The 5-year business plan is designed to transform Daiichi Sankyo toward its “2025 Vision”. Under this plan, we will work to tackle two challenges: “grow beyond FY2017 LOE” and “establish a foundation of sustainable growth” for the future.

**Challenge 1: Grow Beyond FY2017 LOE**

We aim to overcome declines resulting from the loss of exclusivity (LOE) for mainstay products such as olmesartan, an antihypertensive agent, as well as the impacts of National Health Insurance (NHI) drug price revisions in Japan. We will target revenue of ¥940.0 billion and operating profit of ¥100.0 billion in fiscal 2017.

**1) Measures for Recovering Revenue**

By accelerating growth of edoxaban, an anticoagulant, and other mainstay products for the Japanese market and increasing the growth of Luitpold Pharmaceuticals, Inc. (LPI), of the United States, we will strive to achieve revenue of ¥940.0 billion in fiscal 2017.

**2) Measures for Generating Profits**

In addition to cost reduction measures conducted by the end of fiscal 2015, we will pursue further cost reductions and streamlining to achieve operating profit of ¥100.0 billion in fiscal 2017.
Challenge 2: Establish a Foundation of Sustainable Growth

Daiichi Sankyo will strive for a target revenue of ¥1,100.0 billion and operating profit of ¥165.0 billion for fiscal 2020. In addition, in fiscal 2020, we aim to have three to five late-stage pipelines that can be launched within the next five years with the potential to generate annual revenue exceeding ¥100.0 billion each at peak. If we can achieve these targets, we will achieve return on equity (ROE) of more than 8% in fiscal 2020.

To accomplish these targets in fiscal 2020, the following business strategies will be implemented.

(1) Business Strategies

**Strategic Target 1** Grow Edoxaban
We will strive to accelerate growth of edoxaban to cultivate it into a mainstay product that generates more than ¥120.0 billion in revenue in fiscal 2020.

**Strategic Target 2** Establish Oncology Business
We will establish an oncology business and then strive to grow this business revenue to over ¥40.0 billion in fiscal 2020 and approximately ¥300.0 billion in fiscal 2025.

**Strategic Target 3** Grow as No. 1 Company in Japan
We will strive to grow Daiichi Sankyo into the No. 1 company in Japan in terms of quality and quantity by leveraging the strength of our innovative pharmaceuticals business in combination with our generic business, vaccine business, and over-the-counter (OTC) related business.

**Strategic Target 4** Expand U.S. Businesses
Daiichi Sankyo, Inc. (DSI), is targeting revenue from its pain franchise of more than ¥100.0 billion in fiscal 2020. LPI will work toward a revenue target of ¥150.0 billion for fiscal 2020.

**Strategic Target 5** Continuously Generate Innovative Medicine Changing Standard of Care (SOC)
We seek to continuously generate innovative medicine with the potential to change SOC in oncology, which we call our primary focused area, and the other areas which we define as new horizon areas, encompassing pain, central nervous system diseases, heart and kidney disease, and rare diseases.

**Strategic Target 6** Enhance Profit Generation Capabilities
We will push forward with massive cost-reduction and streamlining measures on a group-wide basis, reviewing cost of sales, selling, general, and administrative (SG&A) expenses, and R&D expenses to enhance profit generation capabilities.

(2) Policies for Growth Investment, Shareholder Returns and Cash Allocation

Under the 5-year business plan, our policy will be to prioritize growth investments while also enhancing shareholder returns.

As of March 31, 2016, cash-on-hand totaled roughly ¥700.0 billion. Our activities over the five years of the plan will be funded by this cash as well as the approximately ¥2,200.0 billion to be generated in the form of free cash flow before R&D expenses (Profit before R&D, depreciation and amortization), and cash recovered through asset downsizing. As for specific allocations, we plan to conduct growth investments of ¥900.0 billion in R&D expenses and ¥500.0 billion in business development investments. The remainder of the funds will be used for shareholder returns, capital expenditure and working capital.

(3) Shareholder Returns Policy

We will seek a total return ratio of 100% or more over the period of the plan and annual ordinary dividends of more than ¥70 per share. While continuing stable dividend payments, we will conduct flexible acquisition of our own shares.

