

Management's Discussion and Analysis

Financial Results for the Year Ended December 31, 2016

The business environment for the pharmaceutical industry was very challenging in fiscal 2016 due to an effect of drug price revision implemented in April 2016 as well as healthcare reforms to regulate healthcare expenditures including measures to increase the use of generic drugs.

Under these circumstances, Torii strove to maximize the value of its mainstay products while focusing on prompt market penetration and expansion of the new products in the following priority areas; 1) the renal and hemodialysis area represented by REMITCH CAPSULES (an oral antipruritic drug for hemodialysis patients) and Riona Tablets (a hyperphosphatemia drug), 2) the HIV area represented by Truvada Combination Tablets (an anti-HIV drug), and 3) the skin disease area represented by ANTEBATE (a topical corticosteroid), and 4) the allergen area represented by CEDARTOLEN SUBLINGUAL DROP - Japanese Cedar Pollen (a sublingual immunotherapy drug).

In July 2016, we launched Genvoya Combination Tablets (an anti-HIV drug) which Torii acquired the sales right from Japan Tobacco Inc. (hereinafter "JT"). We also launched Descovy Combination Tablets (an anti-HIV drug) in January 2017, for which JT received manufacturing and marketing approval in Japan in December 2016.

In addition, Eli Lilly Japan K.K. (hereinafter "Eli Lilly Japan") launched Taltz indicated for psoriasis vulgaris in November 2016, for which Eli Lilly Japan and Torii has signed the co-promotion contract.

Net Sales

Net sales decreased by ¥2,171 million (3.5%) over the previous corresponding period to ¥60,206 million. This is due to the inclusion of REMITCH CAPSULES and Riona Tablets in items subject to repricing for market expansion under the drug price revisions implemented in April 2016, in addition to usual reduction of drug prices under the revisions.

Sales of mainstay products in the priority areas were as follows.

In the renal and hemodialysis area, both REMITCH CAPSULES and Riona Tablets were affected negatively by repricing for market expansion under the drug price revisions. However, sales of REMITCH CAPSULES decreased only by ¥1,991 million (12.7%) over the previous corresponding period to ¥13,645 million partially offset by increase in sales volume, while sales of Riona Tablets increased by ¥599 million (11.9%) over the corresponding period to ¥5,634 million by focusing on prompt market penetration and expansion.

In the skin disease area, sales of ANTEBATE decreased by ¥603 million (8.8%) to ¥6,277 million compared to the previous corresponding period.

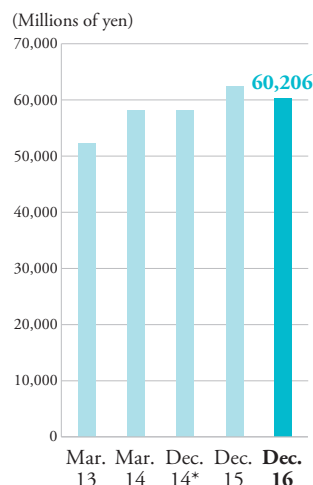
In the allergen area, CEDARTOLEN SUBLINGUAL DROP - Japanese Cedar Pollen increased by ¥425 million (83.2%) over the previous corresponding period to ¥937 million, as we focused on propagating allergen immunotherapy.

In the HIV area, sales of Truvada Combination Tablets decreased by ¥183 million (1.4%) to ¥12,754 million, and Stribild Combination Tablets (an anti-HIV drug) decreased by ¥762 million (24.3%) to ¥2,371 million over the corresponding period, respectively. On the other hand, Genvoya Combination Tablets, a successor of Stribild Combination Tablets launched in July 2016, recorded its sales of ¥1,865 million.

Cost of Sales

Cost of sales decreased by ¥526 million (1.7%) over the previous corresponding period to ¥30,287 million due to changes in our internal product sales ranking in addition to a decrease in net sales.

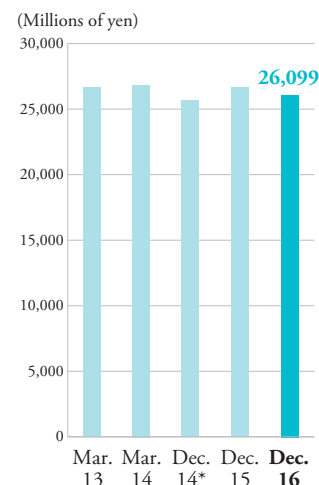
Net Sales



Sales of Mainstay Products

	Dec. 2015	Dec. 2016	Change
REMITCH	¥15,636	¥13,645	¥(1,991) (12.7)%
Truvada	12,938	12,754	(183) (1.4)%
ANTEBATE	6,881	6,277	(603) (8.8)%
Riona	5,034	5,634	599 11.9%
Stribild	3,133	2,371	(762) (24.3)%

Selling, General and Administrative Expenses



*Torii has changed the closing date of the accounting period from March 31 to December 31 since FY2014. Figures from Jan to Dec 2014, the same term of the last year, is presented with Financial Results for FY2015.

