Business Units (Japan)
Sales & Marketing Unit
(Impacting Pharmaceuticals Business)

Sales & Marketing Unit 5-Year Business Plan

• Enhance our reputation as an ethical, trusted, and respected partner
• Construct systems and functions compatible with operating environment changes
• Promote multichannel approach

Major Achievements in Fiscal 2016

• Achieved revenue of ¥447.8 billion (up 1.9% year on year)
• Revenue was impacted by national health insurance (NHI) drug price revisions and increased prescriptions of generic drugs. Nonetheless, overall revenue was up due to increased revenues from mainstay products, including LIVANAN, an anti-angiogenic; NEXUM, an ulcer treatment; Memory, an Alzheimer’s disease treatment; PRAJAL, an osteoporosis treatment; RAMARK, a treatment for bone metastasis associated with cancer; Effent, an antiallergic agent; and TENVLEA, a type 2 diabetes mellitus treatment.
• MRs ranked No. 1 for first consecutive year
• In fiscal 2016, Daiichi Sankyo was ranked No. 1 in Japan in an overall assessment of MR activities in both the entire market and the hospital and private practice market categories. In the entire market category, we have maintained the top ranking for five consecutive years beginning with fiscal 2012. In addition, we have also been ranked No. 1 in media surveys by Mikkei Medical and other publications.
• All MRs pass certificate test for seventh consecutive year
• All MRs have passed the certificate test held in December for the seventh consecutive year since fiscal 2010.

Innovative Pharmaceutical Revenue

(Billions of yen)

<table>
<thead>
<tr>
<th>Year</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revenue</td>
<td>¥433.4</td>
<td>¥439.4</td>
<td>¥447.8</td>
</tr>
</tbody>
</table>

Percentage of Total Consolidated Revenue

46.9%

Initiatives for Fiscal 2017

• Achieve rapid growth in sales of mainstay innovative pharmaceuticals
• We will continue to expand our business by achieving rapid growth in sales of mainstay innovative pharmaceuticals, including LIVANAN as well as NEXUM: Effent type II diabetes mellitus treatment TENVLEA, CANALUO, and CANALIA: PRAJAL, RAMARK, and osteoporosis treatment VMPHAT.

• Build upon MR activities based on BRIDGE
• By providing accurate information and products with an emphasis on the importance of interpersonal connections, we aim to form a bridge to bridge for patients, their families, and healthcare professionals. In addition, we hope that our ongoing efforts in this area will enhance Daiichi Sankyo’s reputation as an ethical, trusted, and respected partner.

• Promote and enhance area marketing
• We will commence full-fledged operation based on the area marketing system we have been building throughout fiscal 2016 and prior, which entailed reorganizing sales offices and teams within medical community areas and appointing staff responsible for supporting community medical collaboration. With this new system in place, we will deploy and accelerate marketing activities based on regional characteristics as we pursue sustainable growth as an ethical, trusted, and respected partner.

• Enhance information provision capabilities through multichannel approach
• By incorporating a multichannel approach utilizing lectures, e-promotions, and other venues in information provision activities by MRs, we will endeavor to provide information that is even more valuable in greater quantities.

• Promote compliance
• We exercise thorough compliance with a strong focus on acting with the highest level of ethics and social consciousness, which is essential for a life science-oriented company, in order to further increase society’s trust in Daiichi Sankyo.

Examples of CSR Activities

• Initiatives to become a trusted medical partner to healthcare professionals and patients

Initiatives for Fiscal 2017

• Reinforce operating foundations and prepare to launch major products
• The multiple AGs for which manufacturing and marketing approval was acquired in February 2017 will no doubt make large contributions to earnings in fiscal 2017 and beyond. Accordingly, we will work to ensure smooth launches of these products.
• Promote and enhance area marketing
• We will commence full-fledged operation based on the area marketing system we have been building throughout fiscal 2016 and prior, which entailed reorganizing sales offices and teams within medical community areas and appointing staff responsible for supporting community medical collaboration. With this new system in place, we will deploy and accelerate marketing activities based on regional characteristics as we pursue sustainable growth as an ethical, trusted, and respected partner.

• Enhance information provision capabilities through multichannel approach
• By incorporating a multichannel approach utilizing lectures, e-promotions, and other venues in information provision activities by MRs, we will endeavor to provide information that is even more valuable in greater quantities.

• Promote compliance
• We exercise thorough compliance with a strong focus on acting with the highest level of ethics and social consciousness, which is essential for a life science-oriented company, in order to further increase society’s trust in Daiichi Sankyo.

