

Kyowa Hakko Kirin Group  
FY2016-2020 Mid-term Business Plan

# Leaping Forward



Leaping Forward for Global Specialty Pharmaceutical Company

Kyowa Hakko Kirin Co., Ltd.  
President and CEO

**Nobuo Hanai**

## Forward-looking statements

*This document contains certain forward-looking statements relating to such items as the company's (including its domestic and overseas subsidiaries) forecasts, targets and plans. These forward-looking statements are based upon information available to the company at the present time and upon reasonable assumptions made by the company in making its forecasts, but actual results in practice may differ substantially due to uncertain factors.*

*These uncertain factors include, but are not limited to, potential risks of the business activities of the pharmaceutical industry in Japan and overseas, intellectual property risks, risk of side effects, legal regulation risks, product defect risks, risks of changes to prices for raw materials, risks of changes to market prices, as well as risks of changes to foreign exchange rates and financial markets.*

*This document contains information on pharmaceutical products (including products under development), but its contents should not be construed as promotion, advertising or as a medical recommendation.*

# Agenda

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## **1 Executive Summary of FY2013-2015 Mid-term Business Plan**

## **2 FY2016-2020 Mid-term Business Plan**

### **■ Qualitative Plan: “Four Strategic Pillars”**

- 1) Improvement of Global Competitiveness
- 2) Creating Innovation
- 3) Continuous Improvement for Operational Excellence
- 4) Contribution to Health and Well-being of People

### **■ Financial Strategy**



**FY2013-2015 Mid-term  
Business Plan  
Executive Summary**

## Visions in 2015 **Pharmaceutical**

### **Kyowa Hakko Kirin Group management philosophy**

The Kyowa Hakko Kirin Group companies strive to contribute to the health and well-being of people around the world by creating new value through the pursuit of advances in life sciences and technologies.

### **Business Vision**

Kyowa Hakko Kirin will be a Japan-based Global Specialty Pharmaceutical Company contributing to human health and well-being worldwide through innovative drug discovery and global commercialization, driven by state-of-the-art antibody technologies mainly in the core therapeutic areas of oncology, nephrology, and immunology.

## **Aims for 2015**

### **Category-based Strategy**

Accelerate therapeutic competitive advantage by becoming a major category player

### **Overseas Strategy**

Expand global business in accordance with country- and region-specific business strategy

### **Compliance / Organization**

Build a structure and environment appropriate for a global specialty pharmaceutical company

### **Productivity**

Create a high-productivity environment that brings out individual abilities and organizational strengths

## Executive Summary **Qualitative**

### Pharmaceuticals

#### Further Strengthening of Competitiveness in Japan through Category-based Strategy

- Formed four category teams for nephrology, oncology, immunology and allergy, and the central nervous system. Effectively performed portfolio management in each category, from R&D to Sales & Marketing with consideration of alliance strategies.
- Made steady progress with new products G-Lasta<sup>®</sup>, Dovobet<sup>®</sup>, Onglyza<sup>®</sup>, and NOURIAST<sup>®</sup>, as well as our major product NESP<sup>®</sup>.

#### Expansion of Business Base in the USA, Europe and Asia toward Global Specialty Pharmaceutical Company

- Made progress in the global development of KW-0761, KW-6002, and KRN23 in the West. Pursuing strategic partnering for KW-0761 in the immuno-oncology field.
- Succeeded in expanding sales organization in Europe through the acquisition of Archimedes Pharma.
- Promoted development and commercialization based on country-specific strategies in Asia.

#### Productivity Enhancement

- Implemented our basic production strategy for enhancing profitability by reorganizing production activities as planned (closed Yokkaichi and Sakai Plants)