Selling, General and Administrative Expenses

Selling, general and administrative expenses were ¥545 million (2.0%) lower than the previous corresponding period at ¥26,099 million. This resulted mainly from a decrease in research and development costs, partially offset by a one-time expense relating to replacement of personal computers.

Operating Income, Net Income

As a result of the above, operating income was ¥3,819 million, a decrease of ¥1,099 million (22.4%) over the previous corresponding period. Net income decreased by ¥687 million (19.5%) to ¥2,839 million compared to the previous corresponding period.

Financial Position at December 31, 2016

Assets, Liabilities and Equity

Total assets decreased by ¥343 million (0.3%) from the end of the previous fiscal year to ¥98,525 million as of December 31, 2016. Current assets increased by ¥2,968 million (3.8%) from the end of the previous fiscal year to ¥80,123 million mainly due to a ¥2,475 million increase in cash and cash equivalents partially offset by a ¥1,335 million decrease in trade accounts receivable. Investments and other assets decreased by ¥2,882 million (18.6%) from the end of the previous fiscal year to ¥12,649 million due to a ¥2,923 million decrease in investment securities.

Total liabilities decreased by ¥1,073 million (6.7%) from the end of the previous fiscal year to ¥14,969 million. Reasons for this decrease included a ¥1,148 million decrease in income taxes payable.

Total equity increased by ¥729 million (0.9%) from the end of the previous fiscal year to ¥83,556 million. Contributing factors included purchase of treasury shares of ¥615 million, surplus dividends of ¥1,358 million and net income of ¥2,839 million.

Cash Flows

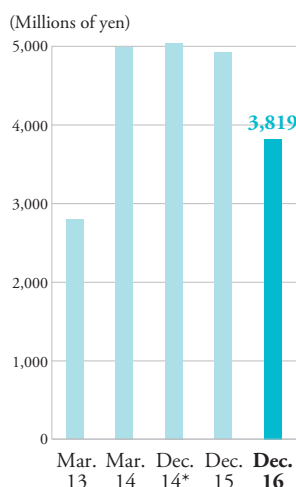
At ¥38,685 million, cash and cash equivalents as of December 31, 2016 were ¥2,475 million (6.8%) higher than at the end of the previous fiscal year.

Net cash provided by operating activities amounted to ¥3,402 million (Net cash provided by operating activities for the previous corresponding year was ¥4,940 million). This result reflects income before income taxes of ¥4,056 million, depreciation and amortization of ¥1,339 million, a ¥1,344 million decrease in trade notes and accounts receivable, a ¥770 million increase in inventories, income taxes paid of ¥2,500 million.

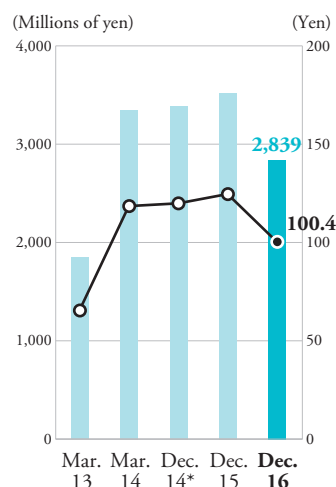
Net cash provided by investing activities amounted to ¥1,361 million (Net cash provided by investing activities for the previous corresponding year was ¥957 million). Major items included inflows of ¥2,203 million in proceeds from sale and redemption of securities and ¥1,414 million in proceeds from sale and redemption of investment securities, as well as outflows of ¥1,611 million of purchases of investment securities and ¥500 million of purchases of property, plant and equipment.

Net cash used in financing activities amounted to ¥2,289 million consisting mainly of ¥1,358 million for dividends paid and ¥615 million for purchase of treasury shares (Net cash used in financing activities for the previous corresponding period was ¥1,582 million).

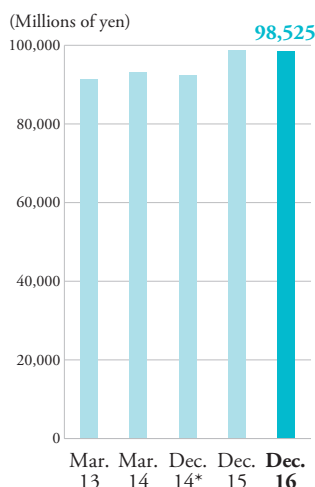
Operating Income



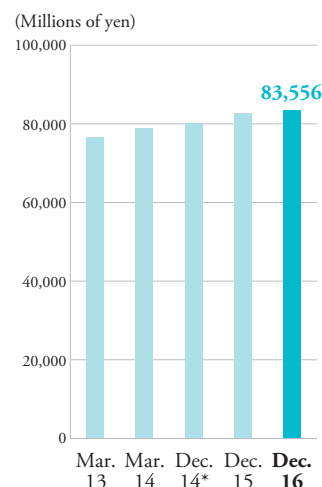
Net Income
Net Income per Share



Total Assets



Total Equity



*Torii has changed the closing date of the accounting period from March 31 to December 31 since FY2014. Figures from Jan to Dec 2014, the same term of the last year, is presented with Financial Results for FY2015.