More information on each of these six strategic targets can be found in the pages that follow.
Strategic Target 1: Grow Edoxaban

The direct oral anticoagulant (DOAC) market, which comprises 4 products—edoxaban, dabigatran, rivaroxaban and apixaban—is growing and has already reached the scale of ¥1,100.0 billion on a global basis. Looking at the ratio of prescription numbers, it is clear that substantial room still exists for DOACs to overtake warfarin, the current standard treatment.

Edoxaban (LIIXIANA in Japan and Europe, and SAVAYSA in the US) has superior bleeding safety compared to warfarin coupled with the convenience of once daily doses, has significant evidence on its efficacy and safety backed by robust clinical trial results, and addresses needs of atrial fibrillation (AF) patients and venous thromboembolism (VTE) patients. In order to solicit its unique characteristics and endeavor to grow LIIXIANA into a pillar supporting medium-to-long-term growth, we commit to advance steadily global launch strategies and generate new evidence to strengthen the appeal of this product.

In Japan, we aim to grow LIIXIANA into the No. 1 DOAC in the domestic market through our high-quality marketing capabilities. In Europe, we established a marketing alliance with Merck Sharp & Dohme Corp., a European subsidiary of Merck & Co., Inc., in February 2016. We will accelerate the growth of LIIXIANA throughout all of Europe, as Daiichi Sankyo markets it in Western Europe and Merck Sharp & Dohme focuses on Northern and Central Eastern Europe. In the United States, we will continue to market SAVAYSA for appropriate patients and seek to implement measures to improve access environment. Meanwhile, we will strive to realize early approval and launch of edoxaban in other regions while seeking best partners who we can collaborate with to develop full-fledged promotional activities in those new markets.

By advancing these initiatives, we aim to grow edoxaban into a product with annual global revenue of more than ¥120.0 billion.

Grow Edoxaban into a Pillar Supporting Medium-to-Long-Term Growth

Increase global revenue to more than ¥120.0 billion in FY2020

$15.0 billion

2015 2017 2020 (FY)

Characteristics
- High safety and convenience
- Ability to adjust dosage amounts based on patient condition

Strategies
- Advance global launch strategies
- Continue to appeal product profile
- Generate new evidence

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*1. DOAC: Another term commonly used to refer to novel oral anticoagulants or Non-vitamin K antagonist oral anticoagulants (NOAC)
Strategic Target 2: Establish Oncology Business

We will establish an oncology business by launching several drugs currently in late-stage development. Concurrently, we will accelerate early-stage pipeline development and evaluate further enrichment in oncology through the acquisition of external assets. Through the acceleration of oncology research and development, we aim to grow our oncology business revenue to more than ¥40.0 billion in fiscal 2020 and ¥300.0 billion in fiscal 2025.

<table>
<thead>
<tr>
<th>Revenue</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>FY2020</td>
<td>FY2025</td>
</tr>
<tr>
<td>More than ¥40.0 billion</td>
<td>Approx. ¥300.0 billion</td>
</tr>
</tbody>
</table>

- Establish oncology business by launching current late-stage pipeline products
- Accelerate early-stage pipeline development
- Enrich pipeline by acquisition of external assets
- Accelerate oncology research and development by a new organization

(1) Establish Oncology Business by Launching Current Late-Stage Pipeline Products

By launching **quazartinib**, **tivantinib**, and **pexidartinib** prior to fiscal 2020, we will target revenue contributions of ¥40.0 billion by fiscal 2020.

**Quazartinib** is currently in phase 3 studies for newly-diagnosed and relapsed/refractory FLT3-ITD-positive (FMS-like tyrosine kinase 3 internal tandem duplication) acute myeloid leukemia (AML). We expect top-line results (TLR)* of the phase 3 study for relapsed / refractory AML patients (QUANTUM-R study) during the first half of 2018. If **quazartinib** is approved for newly-diagnosed and relapsed/refractory treatment, we believe it will generate peak annual revenue of approximately ¥100.0 billion.