### Bio-chemicals

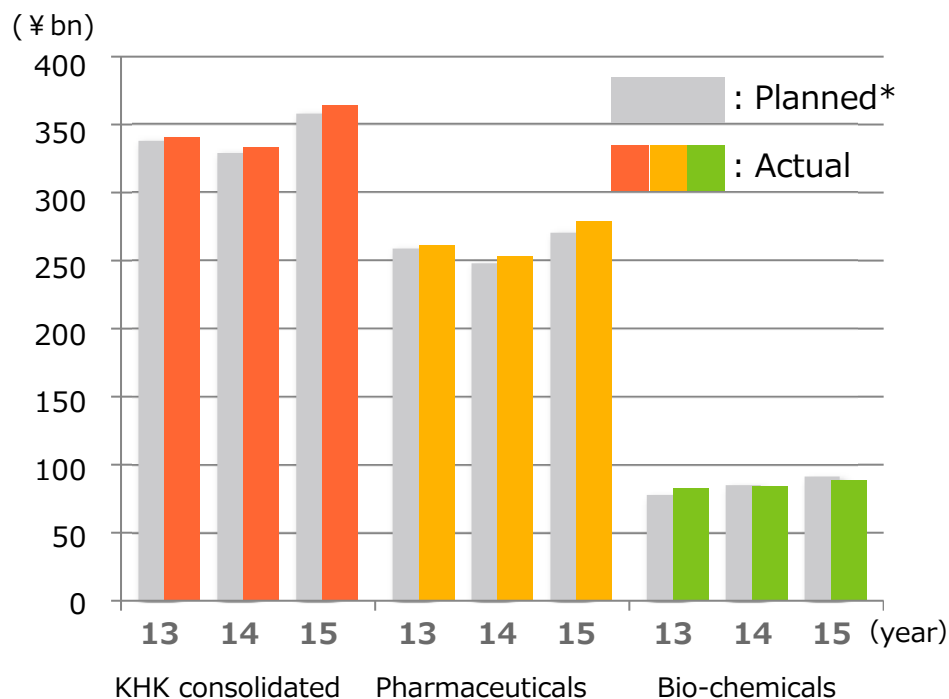
#### Improvement of Revenue & Profitability

- Expanded overseas plants such as Thai Kyowa and Shanghai Kyowa
- Steady progress in streamlining operations at the Japanese plant
- In API business, discontinued unprofitable products and expanded highly profitable products
- Healthcare business expanded as awareness of Ornithine increased and mail-order business grew

# Executive Summary Quantitative

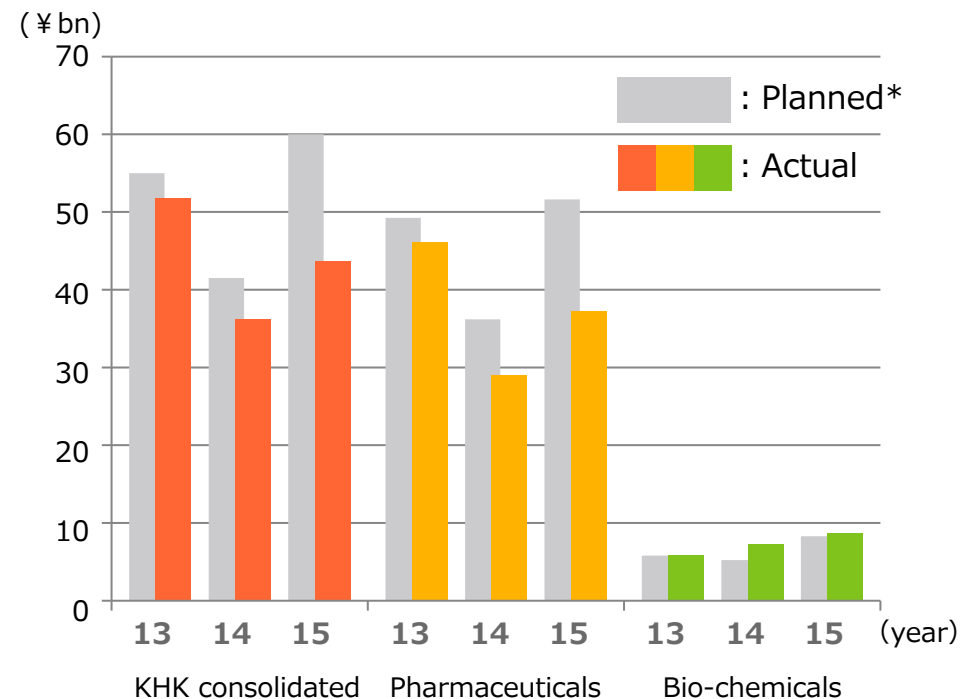
## Sales

\*Disclosed on January 31<sup>st</sup>, 2013



## Operating Profit

\*Disclosed on January 31<sup>st</sup>, 2013



KHK Consolidated	FY2013		FY2014		FY2015	
	Planned	Actual	Planned (Not disclosed)	Actual	Planned	Actual
Sales	338.0	340.6	329.0	333.4	358.0	364.3
Operating Profit	55.0	51.8	41.5	36.2	60.0	43.7



**FY2016-2020  
Mid-term Business Plan**



## Environmental Analysis of Pharmaceutical Business

- Need to accelerate the transformation of business model,**
- **from domestic market to global market;**
  - **from patent-expired products to innovative new drugs**

