

## [Descriptive Information and Financial Statements]

### 1. Descriptive Information on Consolidated Operating Results

#### (1) Introduction

In order to realize Takeda's goal of establishing itself as a "global pharmaceutical company", the Company has been working on the various strategies defined in the 2006–2010 Medium-term Plan. Of those strategies, with respect to "further strengthening ability to create new drugs", the Company has completed several important transactions this calendar year.

Firstly, the acquisition of U.S.-based Millennium Pharmaceuticals Inc. (Millennium) provides Takeda Group—in addition to its own historical strength in research technology that inhibits cancer cell proliferation—the additional strength of Millennium's novel research technology based on inducing cancer cell apoptosis and also provides outstanding clinical development capabilities, both of which significantly strengthens our in-house R&D capability in the oncology area. By focusing the Group's oncology efforts around Millennium, Takeda will further enhance its presence in the field and will continue to create superior new drugs that meet both the needs of patients suffering from cancer and the needs of the medical community.

Also, as a result of the Company acquiring US-based Amgen Inc. (Amgen)'s Japanese subsidiary, Amgen K.K., and also in-licensing the global rights for one candidate and domestic rights for 12 others from Amgen, a New Drug Application (NDA) was submitted to the Japanese Ministry of Health, Labour and Welfare for the anticancer drug Panitumumab, which was one of the in-licensed products. Also, in the U.S., Millennium's Velcade received an additional indication for first-line treatment of multiple myeloma—which enables the product's use in patients who have not yet received any prior medication.

Moreover with regard to Takeda's U.S. operations, the Company was able to combine the previously independent sales function of TAP Pharmaceutical Products Inc. ("TAP") with Takeda Pharmaceuticals North America Inc. ("TPNA"), and the development function of TAP with Takeda Global Research and Development Center Inc. ("TGRD") in June 2008. Thus, the long-term issue of the Company's U.S. operations structure has been resolved, allowing the creation of a more efficient and robust organization.

Although the consolidation of TAP and Millennium in May increases consolidated sales, there is a concentration of expenses, such as acquisition costs, that will cause a temporary decrease in profit in this fiscal year. However, it is expected these transactions will contribute to Takeda's growth and maximization of Takeda's corporate value over the medium-to-long term, thereby allowing for greater profit distribution to shareholders through a stable increase of dividend payouts and the flexible conduct of share buybacks.

However, due to the U.S. financial crisis which has caused drops in global share indexes of historical proportion and rapid variations in the exchange rate markets, it seems more likely that there will be a global slowdown. Our market environment is becoming more challenging due to the implementation of a stricter approval process for new drugs, in addition to initiatives in Japan, the U.S., and Europe to promote generic drug use and further restrain healthcare expenditures. The Company pays keen attention to changes in its business environment and continues to closely monitor a variety of risk factors affecting its business in order to make steady efforts towards achieving sustained growth of sales and profits. In particular, the priority in this financial year is the leveraging of the Company's established U.S. franchises for Actos and Lansoprazole (U.S. product name; Prevacid), to achieve U.S. marketing approval of SYR-322 (generic name: alogliptin, a drug for Type 2 diabetes treatment), and TAK-390MR (generic name: dexlansoprazole, a drug for peptic ulcer treatment)—both of which are under review by the FDA for marketing approval—and to maximize each product's market potential.

Takeda received notification from the U.S. Food and Drug Administration (FDA) that the agency would not be able to complete its review of the SYR-322 NDA and TAK-390MR NDA by their respective original Prescription Drug User Fee Act (PDUFA) dates(\*). These postponements were due to delays in the review process by the FDA, and not related to the data contained in the NDAs. The Company was notified by the FDA that the revised date to complete the review of TAK-390MR is January 31, 2009. The Company has not received any indication from the FDA with respect to the revised date for SYR-322. The Company will continue to work closely with the FDA providing timely and appropriate responses with the aim of receiving market approvals for the two candidates by the end of this fiscal year. We will also aim to receive market approval for TMX-67, a drug for Hyperuricemia in patients with chronic gout, by the end of this fiscal year.

(\* ) SYR-322: October 27, 2008; TAK-390MR: October 31, 2008 (U.S. time in both cases)