Examples of CSR Activities

• Initiatives to become a trusted medical partner to healthcare professionals and patients

Business Units (Japan)
Sales & Marketing Unit: Daiichi Sankyo Espho Co., Ltd.
(Generic Business)

Daiichi Sankyo Espho takes advantage of the reputation for reliability and peace of mind we have fostered as an innovative pharmaceutical manufacturer to act as an innovator in the domestic generic pharmaceutical industry.

With an emphasis on quality control, stable supply, information provision, and affordability, we will contribute to national healthcare in a rapidly aging Japan.

Major Achievements in Fiscal 2016

• Achieved revenue of ¥20.2 billion (up 9.2% year on year)
• Although revenue was impacted by the NHI drug price revisions instituted in April 2016, we were able to achieve revenue growth that exceeded the market average thanks to government measures for promoting generic usage and the benefits of new products.

• Expanded product portfolio
• We launched generic drugs with two new active ingredients in June 2016 and two new secondary ingredients in December, bringing our total portfolio to 163 products with 64 active ingredients. In order to strengthen our AG lineup, a central pillar of our 5-year business plan, we acquired manufacturing and marketing approval for AGs with 10 new active ingredients in February 2017, including AGs for such major drugs as olmesartan, the telmisartan family, and rosuvastatin. These products were not limited to AGs of Daiichi Sankyo products but also included AGs for which permission was acquired from other companies.

Examples of CSR Activities

• Provision of information on premium generics featuring formulation, display, and packaging innovations via the website
As vaccines become increasingly more important to Japanese society, the Vaccine Business Unit is working to contribute to public health in Japan by creating innovative vaccines that address social needs and reliably supplying high-quality vaccines.

---

### Major Achievements in Fiscal 2016

- Achieved revenue of ¥38.5 billion (up 4.7% year on year)
- Squarigel, a 4-valent combination vaccine for the prevention of pertussis, diphtheria, tetanus, and poliomyelitis (polio), contributed to higher revenues.
- Stably supplied HA vaccine for seasonal influenza
- By basing vaccine supply activities on the seasons in which the vaccines are used, we realized a substantial decrease in the amount of vaccines returned.
- Recommended production of measles-rubella combined vaccine (MR vaccine) Following the voluntary recall of the MR vaccine in fiscal 2015, we resolved the issues faced by this vaccine and recommended production to resume shipments.

### Initiatives for Fiscal 2017

- Maintain reliable supplies and reduce costs to secure profits
- In fiscal 2017, new organizations specializing in planning, production, and other functions were established. Coordination will be pursued among these organizations to revise operating processes in order to reduce costs at production sites and lower expenses through refinements to the manufacturing processes for existing vaccines.
- Reinforce foundations for quality and safety management
- We aim to contribute to stable supplies of high-quality products by enhancing quality assurance systems. In addition, training, education, and other human resources development initiatives will be implemented in order to reinforce internal foundations for quality and safety management.

---

### Examples of CSR Activities

- Provision of basic knowledge on vaccines to patients via the website

---

### Daichii Sankyo Healthcare Co., Ltd., 5-Year Business Plan

- Improve product brand value in the OTC business
- Accelerate growth of the direct marketing business through synergies with Im Co., Ltd., in the direct marketing business
- Achieve independence in overseas businesses
- Strengthen operating foundations to ensure responsiveness to market environment changes

### Major Achievements in Fiscal 2016

- Achieved revenue of ¥66.7 billion (up 25.0% year on year)
- Substantial revenue growth was achieved due to the steady expansion of sales of mainstay OTC medicine brands, higher sales in the functional skincare field, and contributions from Im Co., Ltd. 
- Grew sales through improved brand value and enhanced lineup, Smooth sales growth was once again seen for Lulue and MINON W brand products. As for the Lulue S brand, we enhanced our image of ingested medicines with the launch of Lulue S Premium while also introducing external application Lulue S products, including tapes, calluses, and gels.
- Increased sales of direct marketing subsidiary Im In addition to establishing direct marketing operating foundations, we achieved a large increase in sales of Im’s mainstay RICE FORCE brand of skincare products.
- Expanded overseas
- A new operating base was established in China, and we succeeded in launching MINON Amino Moist® in this market.

### Initiatives for Fiscal 2017

- Expand new product pipelines based on consumer perspective
- In April 2017, two new organizations were established, one equipped with marketing research, product planning, and learning functions and the other designed to quickly reflect customer input in business activities. Through these new organizations, we will formulate product strategies and conduct product planning based on a consumer perspective to cultivate strong brands and products that win customer favor.
- Maximize revenue of the Lulue S and Lulue brands and further expand skincare and oral care brand revenue in OTC business

---

### Examples of CSR Activities

- Provision of product information in various languages via the websites

---

---

---

---
Daiichi Sankyo, Inc., is branching out from the cardiovascular field, which centers on physicians in private practices, to transform into a company with product portfolios for the pain, oncology, and other specialty fields. This company is committed to contributing to the advancement of medicine in the United States by supplying new drugs that help people live longer and healthier lives and providing reliable evidence based on high-quality clinical and outcomes data.