### External Environment

- **Lower probability of success in new drug development and increase in development costs**
- **Reinforced measures for healthcare cost containment**
- **Fragmentation and diversification of medical needs**
  - Preventive and presymptomatic care expected to expand
  - Regenerative medicine, genetic testing, and gene therapy

### Internal Environment

- **Rich innovative pipeline in the late stage of development, including biosimilar products**
- **Various business bases within the Group**
- **Patent expiration for major products**

# Leaping Forward for Global Specialty Pharmaceutical Company

Achieve outstanding growth through  
the “Four Strategic Pillars”

**Improvement of  
Global  
Competitiveness**

(Leaping Forward to US/EU Market)

**Creating  
Innovation**

(Proactive Investment for R&D)

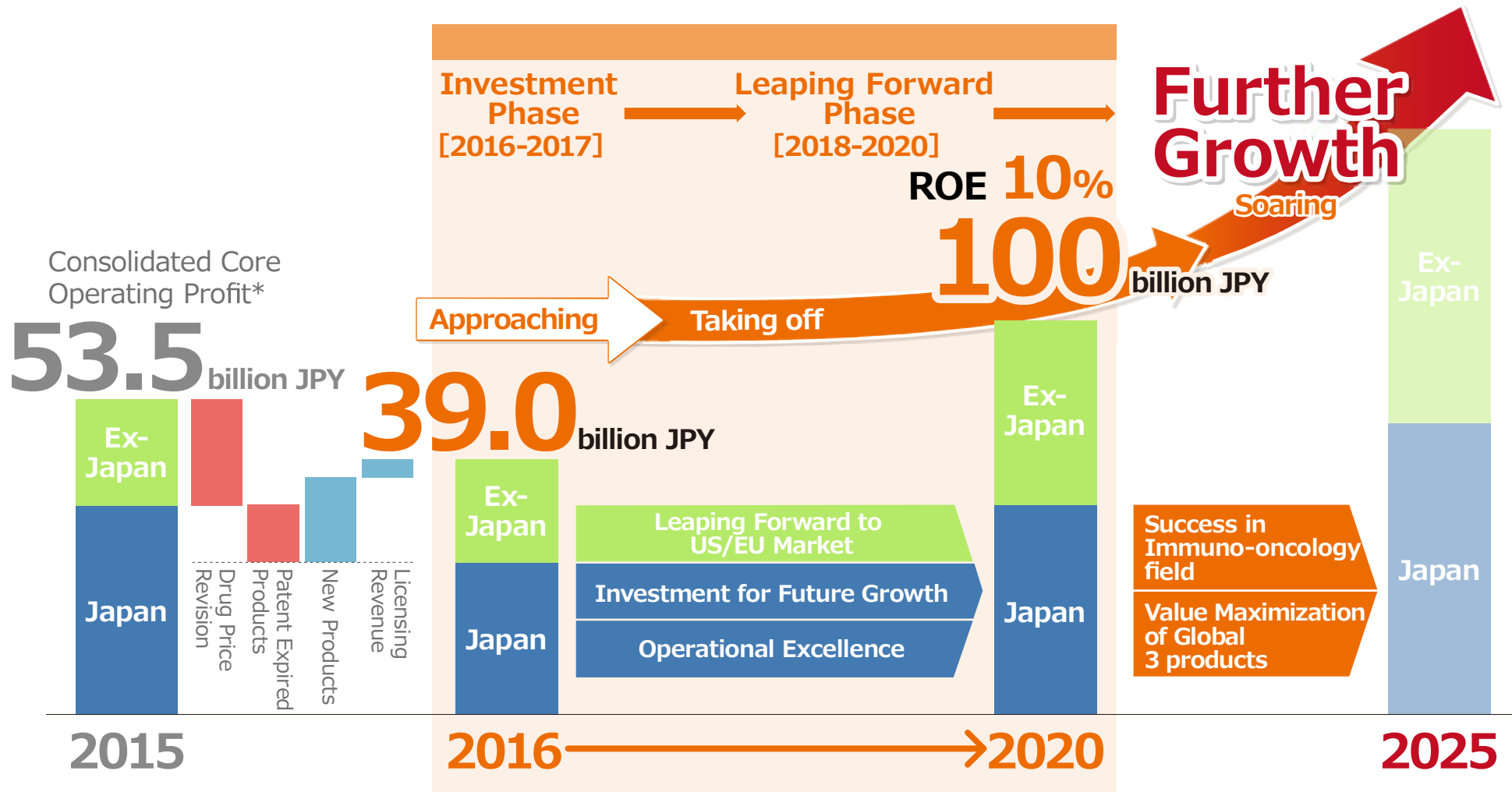
**Continuous  
Improvement for  
Operational Excellence**