**Tivantinib** is being developed in partnership with ArQule Inc. in the United States and Europe for the treatment of refractory hepatocellular carcinoma. In March 2016, the independent data monitoring committee of the phase 3 study (METIV-HCC study) conducted the planned interim assessment, and it was determined the study will continue to its final analysis. We expect TLR during the first half of 2017. **Tivantinib** is expected to generate peak annual revenue of around ¥30.0 billion.

**Pexidartinib** was discovered by Plexxikon Inc., and has been granted Breakthrough Therapy Designation by the U.S. Food and Drug Administration (FDA) for the treatment of tenosynovial giant cell tumor. It is being evaluated in a phase 3 study and we expect TLR during the first half of 2018. In addition, we are currently engaged in a collaborative study (phase 1/2a study) with U.S.-based Merck & Co. to investigate **pexidartinib** in combination with Merck’s anti-PD-1 antibody (immune checkpoint inhibitor). We expect the TLR of this study in the latter half of 2019. We believe that **pexidartinib** will generate peak annual revenue in the range of ¥100.0 billion by expanding the indications.

**Patritumab** is being evaluated as a treatment for head and neck cancer in a phase 2 study. In the preceding phase 1b study, we collected promising data from an analysis of a limited number of cases, and this data was announced at the American Society of Clinical Oncology together with our design for the phase 2 study in June 2016.

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*1. TLR: Anticipated initial results for studies*
(2) Accelerate Early-Stage Pipeline Development

We have focused on drug discovery in oncology since the merger of Daiichi and Sankyo in 2007 and allocated additional management resources to this area since 2009. As a result, we are now advancing many early-stage pipeline molecules with the aim of innovating the current standard of care (SOC). Going forward, we expect revenue contributions of ¥300.0 billion in fiscal 2025 from the total oncology portfolio.

Additionally, the following are four promising early-stage development compounds with different modes of action.

**DS-3032** is an inhibitor of MDM2, a protein that is related to regulation of the p53 tumor suppressor. It is currently in phase 1 studies for the treatment of solid tumors and hematological tumors.

For a subgroup of patients, MDM2 gene amplification has been confirmed inside liposarcoma, a type of solid tumor. We anticipate high efficacy in patients in this subgroup.

**DS-8201** is Daiichi Sankyo’s first antibody drug conjugate (ADC) and was created using innovative ADC technologies. This drug displays the potential for significant efficacy in patients for which the efficacy of currently marketed anti–HER2 antibodies and anti–HER2 ADCs is insufficient. We are currently performing a phase 1 study for **DS-8201** with the goal of acquiring study results during fiscal 2017.

(3) Enrich Pipeline by Acquisition of External Assets

Daiichi Sankyo has continued to pursue the expansion of products and pipelines by acquiring external assets via M&A or alliances. Going forward, we will continue to explore pipeline acquisition, prioritizing those that will contribute to the growth of our oncology franchise.

(4) Accelerate Oncology Research and Development into a New Organization

With the aim of accelerating research and development in the oncology area, Daiichi Sankyo reformed its organizational structure. This reorganization included the April 2016 establishment of the Oncology R&D Sub Unit, which oversees the global research and clinical development functions in the oncology area.

This move will enable us to consolidate our oncology R&D expertise and also facilitate flexible and seamless decision-making in oncology in order to accelerate meeting our research and development objectives in this area.

The Oncology R&D Sub Unit is led by Antoine Yver, MD, MSc, who was appointed to this position in April 2016. Dr. Yver previously led oncology research at global pharma companies, and he has a wealth of experience in the development of oncology drugs. Under his leadership, we will accelerate oncology research and development.
Strategic Target 3: Grow as No.1 Company in Japan

We are striving to grow Daiichi Sankyo into the No. 1 company in Japan in terms of quality and quantity. To accomplish this objective, the Company will address a wide range of medical needs related to areas such as prevention, self-medication and treatment through leveraging the strength of its innovative pharmaceuticals business in combination with its generic business, vaccine business and OTC related business.

In our innovative pharmaceuticals business, we boast top-class sales capabilities in terms of both quality and quantity, and we will utilize these capabilities to drive ongoing growth. Moreover, the strong reputation of these sales capabilities outside of the Company has resulted in successful in-licensing opportunities. We will continue to grow our own in-house products as well as in-licensed products in domestic operations, which in turn builds a stronger reputation for our sales capabilities. The resulting cycle is a source of our ongoing growth.