Daiichi Sankyo, Inc., 5-Year Business Plan

- Become a leader in pain care
- Build and grow oncology capabilities
- Maximize profit for mature products through LOE* timeframe

Major Achievements in Fiscal 2016

- Achieved revenue of US$1,312 million (down 14.8% year on year)
  Effort grew, but total sales revenue decreased due to the impact of LOE of olmesartan.
- Grew MOVANTIK, a treatment for opioid-induced constipation (OIC)
  Co-promoting with AstaVest, the co-promotion revenue was US$38 million increased by US$22 million year on year.
- Integrated LPI sales force into DSAC
- Launched Injectafer into new key markets for the treatment of iron deficiency anemia, with a priority on gastrointestinal conditions (GI). Follow up with women’s health, cardiovascular and other key markets where unmet medical needs exist.
- Bolstered our pain franchise
  Signed licensing agreement with Inspiration Delivery Sciences, LLC for two ADF opioids: MorphaBond ER (morphine sulfate) and ROSA Bond (oxycodone hydrochloride). Launched www.CommitmentToPainCare.com, which hosts an overview of our company’s approach to responsible pain management and our dedication to being part of the solution to controlled substance abuse as we prepare to enter the opioid marketplace.
- Divested packaging plant in Bethlehem

Initiatives for Fiscal 2017

- Accelerate MOVANTIK growth
- Accelerate Injectafer/revenue
  Expand into new markets with unmet medical needs
- Demonstrate launch success for MorphaBond ER and ROSA Bond
- Maximize remaining opportunities for Effient, Welchol and hypertension products
- Enhance operational excellence

Luitpold Pharmaceuticals 5-Year Business Plan

- Build Injectafer into flagship product and market leader
- Expand generic injectable portfolio with a variety of products to support customer needs

Major Achievements in Fiscal 2016

- Achieved revenue of US$912 million (up 7.2% year on year)
  - Initiated business collaboration on Injectafer with DSAC
  - Expanded market reach by leveraging the established market presence in Hem/Onc and marketing excellence.
  - Initiated phase 3 trial to investigate Injectafer for heart failure patients with iron deficiency
  - Expanded generic injectable portfolio
    - Submitted 4 ANDAs and gained 1 ANDA approval.
  - Advanced New Drug Applications
  - Enhanced manufacturing capabilities
  - Started capital investment to become a one of top players in the U.S. generic injectable market.

Initiatives for Fiscal 2017

- Accelerate Injectafer growth
  - Strengthen leadership position in the IV iron market segment with Velofer and Injectafer.
- Expand generic injectable franchise
  - Grow business via optimization of in-market assets and new pipeline development.
  - Submit 3 NDAs and 3 ANDAs.

Examples of CSR Activities

- Participation in U.S. Initiative for Ending Hunger around the World  Page 87

---

Luitpold Pharmaceuticals, Inc., is contributing to healthcare in the United States as an injectable medication specialty pharmaceutical company. This company is driving the growth of the IV iron market with its high-value branded injectable medications while also increasing the flexibility of its growing generic injectable medication franchise in response to market needs.
Daichi Sankyo Europe GmbH

Daiichi Sankyo Europe GmbH is evolving into a specialty care-focused company to complement the manufacturing and sales foundations it has established in the cardiovascular field. As the most prominent Japanese pharmaceutical company with operating foundations in Europe, Daiichi Sankyo Europe develops its business in 12 European countries and will partner with companies in other parts of Europe to contribute to the advancement of medicine in this region.

Daiichi Sankyo Europe 5-Year Business Plan

- Maximize profit from established brands through focused investment
- Maximize LIXIANA’s potential
- Rapid penetration in countries where Daichi Sankyo Europe has a presence, in other countries collaboration with sales partners
- Diversify portfolio
- Establish oncology business
- Develop organization to further evolve into specialty care provider

Major Achievements in Fiscal 2016

- Achieved revenue of €597 million (up 1.8% year on year)
- Further launches of LIXIANA
  - After LIXIANA launched in five European countries (Germany, the United Kingdom, the Netherlands, Switzerland, and Ireland) in Fiscal 2015, launched in Belgium, Spain, Italy, Austria, and Portugal in Fiscal 2016
- Partnership for LIXIANA
  - Agreement for a sales partnership with MSD for the distribution rights for LIXIANA in 14 Northern and Central Eastern European countries as well as agreed with Servier Russia in Russia and CIS countries. LIXIANA launched in Sweden, Norway and Denmark via the partnership with MSD.
  - Men’s Sharp & Dohme Corp.: a European subsidiary of Men’s & Co., Inc.
  - Very good performance of LIXIANA in Germany
  - Since its launch, LIXIANA has grown steadily and the market share reached 7.2% in March 2017.