Research and Development Activities

Research and development functions are divided between Torii and JT. JT is responsible for research and development activities pertaining to new compounds, whereas Torii is responsible primarily for improvements to the formulations of existing products and the development of additional indications. Torii also carries out its own research and development in its specific areas of expertise. Moreover, Torii searches and develops candidates for new in-licensed drugs in alliance with JT.

Total research and development costs in the year ended December 31, 2016, amounted to ¥4,654 million.

Key results of the in-licensing as well as (joint) research and development activities for the fiscal year ended December 31, 2016 are as follows:

- Riona Tablets, a hyperphosphatemia drug (JT development code: JTT-751) developed jointly with JT, entered Phase II of the domestic clinical trials for the treatment of iron-deficiency anemia.
- In August 2016, JT and Torii signed a license agreement with Menlo Therapeutics Inc. (Menlo Therapeutics) for the exclusive rights to develop and commercialize serlopitant in Japan. Serlopitant is a neurokinin (NK-1) receptor antagonist which Menlo Therapeutics has developed. It will be developed jointly by JT and Torii, and will be marketed by Torii.
- Toray Industries, Inc. (Toray) filed for an additional indication for improving pruritus in peritoneal dialysis patients in Japan (used only when sufficient efficacy is not obtained with the existing therapies or treatments) for REMITCH CAPSULES (in partnership with JT), an oral anti-pruritus drug for hemodialysis patients, in September 2016. Toray has already received manufacturing and marketing approval for REMITCH CAPSULES, which is promoted and distributed by Torii in Japan.
- In October 2016, JT and Torii concluded an exclusive agreement for the co-development and commercialization of JT's original compound, JTE-052, in Japan. JTE-052 is a JAK inhibitor for topical use in dermatological indications, and is being clinically developed by JT in Japan. It will be developed jointly by JT and Torii, and will be marketed by Torii.

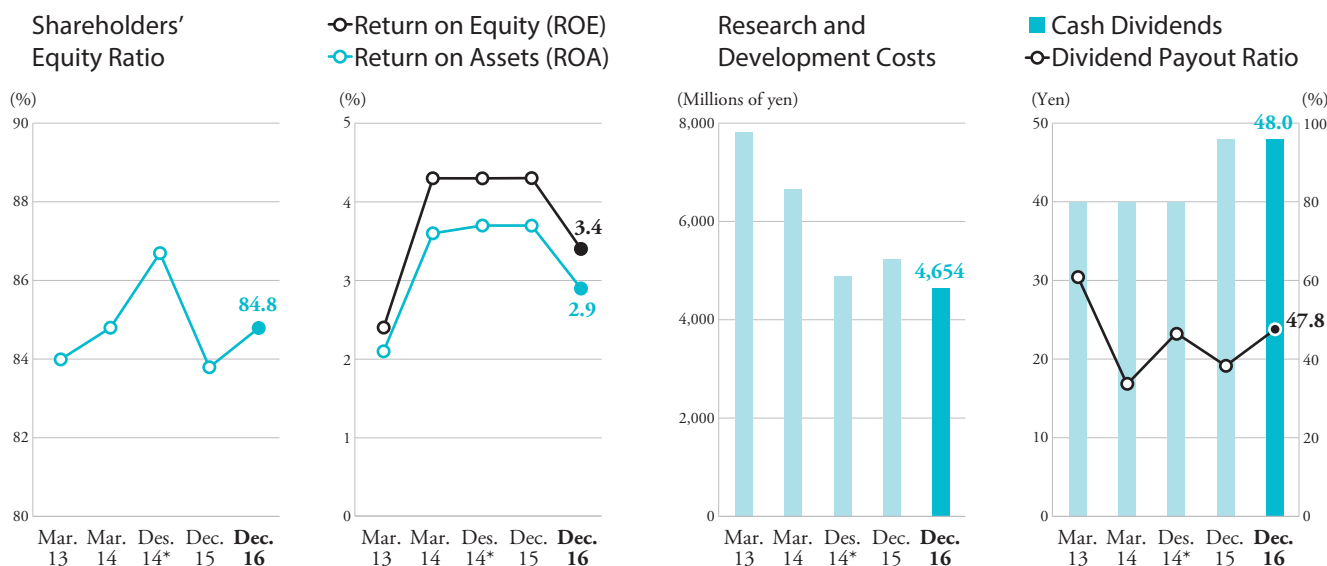
Forecast for the Fiscal Year Ending December 31, 2017

The business environment surrounding the pharmaceutical industry is expected to become increasingly tough due to such factors as the promotion of healthcare reforms to curb healthcare expenditures and intensified competition with rival pharmaceutical companies and their competing products.