With regard to major domestic products, we will pursue growth in revenue of NEXIUM, Memory, PRALIA, RANMARK, Efient, and TENELIA, including seeking additional indications for some of these products. We thereby aim to increase total revenue from these six products to more than ¥263.0 billion.

In fiscal 2016 and beyond, we will proceed with the sequential launches of such new products as VIMPAT (epilepsy treatment), VN–100 (intradermal HA vaccine injection syringe for influenza), hydromorphone (opioid analgesic*1), and Etanercept BS (biosimilar biogeneric of etanercept, a treatment for rheumatoid arthritis). Through this constant reinforcement of our product line, we will grow Daiichi Sankyo into Japan’s No. 1 pharmaceutical company.

*1. Opioid analgesic: Narcotic analgesic

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Growth of Major Products

<table>
<thead>
<tr>
<th>2015</th>
<th>2017</th>
<th>2020 (FY)</th>
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<tbody>
<tr>
<td>¥171.1 billion</td>
<td>¥226.0 billion</td>
<td>More than ¥263.0 billion</td>
</tr>
</tbody>
</table>

Increase revenue to more than ¥263.0 billion in FY2020

Product Strategies

- **NEXIUM (ulcer treatment: proton pump inhibitor)**
  - Maintain No. 1 share by establishing position as “first choice” drug for GERD*1 treatment
- **Memory (Alzheimer’s disease treatment)**
  - Standardize combination therapy with ChE*1 inhibitor for the treatment of moderate–severe Alzheimer’s disease by provision of clinical evidence
- **PRALIA (treatment for osteoporosis)**
  - Increase market penetration by promoting high evaluations received in guidelines
  - Grow by getting additional indication for rheumatoid arthritis
- **RANMARK (treatment for bone complications caused by bone metastasis from tumors)**
  - Maintain position as standard of care (SOC) for treating bone complications caused by bone metastasis from tumors
  - Grow by getting additional indication for breast cancer
- **Efient (antiplatelet agent)**
  - Maintain No. 1 share in heart area by promoting ideal dosage for Japanese people
  - Lead next generation of antiplatelet treatment in Japan by getting additional indication for brain area
- **TENELIA (type 2 diabetes mellitus inhibitor)**
  - Advertise efficacy and ease of use for seniors and patients with renal impairment to become first-line treatment for diabetes and expand market share

*1. GERD: Gastroesophageal reflux disease  
*2. ChE: Cholinesterase
Strategic Target 4: Expand U.S. Businesses

(1) Business Expansion in Pain Franchise (DSI)
Daichi Sankyo, Inc. (DSI), of the United States, will pursue business expansion in its pain franchise through MOVANTIK, CL-108, and mirogabalin.

The pain market in the United States is approximately ¥3,360.0 billion, and approximately 40% of this market is accounted for by opioid analgesics, which is significantly different from the markets of Japan and other countries.

The total number of prescriptions written in the overall US pain market exceeds 330 million per year. The segments of this market targeted by MOVANTIK, CL-108 and mirogabalin each make up approximately 25% of the total market and represent more than 80 million prescriptions.

MOVANTIK is the first once-daily oral treatment for opioid-induced constipation approved by the FDA. It is primarily for adults that have also been prescribed opioids for treating chronic non-cancer pain. We commenced co-promotion of this drug together with AstraZeneca in fiscal 2015.

Approximately 40% of patients taking opioids for non-cancer pain experience constipation. We therefore believe that MOVANTIK can address substantial unmet medical needs.

CL-108 is a novel fixed-dose, immediate-release bi-layered tablet with a rapid release layer containing promethazine and a second layer containing hydrocodone and acetaminophen, which releases after promethazine. A combination of hydrocodone and acetaminophen is the standard treatment for pain after external injury or surgery, and this combination is prescribed to approximately 53 million patients each year. Data show that approximately 40% of opioid patients experience opioid-induced nausea and vomiting (OINV). FDA is currently reviewing the NDA for the management of pain severe enough to require an opioid analgesic, while preventing or reducing the associated OINV. The FDA has set a target action date under the Prescription Drug User Fee Act (PDUFA) of January 31, 2017.

