in Japan. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the 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 the auditor's judgment, including the assessment of the risks of material misstatement of the consolidated financial statements, whether due to fraud or error. The purpose of an audit of the consolidated financial statements is not to express an opinion on the effectiveness of the entity's internal control, but in making these risk assessments the auditor considers internal controls 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. 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 referred to above present fairly, in all material respects, the consolidated financial position of Mitsubishi Tanabe Pharma Corporation and consolidated subsidiaries at March 31, 2012, and their consolidated financial performance and cash flows for the year then ended in conformity with accounting principles generally accepted in Japan.

#### **Convenience Translation**

We have reviewed the translation of these consolidated financial statements into U.S. dollars, presented for the convenience of readers, and, in our opinion, the accompanying consolidated financial statements have been properly translated on the basis described in Note 1.

Ernst & Young Shin Nihon LLC

June 22, 2012 Osaka, Japan

# **Group Companies**

As of March 31, 2012

Japan	Establishment	Paid-in Capital	% Voting Control*	Principal Business
Benesis Corporation •	October 2002	¥3,000 million	100.0%	Manufacture and sale of pharmaceuticals
Mitsubishi Tanabe Pharma Factory Ltd. •	October 2008	¥1,130 million	100.0%	Manufacture and sale of pharmaceuticals
Yoshitomiyakuhin Corporation ●	April 2000	¥385 million	100.0%	Provision of information about pharmaceuticals
MP-Logistics Corporation •	September 1980	¥95 million	65.0%	Distribution, warehouse operations
Bipha Corporation •	November 1996	¥7,500 million	51.0%	Manufacture and sale of pharmaceuticals
Tanabe Seiyaku Yoshiki Factory Co., Ltd. ●	July 1964	¥400 million	100.0%	Manufacture and sale of pharmaceuticals
Tanabe Seiyaku Hanbai Co., Ltd. ●	April 2008	¥169 million	92.9% (7.9%)	Sale of generic pharmaceuticals, etc.
Tanabe R&D Service Co., Ltd. ●	August 1984	¥44 million	100.0%	Support of R&D regarding pharmaceuticals
Tanabe Total Service Co., Ltd. ●	February 1964	¥90 million	100.0%	Real estate management, etc.
Choseido Pharmaceutical Co., Ltd. O	December 1947	¥340 million	52.5%	Manufacture and sale of pharmaceuticals
Hoshienu Pharmaceutical Co., Ltd. O	October 1962	¥75 million	34.2% (34.2%)	Manufacture and sale of pharmaceuticals
API Corporation •	April 1982	¥4,000 million	47.7%	Manufacture and sale of API, etc.
Overseas	Establishment	Paid-in Capital	% Voting Control*	Principal Business
Asia	,			7
Mitsubishi Pharma (Guangzhou) Co., Ltd. •	December 1991	US\$12,000,000	100.0%	Manufacture and sale of pharmaceuticals
Tianjin Tanabe Seiyaku Co., Ltd. •	October 1993	US\$12,000,000	66.7%	Manufacture and sale of pharmaceuticals
Mitsubishi Pharma Research & Development (Beijing) Co., Ltd. •	October 2006	US\$1,000,000	100.0%	R&D of pharmaceuticals
Guangdong Tanabe Pharmaceutical Co., Ltd. •	May 2009	CNY7,000,000	100.0%	Sale of pharmaceuticals
Mitsubishi Tanabe Pharma Korea Co., Ltd. •	April 1989	KRW2,100,000,000	100.0%	Manufacture and sale of pharmaceuticals
Taiwan Tanabe Seiyaku Co., Ltd. ●	September 1962	NT\$90,000,000	65.0%	Manufacture and sale of pharmaceuticals
Tai Tien Pharmaceuticals Co., Ltd. •	July 1987	NT\$20,000,000	65.0%	Sale of pharmaceuticals
P.T. Tanabe Indonesia •	July 1970	US\$2,500,000	99.6%	Manufacture and sale of pharmaceuticals
U.S.	,			7
MP Healthcare Venture Management Inc. •	August 2006	US\$100	65.0%	Investments in bio-ventures
Mitsubishi Tanabe Pharma Holdings America, Inc. •	December 2000	US\$166	100.0%	Management of Group companies in U.S.
Mitsubishi Tanabe Pharma Development America, Inc. •	October 2001	US\$100	100.0% (100.0%)	R&D of pharmaceuticals
Tanabe Research Laboratories U.S.A., Inc.	November 1990	US\$3,000,000	100.0% (100.0%)	R&D of pharmaceuticals
Tanabe U.S.A., Inc. ●	January 1970	US\$1,400,000	100.0% (100.0%)	Sale of chemicals, etc.
Mitsubishi Tanabe Pharma America, Inc. •	July 2009	US\$100	100.0% (100.0%)	Sale of pharmaceuticals
Europe				
Mitsubishi Pharma Europe Ltd. •	October 2001	£4,632,000	100.0%	R&D of pharmaceuticals
Tanabe Europe N.V.	December 1972	€260,330	100.0%	Sale of chemicals, etc.
Mitsubishi Pharma Deutschland GmbH •	June 2003	€25,000	100.0% (100.0%)	Sale of pharmaceuticals
Synthelabo-Tanabe Chimie S.A.	June 1987	€1,600,000	50.0%	Manufacture and sale of pharmaceuticals