Initiatives for Fiscal 2017

- Grow market share of LIXIANA in countries where DSE has a presence
- Launch LIXIANA in more European countries via partnerships
- Strengthen life-cycle management (LCM) activities
  - Our longest and largest pivotal studies as well as our ongoing clinical research program help to reassure healthcare professionals of the dosing, safety and efficacy when prescribing LIXIANA to their patients.
- Establish oncology business
  - Build-out of oncology business unit for flawless execution of our oncology strategy.
  - Further evolution into a specialty care provider
  - Continue to work within the market access model and maintain alignment of European organizational structure with go-to-market strategy.

ASCA Company

The network of the ASCA Company stretches throughout the ASCA region with manufacturing and sales bases in China and Brazil and sales bases in South Korea, Taiwan, Hong Kong, and Thailand. By developing operations that respond to the market and customer needs and regional value of each country, the ASCA Company contributes to the development of medicine in these countries.

ASCA Company 5-Year Business Plan

- Maintain and expand sales of existing products
- Quickly develop, launch, and expand sales of new products
- Enhance portfolio of products matched to the specific needs of respective regions and countries
- Accelerate product development in China
- Strengthen business capabilities and implement measures targeting growth markets with an eye to fiscal 2021 and beyond

Major Achievements in Fiscal 2016

- Achieved revenue of ¥72.1 billion (down 4.2% year on year)
- Revenue was down year on year due to the impacts of foreign exchange rate movements. Nonetheless, we witnessed steady growth in revenue in each country of operation when calculated on a local currency basis. Factors contributing to this growth included efforts to maximize sales of Cravit, Olmetec, and other mainstay products as well as the proactive utilization of external resources through alliances (joint sales and promotions) and product in-licensing. In China, specifically, we strengthened coordination with local alliance partners and thereby achieved increases in sales of products including Cravit; Amacen, a cough suppressant and expectorant; Olmetec; and Mevalol.
- Launched and expanded sales of LIXIANA
  - In South Korea, where LIXIANA saw its first ASCA region launch in February 2016, the share of sales accounted for by this product grew steadily, coming to 15.6% on March 31, 2017. In addition, we were able to release LIXIANA in Taiwan, Hong Kong, and Thailand in fiscal 2016.

Initiatives for Fiscal 2017

- Maximize sales of Olmetec, Cravit, Mevalol, and other existing mainstay products
- Rapidly grow sales of LIXIANA
- Daiichi Sankyo plans to directly introduce LIXIANA into the Brazilian market. In countries where we do not possess our own sales bases, this product will be commercialized via alliances with other companies.
- Augment production capacity in China
  - In China, following the commencement of a new injectable production line at the Beijing Plant, we have been constructing a new formulation manufacturing building at the Shanghai Plant. In this manner, we plan to augment production capacity in line with the growth of our operations in China.
- Launch other pipelines on schedule
  - In addition to LIXIANA and other global products, we will focus on launching pipelines that address the needs and regional value of specific countries on schedule.
  - Create business opportunities and enhance product portfolio by acquiring and utilizing external resources
  - The ASCA Company is working to enhance its product portfolio by acquiring external resources through means such as in-licensing from companies in other countries. In addition, we are forming alliances with local companies in each country of operation and with regard to specific product lines and otherwise utilizing external resources. Through these efforts, we aim to efficiently establish sales networks and increase sales productivity in order to further increase revenue and operating profit.

Examples of CSR Activities

- Receipt of Award for Patient- Accommodating Package Design
- Page 80

Examples of CSR Activities

- Cultivation of healthcare workers in China
- CPR training in South Korea
- Page 85
- Page 87
The R&D Unit is tasked with utilizing the R&D capabilities Dalichi Sankyo has fostered over years of operation as a drug discovery-oriented company in order to continuously create innovative pharmaceuticals. Our passion is to develop treatments and preventative methods that can improve patients’ health and become global standards of care.

