

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 2009 (ended March 31, 2010).

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 compounds currently in the new drug pipeline might be halted in the event that problems with effectiveness or safety are found in clinical trials or other tests or in the event that they are not expected to be profitable. 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 know everything about safety in post-marketing use. At the stage of widespread post-marketing use, 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 compensation to victims exceeds the limits of the Company's product liability insurance, 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

In Japan, the official drug price system, which is a part of the NHI system, has an enormous influence on the sale of ethical drugs. In Japan, drug price standards are revised about once every two years. Accordingly, it is possible that a situation will develop in which it is difficult to secure the expected business results. Further, from the viewpoints of improving health care and separating medical functions, fundamental reform of the NHI system is under way. The details of these reforms could have a significant decline in sales and an adverse influence on the Group's financial position or 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 a 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

To use its management resources effectively, the Group works with other companies in joint research, joint development, product licensing, 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, or if the management policies of alliance partners changes substantially, there could be an adverse influence on the Group's financial position or results.

7. Risks related to production and stable supply

- a) In the event of the emergence of technical or legal / regulatory problems in production and distribution facilities, or in the event of operational stoppages or disorder due to fires, earthquakes, or other disasters, product supply could be delayed or stopped, and there could be an influence on the Group's financial position or results.
- b) For certain raw materials, the Group is dependent on specific sources of supply, and in the event that the supply is interrupted, production could be delayed and there could be a significant influence on the Group's financial position or results.

8. Risks related to legal issues

In the research 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 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, 2010, overseas sales accounted for 6.6% 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 2010, the Group held marketable securities of ¥59.7 billion and investments in securities of ¥139.1 billion, certain of which are marketable 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 serious damage to the environment is caused by hazardous 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 coagulant 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 as of the end of March 2010, of which ¥12.3 billion had already been paid out. 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

Classification	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 coagulation factor IX products on or after January 1, 1984	100%

2. Lump-sum payment of ¥5,186,725 thousand 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 system damage, accidents, etc., there could be an influence on the Group's results, such as a decline in reputation. The Group is working to ensure rigorous information control. In addition to formulating a privacy policy, in order to protect information, the Group has established countermeasures to prevent inappropriate system access and information leakage. In the event that one or more of these situations occurs, the Group's financial position or results could be significantly affected.

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 or to the worsening of diplomatic relations, 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 medical devices, veterinary drugs, and poisonous and toxic substances, the Group is subject to laws and regulations covering the sales and leasing of highly controlled medical devices, 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 the raw materials master file, etc., with the authorities in the importing countries and acquire import permission, local manufacturing permission, etc. In addition, the Group is subject to the pharmaceutical legal / regulatory system in the importing country, as well as the laws and regulations related to customs clearance.

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. In the event that cancellation, etc., of permissions, etc., is ordered, because of the damage to the societal trust or the termination of contract, 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, 2007	Pharmaceutical manufacturing and sales	Osaka Prefecture	Permission to manufacture and sell pharmaceutical products, etc.	Dec. 31, 2011 (5-year renewable)	Disqualification as per Article 12.2 of the Pharmaceutical Affairs Law
Oct. 1, 2009	Manufacturing of narcotics ¹	Ministry of Health, Labour and Welfare	License to manufacture narcotic drugs	Dec. 31, 2010 (2-year renewable)	Disqualification as per Article 3.2 of the Narcotics and Psychotropic Control Act
Oct. 1, 2009	Manufacturing of psychotropic drugs ¹	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 ²	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 ³	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 ⁴	Local governments	Permission to manufacture or import pharmaceutical 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 ⁵	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
Sept. 18, 2007	Sales and leasing of highly controlled medical devices, etc. ⁶	Local governments	Permission to sell or offer highly controlled medical devices	Sept. 17, 2013 (6-year renewable)	Disqualification as per Article 39.3 of the Pharmaceutical Affairs Law
Oct. 19, 2009	General sales of poisonous and toxic substances ⁷	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 Deleterious Substances Control Act

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

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

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

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

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

6 Permission information for West Distribution Center is shown.

7 Permission has been obtained by multiple places of operations, therefore permission information for Head Office (Production Division) is shown.

16. Administrative action issued in regard to a violation of the Pharmaceutical Affairs Law related to Medway Injection

On April 13, 2010, Mitsubishi Tanabe Pharma Corporation and its subsidiary Bipha Corporation received an administrative action issued by the Minister of Health, Labour and Welfare in regard to a violation of the Pharmaceutical Affairs Law. As a result, the Company expects measures to be taken, such as the suspension

by medical institutions of deliveries of the Company's products, as well as damage to the Company's reputation among patients and medical professionals. If these adverse influences continue, the Group's financial position and results of operations could be significantly affected.

