

Pharmaceuticals and Bio-chemicals Strategy

Kyowa Hakko Kirin

KYOWA KIRIN

Domestic market environment

It is possible that the growth of the pharmaceuticals market in Japan could continue to level off due to the market penetration of generics and significant revisions to the drug price system, along with the progress of measures taken to reduce medical costs so that the public health insurance system can be maintained in a society with a declining birthrate and aging population.

Research and development-oriented pharmaceutical companies will have to accelerate their efforts to shift their sources of revenue from long-term listed drugs and the domestic market to new drugs and the global market. Kyowa Hakko Kirin is a corporate group that continuously creates new value based on state-of-the-art biotechnology, pursuing a pharmaceutical business model that combines its biosimilars and bio-chemicals businesses as it leaps forward to become a Global Specialty Pharmaceutical Company (GSP). Under the Kyowa Hakko Kirin Group's five-year 2016 to 2020 Mid-term Business Plan (Figure 11), the management targets for fiscal 2020, the final year of the plan, are to achieve a core operating income of at least ¥100 billion, an overseas sales ratio of 50% and ROE of 10% or higher.

In the five-year Mid-term Business Plan, Kyowa Hakko Kirin is taking steps to achieve its four strategic priorities:

1 Improvement of global competitiveness

Kyowa Hakko Kirin is working toward contributing to the health and well-being of people around the world through its successful launch of KRN23 (burosumab) and KW-0761 (mogamulizumab), its global strategic products, in the European and U.S. markets. (For information about KRN23, please see page 28.) In Europe and the U.S., Kyowa Hakko Kirin filed a biologics license application for mogamulizumab for the treatment of patients with cutaneous T-cell lymphoma, and the drug, like KRN23, was also granted Priority Review status by the FDA. To maximize the value of these global strategic products, Kyowa Hakko Kirin continues to take steps to increase market penetration and expand the business area.

2 Creating innovation

By combining the expertise Kyowa Hakko Kirin has gained by studying diseases and patients' needs at the research facilities it has established in each of the four categories of nephrology, oncology, immunology/allergy, and CNS, with the cutting-edge technology platforms for drug discovery cultivated in the fields of therapeutic antibodies, one of its areas of strength, small molecule drugs, nucleic acid drugs, and regenerative therapeutics, as well as outside technologies through open innovation, Kyowa Hakko Kirin will aim to build an attractive pipeline as a pharmaceutical company that discovers new drugs.

3 Continuous improvement for operational excellence

Kyowa Hakko Kirin is working to heighten its profitability by further strengthening cooperation in a consistent manner across every function from R&D to manufacturing and sales. At the same time, Kyowa Hakko Kirin strives to instill the core values

and the code of conduct that all employees of the Kyowa Hakko Kirin Group around the globe are required to adhere to. Moreover, Kyowa Hakko Kirin makes efforts to build a global governance framework and ensure thorough compliance awareness.

4 Contribution to the health and well-being of people

Kyowa Hakko Kirin is working to engage in efforts that involve discovering innovative drugs that satisfy unmet medical needs, additional indications and dosage formulations of products, and also ensuring stable supplies of high-quality products, while taking action in response to societal demands for lower medical costs. These efforts are part of Kyowa Hakko Kirin's "CSV Management" philosophy to create shared value with society, and Kyowa Hakko Kirin will contribute to helping people with a diverse range of medical needs. In addition, as a member of the Kirin Group, Kyowa Hakko Kirin will continue efforts aimed at contributing to the health and well-being of people in collaboration with the Kirin Group companies.

In the bio-chemicals business, Kyowa Hakko Bio is addressing the key issues of strengthening the profit base and providing value with a focus on people's health by taking advantage of its high share of the market in its specialty area encompassing the pharmaceuticals, medical and healthcare fields. To strengthen its profit base, Kyowa Hakko Bio has made steady progress in reorganizing its production facilities. As for efforts to create high-profit businesses for the future, Kyowa Hakko Bio is now jointly developing new products, which are launched together with the Kirin Group, including some products under the "iMIUSE" brand.

Figure 11: Kyowa Hakko Kirin Group's Mid-term Business Plan



* Gross profit - Selling, General and Administrative expenses - Research and Development expenses + Share of profit (loss) of investments accounted for by the equity method