R&D Unit 5-Year Business Plan

- Continuously generate innovative pharmaceuticals changing the standard of care in the primary focus area of oncology as well as the new horizon areas of pain, central nervous system diseases, heart and kidney disease, and rare diseases
- Acquire approval of at least two major indications per year
- Proceed to phase 3 with at least four major indications per year
- Enter phase 1 with at least nine molecular entities per year
- Acquired approval for at least two drugs
- Nupiap Tablet (immediate-release tablets) for cancer pain (LP)
- Nawri Tablet (extended-release formulation) for cancer pain (LP)
- Submitted applications for two drugs
- Hydromorphone injection for cancer pain (LP)
- PMXLA Subcutaneous Injection Syringe for rheumatoid arthritis (LP): Application for partial change related to additional indication
- Began phase 3 clinical trials for two indications
- Quazaril: Acute myeloid leukemia (first-line treatment)
- Elasserone (CS-3102: Essential hypertension)
- Began phase 1 clinical trials for two new compounds
- DS-8690: Malignant brain tumors (gliomas)
- U-1440: HER2 positive refractory and metastatic breast cancer
- Other accomplishments
- Reorganized oncology R&D organizations
In April 2016, Dalichi Sankyo integrated its oncology R&D organizations, inviting Antoine Yeer, an individual with a breadth of experience and an accomplished background in the field of global cancer treatment development, as its leader. This organization, named the Cancer Enterprise, selected two factions to focus allocation of management resources, antibody drug conjugate (ADC) and acute myeloid leukemia (AML) franchises.

Examples of CSR Activities
- Initiatives based on R&D activities — Page 77
- Good clinical practice and other development-related training — Page 106

Major Achievements in Fiscal 2016

- Promoted open innovation Dalichi Sankyo commenced joint research with Aichiwakawa Medical University regarding capillary stem cells (Cap5C)
In April 2016 and also began research on new immunology oncology treatments with the National Institutes of Biomedical Innovation, Health and Nutrition in March 2017.
- DS-8090/Heartcenter therapy for ischemic heart failure
In May 2016, we concluded an in-licensing agreement with U.K.-based Cell Therapy Ltd. (Celler) at present granting exclusive development and sales rights for Heartcenter in Japan.
- DS-8070 (anti-HER2 ADC)
In November 2016, DS-8070 received Fast Track Designation for HER2 positive metastatic breast cancer from the U.S. Food and Drug Administration (FDA).
- KTE-C19 (anticancer cell therapy)
In January 2017, Dalichi Sankyo entered into a strategic partnership with Kite Pharma, Inc., of the United States that grants the Company exclusive rights for development, manufacturing, and commercialization in Japan of KTE-C19 as well as optional licensing rights for other product candidates, some of which will progress into the clinical development stage over the next three years.

Initiatives for Fiscal 2017

- Pass major milestones identified for fiscal 2017
- Entrench operation of Cancer Enterprise and activate further The R&D Unit will accelerate development and maximize the value of DS-8090 and other compounds belonging to either the ADC or AI/ML franchise.
- Optimize R&D procedures for cardiovascular-metabolics and other therapeutic areas
- Improve productivity in research, translational research, biomarker and companion diagnostic*, and development
- Enhance portfolio of competitive pipelines
In-licensing and open innovation activities will be stepped up.
- Efficiently and effectively manage financial and human resources
Pre-examination to predict the effects and adverse drug reaction risks of specific pharmaceuticals in individual patients.

R&D Pipelines (In-House Development Projects, as of August 2017)

<table>
<thead>
<tr>
<th>Major R&amp;D Pipelines</th>
<th>Therapeutic area</th>
<th>Application</th>
<th>Phase 1</th>
<th>Phase 2</th>
<th>Phase 3</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Oncology</strong></td>
<td></td>
<td></td>
<td>Conduct trials on healthy volunteers to assess safety of drug, including side effects</td>
<td>Conduct trials on a small group of patient volunteers to assess safety, efficacy, dosage and administration regimen</td>
<td>Conduct trials on a large number of patient volunteers to assess safety and efficacy in comparison with existing drugs</td>
</tr>
<tr>
<td><strong>Cardiovascular Metabolic</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Others</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

- Patients volunteers may be included depending on the tests
- *2 Asia, South & Central America

---

Dalichi Sankyo Group Value Report 2017
Biologics Unit

- Contribute to accelerating launch of DS-8201 and other ADC franchise drugs
- Develop manufacturing technologies and accelerate clinical development for biologics

5-Year Business Plan

- Prepare for accelerating commercialization of DS-8201
- Swiftly launch products under development and enhance technology platforms through promotion of development projects
- The on-demand supply of antibody drug substances will be pursued to maximize the value of DS-8201 and other biologics through swift launches and expansion of indications. The Biologics Unit will accumulate experiences through these efforts to further enhance technology platforms.
- Deploy advanced multi-modality strategies
- The Biologics Unit will establish competitive and innovative modality technologies for next-generation ADCs, peptides, nucleic acids, and other substances and make contributions to new drug discovery projects through coordination with the R&D Unit. (See table below)

