

We are strengthening and expanding the foundation of our global business as a specialty & generic pharmaceutical manufacturer in cancer-related fields.



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Business Overview

Our product lineup contains 24 anti-cancer drugs representing 22 product types, the largest such lineup of any pharmaceutical manufacturer in Japan.

The history of Nippon Kayaku anti-cancer drugs began with the marketing of BLEOMYCIN in 1969. Since that time, we have continued with R&D aimed at overcoming cancer, and our current lineup of cancer-fighting drugs has grown to 24 products, including generic versions (as of May 31, 2009). As a cancer specialty pharmaceutical manufacturer, we are proud of our lineup of anti-cancer drugs, which is the largest of any pharmaceutical manufacturer in Japan. These potent drugs are used in treating a broad range of cancers, including cancers of the lung, stomach, breast, liver, and prostate.

It is important that highly reliable information concerning anti-cancer drugs be provided to medical institutions. Nippon Kayaku maintains a staff of more than 400 MRs (medical representatives), of whom approximate 120 are cancer specialist MRs. A variety of training programs give our cancer specialist MRs a broad range of knowledge about cancer, including the latest treatment methods and academic information. These MRs provide fast and highly reliable information to doctors, pharmacists, and nurses at specialized cancer facilities, university hospitals, and key regional hospitals. In June 2007, we opened our Pharmaceutical Information Center, where we also provide information by telephone.

As a specialty & generic pharmaceutical manufacturer in the niche market of cancer-related products, we intend to make full use of the expertise we have developed over many years concerning development, production, and the provision of information in order to contribute to health care.

Overview of Operations for the Fiscal Year Ended May 31, 2009

We achieved four consecutive years of increasing income and profits.

In the fiscal year ended May 2009, the pharmaceutical business realized a complete three-point success: (1) achieving targets for both sales and profits, (2) income growth, and (3) profit growth. As a result, we experienced four consecutive years of increasing income and profits.

In Japan, despite the effects of the drug price revisions, the Pharmaceutical Marketing Division served as the driving force for a strong performance that achieved large increases in both income and profits. Sales of cancer-related generic products grew by 3.7 billion yen, to reach 9.2 billion yen. Sales of generic products overall were 9.8 billion yen, and we nearly achieved our target for the fiscal year ending May 2010 of 10.0 billion yen in sales one year ahead of schedule. This was the result of our dedication to achieving stable supply, quality assurance, and information provision, all of which have earned a high reputation for Nippon Kayaku generic anti-cancer drugs as a brand. In addition, sales were also strong of IA CALL, GELPART, and other LCM (lifecycle management) products.

Overseas, we established GlycoMark Inc., a joint venture company with Toyota Tsusho Corporation, aiming to expand sales of the diabetes diagnostic agent GLYCOMARK in the United States.

In terms of R&D, clinical trials of NK012 (a polymer micelle drug delivery system (DDS) anti-cancer drug) advanced to Phase II in the U.S. for treatment of breast cancer and small cell lung cancer, and also advanced to Phase II in Japan for the treatment of colorectal cancer.

For production, we began operation of a new pharmaceutical production line at our Takasaki Plant and reinforced our stable drug supply system to meet the rapidly growing demand for generic anti-cancer drugs and for the marketing of new generic products.



We are strengthening and expanding our business foundation, aiming for further growth.

We intend to make the fiscal year ending May 2010 a year for rebuilding our business foundation and constructing a base for achieving 100.0 billion yen in sales, as we work for further growth. As a specialty & generic pharmaceutical manufacturer, we are aiming to continue prevailing over our competitors by further improving customer satisfaction, and by combining market-oriented ideas with our company's strengths in order to establish an original position within the industry.

In Japan, we will focus on LCM products and METASTRON, aiming to expand our sales of specialty pharmaceuticals. For the generic anti-cancer drugs that are the primary support for growth, we will work for greater penetration of the NK (Nippon Kayaku) brand into the market, and have set a target of acquiring a 30% share of the brand drug market. At the same time, in order to ensure continued profits into the future, we will review our development system, production system, and sales system, and carry out cost-cutting measures that will give us a further advantage. As a new program, we intend to establish a new business model in the intravascular radiotherapy (IVR) field.

Overseas, we will carry out a far-reaching reconstruction of our business base, aimed at, among other objectives, conforming to the regulations of each country.

For R&D, we will accelerate development of the polymer micelle anti-cancer drugs NK012 and NK105, aiming for early introduction into the market.

For production, we will continue to construct a system for stable supply that will allow us to meet market demand.

Although the results in the Pharmaceuticals Group are on a strong growth path, at times such as these we must not become complacent about the current conditions and must strengthen and construct a business foundation aimed at achieving further growth. With the keyword "Re-Set" expressing our return to basics, we will strengthen both the human and equipment aspects of our business operation systems.