Mirogabalin is a new, oral α2δ-ligand undergoing development for the treatment of pain associated with fibromyalgia in the United States. The U.S. α2δ-ligand market has a scale of 50 million annual prescriptions. Pregabalin has a majority of revenue in this market and achieved sales totaling US$2.7 billion in 2015. However, more than 50% of patients prescribed this drug stop using it within 12 months for reasons such as insufficient pain relief. Accordingly, we feel that there are substantial unmet needs with this regard. We hope that the phase 3 study currently underway will allow us to differentiate mirogabalin from pregabalin in terms of ease of use, efficacy and safety, and we anticipate the acquisition of top-line results in the first half of 2017.

DSI is targeting U.S. launches of CL-108 in fiscal 2017 and mirogabalin in fiscal 2019, and we will endeavor to grow revenue from the pain franchise to more than ¥100.0 billion in fiscal 2020.

Business Expansion for Pain Franchise (DSI)

Key Success Factors and Main Strategies

- MOVANTIK (treatment for opioid-induced constipation)
  - Raise awareness regarding opioid-induced constipation
  - Inspire a conversation about opioid-induced constipation
  - Deliver affordable access

- CL-108 (treatment for pain and opioid-induced nausea and vomiting, targeted launch in FY2017)
  - Raise awareness among healthcare professionals regarding opioid-induced nausea and vomiting
  - Engage the medical community

- Mirogabalin (treatment for pain associated with fibromyalgia, targeted launch in FY2019)
  - Differentiate from pregabalin based on phase 3 clinical trial data
(2) Growth of Luitpold Business

Luitpold Pharmaceuticals, Inc. (LPI), another U.S. subsidiary, is achieving rapid growth by increasing revenue of Injectafer iron injection and its generic injectable franchise.

Positioning Injectafer as its flagship product, LPI will expand the target scope of its sales teams’ coverage to include gastroenterologists, cardiologists and obstetrician-gynecologists that treat iron-deficiency anemia. LPI seeks to acquire a share of more than 40% in the hematology and oncology market. Through these efforts, LPI will realize annual revenue growth of 20% to 30%.

In regard to its generic injectable franchise, LPI will expand capacity for plants and become a top 4 supplier in the United States.

Through the growth of Injectafer and the generic injectable franchise, we will aim to achieve revenue of ¥150.0 billion in the Luitpold business.

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### Growth of Luitpold Business

<table>
<thead>
<tr>
<th>Year</th>
<th>Revenue (¥ billion)</th>
<th>Increase to</th>
</tr>
</thead>
<tbody>
<tr>
<td>2015</td>
<td>18.6</td>
<td>120.0</td>
</tr>
<tr>
<td>2017</td>
<td>91.0</td>
<td>150.0</td>
</tr>
<tr>
<td>2020</td>
<td>150.0</td>
<td></td>
</tr>
</tbody>
</table>

#### Increase revenue to more than ¥150.0 billion in FY2020

- **Iron Franchise**
  - Build Injectafer into a flagship product and a market leader (Compound annual growth rate: 20%–30%)
  - Execute lifecycle management
  - Expand the target scope of promotions to include gastroenterologists, cardiologists and obstetrician-gynecologists that treat iron-deficiency anemia
  - Gain a share of more than 40% in the hematology and oncology segment

- **Generic Injectable Franchise**
  - **Expand and maximize product portfolio**
  - Focus on high-market-value products (e.g., anticancer drugs)
  - **Become a top 4 supplier in the U.S. generic injectable market**
    - Shirley Plant: Upgrade existing manufacturing infrastructure
    - New Albany Plant: Consolidate operations and expand capacity
    - Hillaire Plant: Maximize space use and expand capacity
Strategic Target 5: Continuously Generate Innovative Medicine Changing Standard of Care (SOC)

(1) Create New Drugs in Oncology and New Horizon Areas
Our target therapeutic areas include oncology, which will be positioned as a primary focused area, as well as pain, central nervous system diseases, heart and kidney disease, and rare diseases, which we define as new horizon areas. Research and development of treatments in these areas will be a priority going forward. By taking advantage of partnering, open innovation, and translation research, we will strive to continuously generate innovative medicine changing SOC.