(Group Management)

**Contribution to  
Health and Well-being  
of People**

(Creating Shared Value)

# Leaping Forward for GSP



\*Operating Profit + Amortization of goodwill + Share of profit/loss of entities accounted for using equity method

(Accounting standards will be changed to IFRS from 2017 )

**Improvement of  
Global  
Competitiveness**

(Leaping Forward to US/EU Market)

**Creating  
Innovation**

(Proactive Investment for R&D)

**Continuous  
Improvement for  
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**Contribution to  
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First Strategic Pillar:

# **Improvement of Global Competitiveness**

(Leaping Forward to US/EU Market)

First Strategic Pillar:

## Improvement of Global Competitiveness

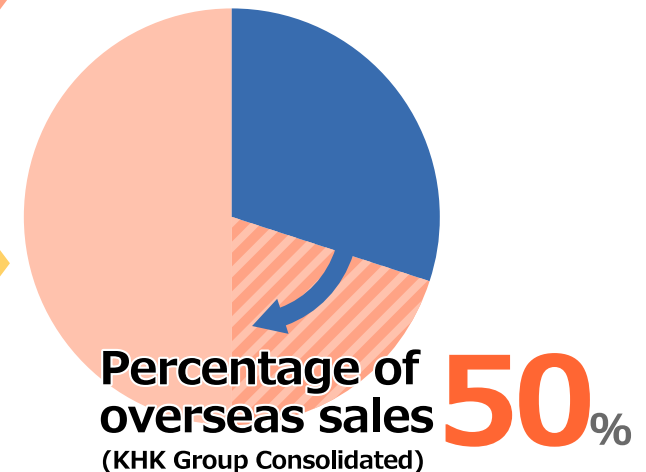


Achieve outstanding growth through the launch of three global products, and establish globalized organization and sales network

