

“ We are strengthening and building our business foundation as a specialty, generic, & IVR pharmaceutical manufacturer for cancer-related fields. ”

The Nippon Kayaku pharmaceutical business is specialized on cancer-related fields and makes full use of its expertise in development, manufacturing, and information provision that was collected over many years to contribute to the field of health care.

Masanobu Suzuki

Member of the Board
Managing Director
Head of Pharmaceuticals Group



Business Overview

The history of Nippon Kayaku anti-cancer drugs began with sales of BLEOMYCIN in 1969, and our product lineup now numbers 26 drugs in 24 types—the largest lineup of any pharmaceutical manufacturer in Japan (as of May 31, 2011). These drugs are used in a broad range of treatments, including treatment for cancers of the lung, stomach, breast, liver, and prostate. In addition to an anti-cancer drug’s expected benefits, information about its side effects is also important. Nippon Kayaku has assigned more than 100 cancer specialist MRs to ensure the rapid provision of highly reliable information to physicians, pharmacists, and nurses at specialist cancer facilities, university hospitals, and core regional hospitals. In addition to specialty pharmaceuticals that contribute to conventional cancer treatment and generic pharmaceuticals that meet the needs of the current times, we also are developing business in the interventional radiology (IVR) field of low-invasive cancer treatment.

During this fiscal year, we began development of biological generic pharmaceuticals known as “biosimilar” drugs. In February 2011, we also completed construction and started trial production at a special plant for the manufacture of polymer micelle anti-cancer drugs—a drug delivery system (DDS) product.

The goal of Nippon Kayaku is “contributing to improving patient quality of life as a partner to health care professionals in cancer-related fields,” and we are working to raise the level of this goal, which is in fact our reason for existing.

Overview of Operations for the Fiscal Year Ended May 31, 2011

Strong performance was achieved by all three divisions: the Pharmaceuticals Marketing Division, Specialty Chemicals & International Division, and Diagnostics Department, for a sixth consecutive year of growing income and profits. Although there were effects from the revision of drug prices, this downturn was covered by growth primarily in sales of generic anti-cancer drugs. Results during this fiscal year were also helped by our subsidiary company Nippon Kayaku Food Techno, and consolidated sales reached the 50 billion yen mark. Despite the Great East Japan Earthquake and the subsequent power blackouts and power conservation in the second half of the year, as a pharmaceutical company with a deep responsibility to society, our plants and all divisions joined together in a systematic effort to prevent shortages. As a result, we were also able to minimize the effects of the earthquake on our business results.

Efforts to Achieve the Targets of the Mid-Term Business Plan

Phase I (Fiscal Year Ended May 31, 2011–Fiscal Year Ending May 31, 2013)

Carrying out certain R&D to match changes in the market

Phase I is positioned as a charging period building up to future great advances. During this period we are prioritizing the development of biosimilar drugs, and are also accelerating the key development of our polymer micelle anti-cancer drugs. We will also market new products in the IVR low-invasive treatment field and also our company's first biosimilar products. We are aiming to market these products at an early date and focus on expanding the market share of our generic anti-cancer drugs. Our policy is for business operations which are focused on the dramatic advances expected in Phase II and which also address personnel development and the use of M&A and alliances to strengthen our business.

Phase II (Fiscal Year Ending May 31, 2014–Fiscal Year Ending May 31, 2016)

Expanding our business across the specialty, generic, and IVR fields

During Phase II, in the specialty pharmaceuticals field we will accelerate development aimed at the marketing of polymer micelle anti-cancer drugs, and will also work to continually expand the new drug pipeline through a broad range of collaborations. At the same time, in the generic pharmaceuticals field, we will market two new biosimilar products. In addition to the development and marketing of new anti-cancer drugs, we will acquire the top share of the market for generic anti-cancer drugs and continue to provide a stable supply of low-priced, high-quality pharmaceuticals to the market. In the IVR business field, we will also work for a rapid launch of our embolization material product and expand our business in the field. In these ways, we are aiming to achieve the Phase II target of 100 billion yen in sales.

Generic anti-cancer drugs



Major Products

The year in parentheses is when the product was first marketed.

■ Anti-Cancer and Cancer-Related Drugs

- GEMCITABINE NK (2010)
- DOXORUBICIN NK (2010) ①
- ROZEUS® Inj (2009) ②
- BICALUTAMIDE NK (2009) ③
- IRINOTECAN Inj NK (2009) ④
- EPIRUBICIN Inj NK (2009)
- GRANISETRON Inj Syringe NK (2009) ⑤
- GRANISETRON Bag NK (2008)
- METASTRON® (2007)
- GRANISETORON Inj NK (2007)
- LEVOLFOLINATE NK (2007) ⑥
- PACLITAXEL Inj NK (2006)
- GELPART® (2006)
- CALSED® (2005)
- EPIRUBICIN NK (2005)
- IA CALL® (2004)
- ONCOVIN® (2004)
- EXAL® (2004)
- CARBOPLATIN Inj NK (2003)
- HYCANTIN® (2003)
- MS-TWICELON® (2001)
- COFORIN® (1996)
- FARESTON® (1995)
- ODYNE® (1994)