Under these circumstances, we will aim to achieve sustainable business growth and improve corporate value by concentrating our management resources in priority areas; the renal and hemodialysis area, the skin diseases area, the allergen area and the HIV area.

With regard to the next fiscal year, we will propel Riona Tablets to be our core product while maximizing the sales of REMITCH CAPSULES. For Genvoya Combination Tablets and Descovy Combination Tablets, our new anti-HIV drugs, we will focus on their prompt market penetration. By propagating allergen immunotherapy, we will also aim for further market penetration of CEDARTOLEN SUBLINGUAL DROP - Japanese Cedar Pollen and MITICURE House Dust Mite Sublingual Tablets (allergen immunotherapy drug), in addition to focusing on further co-promotion of Taltz.

Moreover, we will also make further efforts to acquire and develop in-licensed drugs (including alliances) proactively for medium- to long-term growth.



*Torii has changed the closing date of the accounting period from March 31 to December 31 since FY2014. Figures from Jan to Dec 2014, the same term of the last year, is presented with Financial Results for FY2015.

The current forecast for the year ending December 31, 2017, is as follows:

	(Reference) Results for the twelve months ended December 31, 2016 (Millions of yen)	Forecast for the twelve months ending December 31, 2017 (Millions of yen)	Change (Millions of yen)	% Change (%)
Net sales	¥60,206	¥64,500	¥4,293	7.1%
Operating income	3,819	5,300	1,480	38.8
Net income	2,839	3,900	1,060	37.3

Basic Policy for Distribution of Profits and Dividends for Fiscal 2015 and Fiscal 2016

Torii's basic policy is to distribute its surplus dividends in a stable and continuous manner based on the understanding that generating appropriate shareholder returns, which is one of the key issues for the management.

According to the aforementioned basic policy, Torii will continue to generate stable shareholder returns while preparing for investments from a medium- to long-term perspective, in view of enhancements to its business constitution, future business expansion and other considerations.

Torii decided to pay an annual dividend of ¥48 per share for the fiscal year ended December 31, 2016 (including an interim dividend of ¥24 which has already been paid), in accordance with the aforementioned basic policy.

Torii plans to pay an annual dividend of ¥48 per share (consisting of an interim dividend of ¥24 and a year-end dividend of ¥24) for the fiscal year ending December 31, 2017.

Risk Analysis

A variety of factors could influence the business performance of Torii. The main risk factors are outlined below. All forward-looking statements in this annual report are based on our estimates at the time of submission of the financial statements.

Changes to the Pharmaceutical Affairs Law, Other Acts or Regulations

Because of the importance of pharmaceutical products to human life and health, various aspects of their development, manufacture and sale are regulated under the Pharmaceutical Affairs Law and other legislation. Changes to these regulations could affect the business performance of Torii.

Delay or Discontinuance of Research and Development

New drugs research and development requires long periods of time and substantial investment. In the process leading to market release, some projects may have to be delayed, changed or abandoned. Furthermore, even after having filed applications for manufacturing and marketing approval, some projects may be declined. In such a situation, Torii's future growth potential and profitability will decline and there is a risk that the business performance of Torii could be affected.

Drug Price Listing and Revisions

In Japan ethical drugs are, in principle, covered by the medical insurance system and the prices of ethical drugs are official prices determined by the government. Depending on the determined prices or the details of the revisions, there is a risk that the business performance of Torii could be affected.

Adverse Drug Reactions

Side effects may occur when pharmaceutical products are used. A serious adverse reaction could impact on the business performance of Torii.

Stoppage of Product Supply and Product Recall

Our products are manufactured at the Sakura Plant, which is our only production facility, and at other specified outside manufacturers. In addition, some raw materials are procured from specific outside manufacturers and other sources. If this plant or outside manufacturing plants are closed or those operations are suspended due to technical or regulatory problems; fire, earthquake or other disaster; or, if production becomes difficult due to unavailability of raw materials, fuel, electricity or timely logistics, the supply of our products may stop and the business performance of Torii could be affected.

Furthermore, in the event that our products are subject to quality-related problems, we may voluntarily decide to conduct product recall or follow orders to recall products if instructed by the national or municipal governments. In such a situation, there is a risk that the business performance of Torii could be affected.

Litigation Risk

In the course of our business activities, we are exposed to the risk of litigation, including product liability litigation, litigation relating to side effects and litigation relating to patent infringements. Such litigation could affect the business performance of Torii.