Initiatives for Fiscal 2017

- Construct technology platforms in relation to cell therapies
- The Biologics Unit will undertake the formulation and promotion of concrete plans related to investigation drugs and commercial production processes for XE-991 and other development projects. Also, cell therapy-related platforms will be established by introducing technologies from partners and by drafting development and regulatory affairs strategies.
- Cultivate human resources capable of contributing to diverse biologics drug discovery projects
- Achieve efficient operation of new organization and formulate clearer vision for future
- Functions related to biologics will be effectively consolidated within the new organization in order to quickly stabilize its operations, increase the speed and accuracy of decision-making, and flexibly and appropriately allocate resources. At the same time, research productivity will be improved, human resources will be secured and cultivated, and facilities and equipment will be optimized in order to ensure compatibility with cell therapies and the diverse range of other biologics.

Deployment of Multi-Modality Strategies

<table>
<thead>
<tr>
<th>Modality (Molecule Type)</th>
<th>Strategy</th>
</tr>
</thead>
<tbody>
<tr>
<td>Antibodies</td>
<td>Create foundations for quick launches of DS-8201 and other biologics and establish innovative and competitive modality technologies for drugs such as next-generation ADCs</td>
</tr>
<tr>
<td>Antibody-drug conjugates (ADCs)</td>
<td>Utilize Daichii Sankyo’s globally competitive, original T-cell-activated antibody to cultivate important platforms for conducting drug discovery in the immune-oncology field</td>
</tr>
<tr>
<td>Bispecific antibodies</td>
<td>Antibodies with two antigen-binding sites enabling them to bind to different types of antigens</td>
</tr>
<tr>
<td>Proteins and peptides</td>
<td>Newly designed and prepared proteins and peptides that do not exist naturally in the human body</td>
</tr>
<tr>
<td>Nucleic acids (DNA, oligonucleotides, etc.)</td>
<td>Natural nucleic acids, which contain DNA, RNA and other genetic information, and modified nucleic acids</td>
</tr>
<tr>
<td>Vaccine and adjuvants</td>
<td>Provide innovative treatment methods for previously difficult-to-treat diseases, such as modifying viruses for therapeutic purposes, administering normally functioning cells to support the functioning of abnormal cells, and utilizing cells from a patient or another individual to treat diseases</td>
</tr>
<tr>
<td>Viruses</td>
<td>Provide preventative medicine and treatment benefits through development of adjuvants that are administered together with vaccines to augment their effectiveness</td>
</tr>
<tr>
<td>Cells</td>
<td>Continue trend of DS-8201, which utilizes Daichii Sankyo’s proprietary E4A oligonucleotide technology, to develop pipelines targeting rare diseases</td>
</tr>
<tr>
<td>Target development of platform for oral administration modalities for peptides</td>
<td></td>
</tr>
</tbody>
</table>

Pharmaceutical Technology Unit

- Accelerate and improve efficiency of oncology development
- Enhance key technologies of biologics manufacturing platforms (for ADCs)
- Develop high-value-added formulations, reduce costs, and establish new production methods

5-Year Business Plan

- Provided flexible support for accelerating the development of DS-8201
- Close coordination was pursued with the Cancer Enterprise to realize the quick and efficient supply of investigational drugs to support the acceleration of clinical development.
- Developed formulations that accurately address patient needs and improve quality of life
- Applications for manufacturing and marketing approval were submitted for LIXIANA OD Tablets, a highly stable orally disintegrating tablet (that does not require a drying agent) and Memory Dry Spray™. At the same time, manufacturing and marketing approval was received for Naruvapro Tablets (immediate-release tablets) and Naruvapo Tablets (extended-release tablets), two narcotic analgesics that alleviate pain over different periods of time.
- Tablets that dissolve in the mouth without water
- Formulations in the form of granules or powders that become syrups when mixed with water and are thus easy to preserve and transport
- Tablets that immediately release their active ingredient
- Tablet designed to release their active ingredient gradually over time
- Quickly launched LIXIANA OD Tablet through strategic application

A quick launch of LIXIANA OD Tablet was achieved by strategic consulting with the authorities and carrying out efficient clinical trials to submit approval applications six months ahead of schedule (in August 2016).