- STARASID® (1992)
- PINORUBIN® (1988)
- LASTET® Inj / Cap (1987)
- BESTATIN® (1987)
- RANDA® Inj (1984)
- PEPLEO (1981)
- BLEO (1969)



■ Immunosuppressants

- SPANIDIN (1994) ⑦

■ Cardiovascular Drugs

- MILLISROL® for Coronary Infusion (2001)
- ADEHL® (1999)
- MILLISTAPE® (1998)
- NITROPEN® TABLETS (1988)
- MILLISROL® (1984) ⑧
- NITROGLYCERINE TABLETS (1953)



■ Neurological Drugs

- SALIGREN® (2001)
- MUSCALM® (1975)



■ Other Drugs

- ASTRIC DRY® SYRUP (2002) ⑨

■ Diagnostic Agents

- LANA MAMMO CARD CEA (2002) ⑩
- LANA 1,5AG AUTO LIQUID (2000)
- LANAZYME BFP PLATE (2000)
- LANAZYME ST-439 PLATE (1999) ⑩



Status of New Product Development

(as of October 1, 2011)

Stage	Development code (Product name)	Administration route	Therapeutic category (Indications)	Origin	Characteristics/Others
Phase II (Japan)	NK012 (Polymeric micelle camptothecin analog)	Injection	Anti-cancer (Solid cancers)	Nippon Kayaku	Macromolecular micelle anti-cancer drug Simultaneous development in Japan and U.S.
Phase II (USA)					
Phase II	NK105 (Polymeric micelle paclitaxel)	Injection	Anti-cancer (Stomach cancer)	NanoCarrier	Macromolecular micelle anti-cancer drug
Phase II	NKQ-01 (Fentanyl film)	Adhesive to oral cavity mucosa	Supportive care (Analgesic)	Kyukyu Pharmaceutical	Opioid for cancer pain
Phase I	EO9 (Apaziquone)	Bladder instillation	Anti-cancer (Bladder cancer)	Spectrum Pharmaceuticals (USA)	Prevention against recurrence of bladder cancer
Phase I	TKN732 (Filgrastim biosimilar)	Injection	Supportive care (Neutropenia)	Teva Pharmaceutical Industries (Israel)	Development as a biosimilar product
Phase I in preparation	CT-P6 (Trastuzumab biosimilar)	Injection	Anti-HER2 monoclonal antibody (HER2-overexpressing breast cancer, etc.)	Celltrion Group (Korea)	Development as a biosimilar product
Phase I	CT-P13 (Infliximab biosimilar)	Injection	Anti-TNF alpha monoclonal antibody (Rheumatoid arthritis, etc.)	Celltrion Group (Korea)	Development as a biosimilar product
Phase I	NK938 (HepaSphere)	Arterial injection	Embolotherapy	Merit Medical Systems (USA)	Medical device
Phase I	NK939 (Embosphere)	Arterial injection	Embolotherapy	Merit Medical Systems (USA)	Medical device

Topics in the Health Care Field

Starting Japan clinical trials of a biosimilar antibody drug during 2011

Nippon Kayaku is working on the development of the biological pharmaceutical generic drugs known as biosimilar drugs, in particularly antibody drugs, in collaboration with the Korean bio-pharmaceutical company Celltrion. Clinical trials in Japan will be started during 2011 as part of the development of two products: trastuzumab (generic name)—an anti-cancer drug, and infliximab (generic name)—a drug used for treatment of rheumatoid arthritis and similar ailments. At present because there are only two biosimilar drugs that have been approved and marketed in Japan, and there are no biosimilar antibody drugs on the market, Nippon Kayaku is aiming to market its products in advance of other companies.

Starting development of polymer micelle anti-cancer drugs in a new field

Polymer micelle anti-cancer drugs are a kind of anti-cancer drug that is a drug delivery system (DDS) utilizing a polymer to contain the pharmaceutical inside a micelle structure. They were developed in order to reduce side effects by delivering the drug efficiently to the affected tissue. Nippon Kayaku is planning new-drug application tests of polymer micelle PACLITAXEL, which has already completed its Phase II clinical trials for treatment of stomach cancer. There is expected to be high demand for drug treatment using DDS from the health care field, due to its effectiveness, reduced side effects, and improved tolerability.

Application for recognition (as an unapproved/off-label drug which is highly needed in health care)

Nippon Kayaku has applied and received approval for additional indication of the anti-cancer drug HICAMTIN Inj. (generic name: nogitecan hydrochloride) for treatment of ovarian cancer and EXAL Inj. (generic name: inj. vinblastine sulfate) for treatment of Langerhans Cell Histiocytosis, two drugs that received notice related to application for recognition from the Ministry of Health, Labor, and Welfare. Applications for additional indication are also in process related to RANDA Inj. (generic name: cisplatin) for treatment of bile duct cancer and LASTET S Cap. (generic name: etoposide) for treatment of ovarian cancer that deteriorates following chemotherapy. Approval is expected during the first half of 2012.