Major Products

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

■ Anti-Cancer and Cancer-Related Drugs

- BICALUTAMIDE NK (2009) ①
- IRINOTECAN Inj NK (2009) ②
- EPIRUBICIN Inj NK (2009) ③
- GRANISETRON Inj Syringe NK (2009) ④
- GRANISETRON Bag NK (2008)
- METASTRON (2007)
- GRANISETORON Inj NK (2007)
- LEVOFOLINATE NK (2007) ⑤
- PACLITAXEL Inj NK (2006) ⑥
- GELPART (2006)
- CALSED (2005)
- EPIRUBICIN NK (2005)
- IA CALL (2004)
- ONCOVIN (2004)
- EXAL (2004)
- CARBOPLATIN Inj NK (2003)
- IMMUCYST (2003)
- HYCAMTIN® (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)



Status of New Product Development

(as of October 1, 2009)

Stage	Development code Product name (Generic name)	Dosage form or route of administration	Therapeutic category (Indications)	Origin	Characteristics/Others
NDA	PMCJ-9/IMMUCYST (Connaught strain BCG)	Bladder instillation	Anti-cancer (for preventing recurrence of bladder cancer)	Sanofi Pasteur (Canada)	Extended indication
Additional trials	NK211/HYCAMTIN® (Nogitecan hydrochloride)	Injection	Anti-cancer (Ovarian cancer)	GlaxoSmithKline	Extended indication
Phase II (Japan)	NK012 (Micelle camptothecin analogue)	Injection	Anti-cancer (Solid cancers)	Own development	Macromolecular micelle anti-cancer drug Developed simultaneously in Japan and U.S.
Phase II (USA)					
Phase II	NK105 (Micelle paclitaxel)	Injection	Anti-cancer (Stomach cancer)	NanoCarrier	Macromolecular micelle anti-cancer drug
Phase II	NK911 (Micelle doxorubicin hydrochloride)	Injection	Anti-cancer	Tokyo Women's Medical University	Macromolecular micelle anti-cancer drug Under consideration of object development area
Phase I	NK0-01 (Phentanyl)	Adhesive patch for application to oral- cavity mucosa	Alleviation of cancer-related pain	Kyukyu Pharmaceutical	

● **Start of a joint promotion for the new anti-cancer drug TYKERB®**

Together with GlaxoSmithKline (GSK), on April 22, 2009 Nippon Kayaku started joint promotion of TYKERB® Tablets 250 mg. This drug is an anti-cancer drug approved by the Ministry of Health, Labor, and Welfare for treatment of inoperable or recurring breast cancer where overexpression of HER2 has been confirmed. Distribution and sales operations will be handled by GSK, and both companies will jointly provide and collect product information to/from medical institutions involved in cancer treatment across Japan.

● **Introduction of two products from U.S. companies, aiming to expand our presence in the IVR field**

Nippon Kayaku has positioned intravascular radiotherapy (IVR), in which cancer is treated by inserting a catheter into the blood vessel close to the location of the tumor, as a key area of business activity, and has marketed GELPART — a drug used in embolization treatment of hepatocellular cancer. Working to expand our presence in this field, in April 2009 we acquired the exclusive rights from the U.S. company BioSphere Medical for development, distribution, and sales in Japan of two embolotherapy microsphere products that are used to treat cancer and hysteromyoma.

● **Establishment of a new company in the U.S. for expanding sales of our diabetes diagnostic agent**

In order to strengthen our overseas business, on July 17, 2009 we established GlycoMark Inc., a joint venture company with a subsidiary of Toyota Tsusho Corporation. This new company is intended to expand the use in the U.S. of the diabetes diagnostic agent 1,5-AG, which has been sold in Japan since 1990. We are also proceeding with preparation for marketing this product in Europe.

● **Addition of four products to strengthen our lineup in cancer-related fields**

Nippon Kayaku is strengthening its product lineup by expanding it from anti-cancer drugs to also include drugs for the suppression of anti-cancer drug side effects. In this way, we are working to construct an NK (Nippon Kayaku) brand in the cancer chemotherapy field. On May 15, 2009, we marketed four new products in order to further strengthen our product lineup in cancer-related fields. These four new products were the generic drug BICALUTAMIDE Tablets 80 mg NK for treatment of prostate cancer, the anti-cancer drug IRINOTECAN HYDROCHLORIDE Drip and Intravenous Injection 40 mg and 100 mg NK, the anti-cancer drug EPIRUBICIN HYDROCHLORIDE Drip and Intravenous Injection 10mg/5mL and 50mg/25mL NK, and the anti-emetic drug GRANISETRON Intravenous Injection 1 mg Syringe NK.

● **Joint development of drugs for the alleviation of cancer-related pain**

Nippon Kayaku and Kyukyu Pharmaceutical Co., Ltd. have been jointly developing drugs for the alleviation of cancer-related pain since 2006. The adhesive patch for application to oral-cavity mucosa (development code: NKQ-01, contains phentanyl) was developed based on the proprietary technologies of Kyukyu Pharmaceutical, and is intended to provide rapid pain relief when applied to mucosa inside the mouth. Phase I clinical trials have been carried out and demonstrated good absorption characteristics, and further clinical trials aimed at commercialization of this product are under way.

● **Expanding our contracted-production service for anti-cancer drugs, immunosuppressants, and other highly pharmacologically active substances**

Nippon Kayaku is applying the anti-cancer drug production technology we developed over many years to perform production of highly pharmacologically active study drugs and other products under contract from customers in Japan and overseas. We produce these products using equipment capable of a high level of containment, and provide them to locations worldwide.