Formulation Technologies Catering to Diverse Needs

- LIXIANA anticoagulant OD tablets (orally disintegrating tablets) for venous and arterial disease treatment
- Dry spray
- Easy-to-use medicine
- Pain control as part of total cancer care

Examples of CSR Activities

- Incorporation of input from overseas healthcare professionals into formulation development

Initiatives for Fiscal 2017

- Advance CMC strategies and reinforce fundamental technologies for ADC development
- In addition to promoting the transfer of technologies to prepare for commercial production of DS-8201, the Pharmaceutical Technology Unit will acquire fundamental ADC technologies and apply these technologies to pipelines. In addition, CMC strategies will be formulated and implemented to facilitate applications and approvals for ADC franchise drugs.
- Chemistry manufacturing and controls strategies: R&D strategies pertaining to drug substances, formulations, and quality that aim to maximize the value of pharmaceuticals
- Accelerate and improve efficiency of development projects to expand product pipelines
- Accelerate development of anticancer drugs while also enhancing treatment management to maximize product value.
- Develop and utilize advanced technologies
- New technologies will be developed and utilized in regard to the manufacture and quality assessment of drug substances and formulations.
- Quickly and effectively launch under-development products to increase earnings
- Supply investigational drugs and transfer manufacturing technologies as required by development strategies in a timely and waste-free manner while steadily submitting applications and receiving approval.
Functional Units
Supply Chain Unit

Supply Chain Unit 5-Year Business Plan

- Transform and rebuild supply chain structures adopted to change the product volume and the product mix in the medium-to-long term
- Advance cost reduction measures globally
- Establish new manufacturing systems and absorb new technologies based on pipeline and life-cycle management strategies

Major Achievements in Fiscal 2016

- Commenced construction of manufacturing systems for anticancer drugs and biologics
  Established capital investment and staffing plans for manufacturing Active Pharmaceutical Ingredients (API) and Drug Product (DP) to support new biologics, each with DS–BD01 and also for wide-variety, low-volume product of anticancer drugs. These plans were implemented to work toward quick launches of products in these areas.
- Developed manufacturing and supply systems optimized to specific regions
  The Hiratsuka Plant of Daiichi Sankyo Chemical Pharma Co., Ltd., completed its final product activities (and is scheduled for closure on September 30, 2017) and the Bethlehem Plant of U.S. subsidiary was sold. Meanwhile, production facilities were augmented at the Beijing Plant and the Shanghai Plant in preparation for the expansion of operations in China. These moves will enable us to optimize our global manufacturing and supply systems over the medium-to-long term.
- Achieved stable supply corresponding to edoxaban demand forecast

Initiatives for Fiscal 2017

- Construct manufacturing systems for anticancer drugs and biologics
  Based on API and DP equipment investment plans, we will design and commence construction of equipment for product, including wide-variety, low-volume product, of ADCs. At the same time, we will secure human resources for the biologics field and enhance their skills to fulfill the foundations for manufacturing systems.
- Support introduction of edoxaban into other countries and maintain stable supply
  In addition to Japan, the United States, and Europe, manufacturing and supply systems will also be introduced into the ASCA region in order to support the introduction of edoxaban into other countries and maintain a stable supply.
- Contribute to expansion of opioid analgesics business in Japan
  The Supply Chain Unit will help ease the pain of patients suffering from cancer pain and improve their quality of life by stably supplying opioid analgesics, developing new formulations, and preparing for launches.

Transition to Supply Chain Compatible with Shift to Oncology and Biologics

- Loss of exclusivity for olmesaran
- Focus on oncology and other specialty fields

Drastic changes in product mix
Introduction of new technologies and equipment

Examples of CSR Activities

- Sustainable Procurement Promotion... O Page 77

Quality & Safety Management Unit

Quality & Safety Management Unit 5-Year Business Plan

- Continue post-marketing study on edoxaban and prasugrel to create additional evidence
- Introduce quality risk analysis and evaluation systems for new fields and new technologies
- Strengthen safety monitoring measures and verify effectiveness of safety measures

Major Achievements in Fiscal 2016

- Steady advancement of safety measures and post-marketing study for innovative pharmaceuticals
  Safety measures were advanced by the provision of information to healthcare professionals on the importance of monitoring seasonal blood pressure fluctuations.
  Safety information was globally collected and identified risks were distributed to Japanese healthcare professionals.
  We sought to reinforce platforms for the practical application of medical database research utilizing big data.
- Post-marketing study coordinators were introduced, and large-scale studies on edoxaban and prasugrel were carried out as planned.
- Improvement of product quality (GMP) and application materials reliability
  Quality management systems in factories were reinforced to ensure product quality.
  Audit systems were established to ensure that clinical trials in China were advanced appropriately.
  Implementation of regulatory affairs measures that contribute to product life-cycle management
  Proper regulatory affairs measures were implemented to facilitate new product launches, expand existing products, and maintain stable supplies.
  Inspections for consistency between marketing approval documents and actual manufacturing process were conducted to confirm that there were no issues that could impact product quality or safety.