To facilitate drug discovery efforts in new horizon areas, we transformed our research organization in April 2016 to transition to a biobusiness model. Under this model, the Company created small organizations that possess either pharmacology and medicinal chemistry functions or pharmacology and biologics functions. These organizations will be granted decision-making authority in relation to research themes and receive resource allocations based on the results they generate. We expect that this change will give rise to an innovative, venture mind-set and serve to expedite decision making. Consequently, we anticipate a rise in research speed and productivity.

(2) Realize Clinical Application of Innovative Technology
In regard to our advanced fundamental bio technologies, we will have already commenced phase 1 studies for several compounds that utilize antibody dependent cellular cytotoxicity (ADCC), antibody drug conjugate (ADC) and nucleic acid drug technologies. As for bispecific technologies and cell therapies, we are advancing research and preclinical studies on compounds that may be the next candidates to proceed on to the clinical phase.

One example of our nucleic acid drugs is DS-5141, a treatment for Duchenne muscular dystrophy that went into phase 1/2 studies in Japan in February 2016. Committed to providing a treatment option for patients suffering from serious cases of this disease, we are working in close coordination with specialists with the aim of acquiring domestic manufacturing and marketing approval for this drug in 2020.

At the same time, we are stepping up initiatives to realize clinical application of our cell therapy technologies. Through efforts out of the Cell Therapy Laboratories established in April 2016 and Asubio Pharma Co., Ltd., which has been advancing research for regeneration and cell therapy with academia, we will lead the advancement of cell therapy in Japan as an industry representative.

In May 2016, we concluded an in-licensing agreement with U.K.-based Cell Therapy Ltd. (Celixir at present), where Nobel Laureate Professor Martin Evans works as chief science officer, for Heartcel, an allogeneic cell therapeutic agent for ischemic heart failure currently in development. Under this agreement, Daiichi Sankyo will be responsible for development and sales of Heartcel in Japan. Preparations for a domestic phase 1 study are currently being made.

Furthermore, we have commenced joint research with Asahikawa Medical University targeting the creation of cell therapies using capillary stem cells. Research is currently moving forward to verify the therapeutic effect and realize practical application of these cells for the treatment of patients with a wide range of diseases, including lower leg ischemia and ischemic heart disease.

*1. Open innovation: Development method in which external development capabilities and ideas are used to overcome internal development challenges and create innovative new value
*2. Translation research: Integrated research process encompassing development of new medical innovations, testing in clinical settings to verify safety and efficacy, and application in everyday medical practice
*3. Nucleic acid drugs: Drugs utilizing nucleic acids comprised of genes
*4. Bispecific technologies: Technologies for simultaneously inhibiting the functions of two antigens
*5. Cell therapies: Treatment methods in which cells are extracted from a patient and then selected, activated, multiplied, differentiated, or otherwise manipulated before being administered to the patient to treat various diseases
Strategic Target 6: Enhance Profit Generation Capabilities

To enhance our profit generation capabilities, we will build upon the business restructuring measures conducted by fiscal 2015. Efforts during the period of this 5-year business plan will include optimizing manufacturing systems globally and further enhancing procurement. In addition, we will pursue further cost reductions and streamlining across the Group, advancing a concerted effort to review cost of sales, SG&A expenses, and R&D expenses to boost our ability to generate profit.

Growth Investments for Advancing Strategic Targets

Daiichi Sankyo will actively conduct growth investments to facilitate the advancement of these strategic targets. The Company will utilize cash on hand of roughly ¥700.0 billion as of March 31, 2016, as well as the approximately ¥2,200.0 billion in cash to be generated during the period of this 5-year business plan to conduct growth investments of ¥900.0 billion in R&D expenses and ¥500.0 billion in business development. In conducting these investments, our top priority will be to acquire oncology products and pipelines, and investments will be made for advancing other growth strategies as necessary.