<sup>\*</sup> Figures in parentheses show indirect control

Note: Aside from the companies mentioned above, there are two consolidated companies under the liquidations.

• Consolidated subsidiary • Affiliated company accounted for by the equity method

# **Corporate Data / Investor Information**

As of March 31, 2012

# **Corporate Data**

#### Mitsubishi Tanabe Pharma Corporation

2-6-18, Kitahama, Chuo-ku, Osaka 541-8505, Japan

URL: http://www.mt-pharma.co.jp/e/

#### Incorporated

December 1933

#### Date of Merger

October 1, 2007

#### **Number of Employees**

9,180 (Consolidated)

4,826 (Parent company only)

#### For Further Information

Investor Relations Group

Corporate Communications Department

TEL: 81-6-6205-5211 FAX: 81-6-6205-5105

URL: http://www.mt-pharma.co.jp/e/

#### **Investor Information**

#### **Stock Exchange Listings**

Tokyo and Osaka

#### Stock Code

4508

### Paid-in Capital

¥50.000 million

#### **Common Stock**

Authorized: 2,000,000,000 shares

Issued: 561,417,916 shares

#### Closing Date of Accounts

March 31

#### **Number of Shareholders**

15,669

### Major Shareholders (% voting rights)

Mitsubishi Chemical Holdings Corporation (56.3)

Japan Trustee Services Bank, Ltd. (5.8)

The Master Trust Bank of Japan, Ltd. (5.0)

Nippon Life Insurance Company (2.7)

Nipro Corporation (1.4)

The Bank of Tokyo-Mitsubishi UFJ, Ltd. (1.3)

JPMorgan Chase Bank, N.A., 385147 (1.3)

Employee Stock Ownership Plan (0.8)

Goldman Sachs & Company Regular Account (0.8)

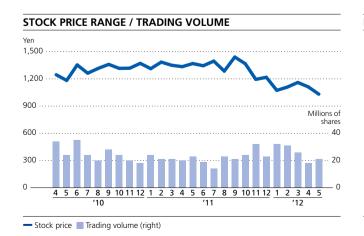
Tokio Marine & Nichido Fire Insurance Co., Ltd. (0.7)

#### Shareholder Register Agent for Common Stock in Japan

Mitsubishi UFJ Trust and Banking Corporation

Osaka Corporate Agency Division

3-6-3 Fushimi-machi, Chuo-ku, Osaka 541-8502, Japan



# DISTRIBUTION OF SHARE OWNERSHIP BY TYPE OF SHAREHOLDER