Initiatives for Fiscal 2017

- Steadily advance safety measures and post-marketing surveillance for innovative pharmaceuticals
  Appropriate measures will be taken to ensure patient safety.
  Systems will be constructed to grow oncology field operations into a core business.
  Medical database research will be accelerated in light of revisions to ordinances pertaining to good post-marketing study practices.
- Large-scale post-marketing studies on edoxaban and prasugrel will be advanced steadily.
- Continue to improve reliability with regard to products manufactured by the Daiichi Sankyo Group (adhere to GMP) and application materials
  Quality management systems will be established in preparation for the launch of DS–BD01.
  Reinforce quality management systems with a view to the growth of mainstay products and launches of new products.
- Realize regulatory affairs measures that contribute to product life-cycle management
  Appropriate regulatory affairs measures will be implemented to expand usage and secure stable supplies of existing products on a global scale.
- Scientific data inspections will be enhanced and compliance measures will be reinforced in response to regulatory affairs-related laws and systems.
- Support efforts to receive approval for regenerative medicines and establish related systems

Examples of CSR Activities

- Good vigilance practice training related to pharmaceutical safety... O Page 106
The Medical Affairs Division implements a value linkage scheme that connects functions related to the collection, analysis, evaluation, creation, and distribution of information related to pharmaceuticals. Through this scheme, the division strives to maximize product value evaluated as contribution to treatment in the medical field and thereby contribute to the development of medicine.

Medical Affairs Division 5-Year Business Plan

- Conduct large-scale observational studies for prasugrel and edoxaban and collect clinical evidence
- Create and distribute information on priority drugs and new products based on the Medical Strategies
- Develop more sophisticated medical affairs systems corresponding to environment changes
- Strategies for improving product value and establishing and increasing Daiichi Sankyo’s market presence that entail identifying clinical questions and creating and distributing information in response to these questions
- Strive to improve customer loyalty
- Enhance medical information (information related to pharmaceuticals)
- Entrench practice of utilizing Voice of Customer (VOC)

Major Achievements in Fiscal 2016

- Quickly achieved target enrollment of large-scale observational studies for prasugrel and edoxaban
- Started new clinical research for collecting clinical evidence in relation to priority drugs
- Established Daiichi Sankyo Medical Library as a new information distribution tool
  - New tool for distributing medical information to healthcare professionals through the Internet
- Established guidance for Medical Affairs Division staff when interacting with individuals from outside of the Company and conducted education programs to improve compliance
- Formulated grand design for new global systems and decided to appoint medical science liaisons inside Japan organizations
  - Position responsible for collecting clinical evidence and identifying and answering clinical questions by engaging in medical and scientific discussions with healthcare professionals and researchers and by promoting clinical research and academic activities
- Ranked No. 1 in inquiry responses by pharmacists working in pharmacies utilizing health insurance plans
  - Based on a survey we conducted through an outside private research company

Initiatives for Fiscal 2017

- Create and distribute information based on the enhancement of Medical Strategies for edoxaban (domestically and globally)
- Create and distribute information based on the enhancement of Medical Strategies for prasugrel and other priority drugs
- Execute measures for reinforcing domestic functions and systems and construct and institute global systems
- Enhance medical intelligence
  - Meaningful (valuable) information that has been created by collecting, integrating, evaluating, and analyzing medical information
- Continue to be ranked No. 1 in inquiry responses by pharmacists working in pharmacies utilizing health insurance plans
- Examine the possibility of introducing artificial intelligence (AI) technologies to reinforce inquiry response functions

Value Linkage Based on Medical Strategies

Daiichi Sankyo collects, analyzes, and evaluates information to identify clinical questions and then formulates medical strategies for creating and distributing information. Based on these strategies, the Company enhances and steps up coordination between functions related to processes spanning from collection to distribution of information in order to create the value linkage that is essential to medical affairs activities.

Information Distribution
  Hold academic events as a part of Medical Affairs

Information Creation
  Promote company-sponsored clinical research
  Support investigator-sponsored clinical research
  Perform non-clinical research on marketed products
  Publish theses and make academic announcements

Information Collection
  Respond to key opinion leaders
  (clinical research measures)
  Consolidate academic events and thesis information

Information Analysis and Evaluation
  Identify clinical questions
  Formulate medical strategies

Examples of CSR Activities

- Communication with healthcare professionals and patients