17. Relationship with parent company and other Group companies

Position in the Group centered on Mitsubishi Chemical Holdings Corporation

The Company belongs to the Mitsubishi Chemical Holdings Group, which is centered on Mitsubishi Chemical Holdings Corporation, the Company's parent company. Mitsubishi Chemical Holdings Corporation was jointly established by Mitsubishi Chemical Corporation and Mitsubishi Pharma Corporation, one of the Company's predecessor companies, by means of a stock-for-stock exchange effective in October 2005. Due to the merger of Mitsubishi Pharma Corporation and Tanabe Seiyaku Co., Ltd., in October 2007, the ownership of Mitsubishi Chemical Holdings Corporation in Mitsubishi Tanabe Pharma Corporation reached 56.34%.

The Mitsubishi Chemical Holdings Group has three core 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 Mitsubishi Chemical Holdings Group's health care operations.

Operations are currently divided as described above, but in the future, in the event that there is a change in the Mitsubishi Chemical Holdings Group's management policies, the financial position and results of operations of the Mitsubishi Tanabe Pharma Group could be affected.

Transactions with Mitsubishi Chemical Holdings Group

The Company's relationship with its parent company, Mitsubishi Chemical Holdings Corporation, and Mitsubishi Chemical Holdings Corporation's corporate group, includes the following transactions:

- 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. Payment of compensation for exclusive rights ended on September 30, 2009, but those rights would continue on and after October 1, 2009, and will not be cancelled without the Company's agreement.

The Company leases buildings used for the research laboratory in Yokohama, Kanagawa. The Company formulated plans to construct a laboratory building of its own on that site, and the construction of the Medicinal Chemistry Research Laboratories began in January 2010. In line with the progress of this project, the lease on the buildings used for the research laboratory will be canceled in stages.

Also, plans call for the outsourcing of work by overseas subsidiaries to be gradually eliminated as the Company's international operations progress from 2011 to 2012.

In addition, a contract has been concluded with Mitsubishi Chemical Holdings Corporation regarding the burden of operational expenses, and for enjoyment of benefits based on the brand value and comprehensive strengths of Mitsubishi Chemical Holdings Corporation in the development of operations in Japan and overseas, the Company is responsible for certain expenses arising in regard to the operation of Mitsubishi Chemical Holdings Corporation. Operational expenses are calculated in accordance with the burden on the workforce, total assets, and gross profit, with an upper limit of 0.5% of sales.

In the year ended March 31, 2010, the Company's expense included the following: procurement of raw materials, etc., of ¥0.4 billion, sales of chemical products, etc., of ¥0.1 billion, conclusion of leases and consign-ment 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 ¥1.9 billion, payment as consideration for exclusive rights to intellectual property held by the corporate group including the parent company of ¥1.4 billion, and operating expenses of ¥0.4 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 Mitsubishi Chemical Holdings 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 Mitsubishi Chemical Holdings Group, is an associated company of the Mitsubishi Tanabe Pharma Group, and the above amounts do not include transactions with API Corporation (purchases of raw materials, etc.: ¥9.4 billion, etc.)

Personnel relationships with Mitsubishi Chemical Holdings Group

(a) Concurrent service of directors and corporate auditors

As of June 22, 2010, the directors and corporate auditors and employees of Mitsubishi Chemical Holdings Corporation and its Group companies include one person who is concurrently serving as a corporate auditor (non-full time). 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)	Takashi Nishida	Mitsubishi Chemical Holdings Corporation Corporate Auditor (full time / 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 Mitsubishi Chemical Holdings Corporation.

(b) Acceptance of reassigned personnel

The Group has accepted the reassignment of 7 people from Mitsubishi Chemical Holdings Group for limited periods of time with such objectives as enhancing links among research functions and information systems departments.

Capital relationship with Mitsubishi Chemical Holdings Corporation

Currently, Mitsubishi Chemical Holdings Corporation 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 Mitsubishi Chemical Holdings Corporation, the Company's parent company. Also, the percentage of the Company's stock held by Mitsubishi Chemical Holdings Corporation 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 Mitsubishi Chemical Holdings Group, the Company's financial position and results of operations could be affected.

18. Risks related to delisting

On October 1, 2007, the date of the merger, the Company received notice from the Tokyo Stock Exchange and Osaka Securities Exchange regarding the commencement of a grace period (October 1, 2007 to March 31, 2011) in accordance with rules for inappropriate mergers for stock delisting criteria.

Targeting the termination of the grace period, the Company is cooperating with suitability examinations on both of the exchanges. In the event that the grace period is not terminated, it is possible that the Company could be delisted and there could be a significant influence on the Group's financial position or results.

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