Continuous Creation of Innovative Drugs

Leaping Forward to US/EU Market

Expansion of Overseas Business in Bio-chemicals and Diagnosis



# Continuous Creation of Innovative Drugs

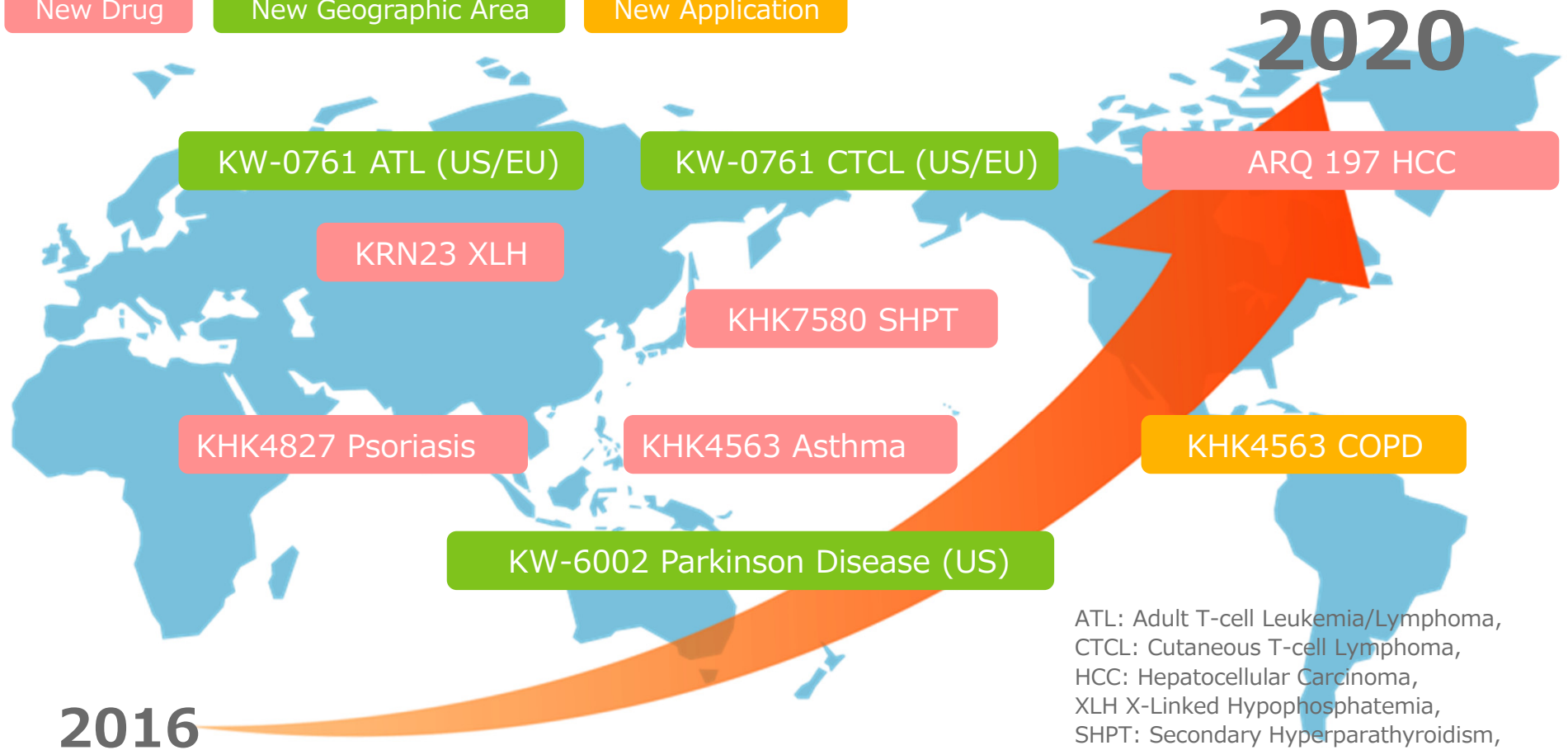


## Major Pipeline Drugs Targeted for Approval

New Drug

New Geographic Area

New Application



ATL: Adult T-cell Leukemia/Lymphoma,  
CTCL: Cutaneous T-cell Lymphoma,  
HCC: Hepatocellular Carcinoma,  
XLH X-Linked Hypophosphatemia,  
SHPT: Secondary Hyperparathyroidism,  
COPD: Chronic Obstructive Pulmonary Disease



## KRN23: Key Driver for Becoming GSP

### Global Sales & Marketing

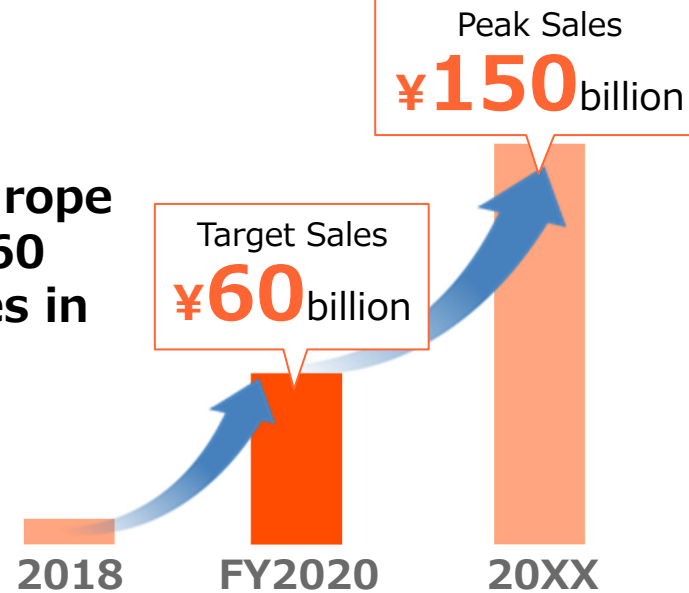
Accelerating the launch readiness activities for the initiation of sales in Western countries

- Expanding sales forces utilizing ProStrakan's sales network in Europe.
- Establishing a sales network in the US working together with Ultragenyx.

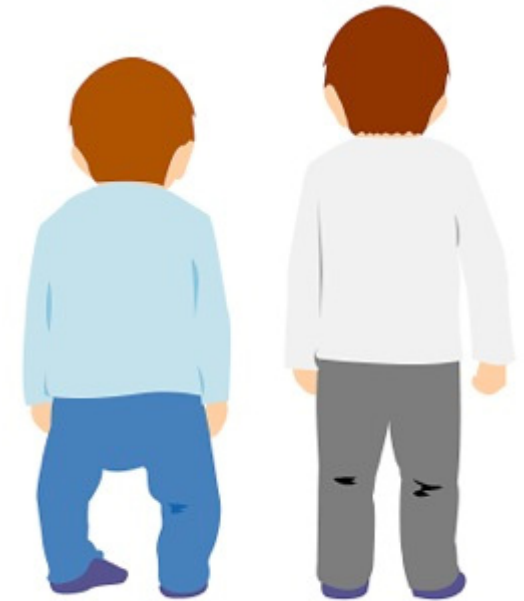
### Expectation and Target Growth

Obtain approval in Europe in 2018 and achieve 60 billion JPY target sales in 2020

Maximizing the product value as a key driver potentially generates 150 billion JPY in peak sales

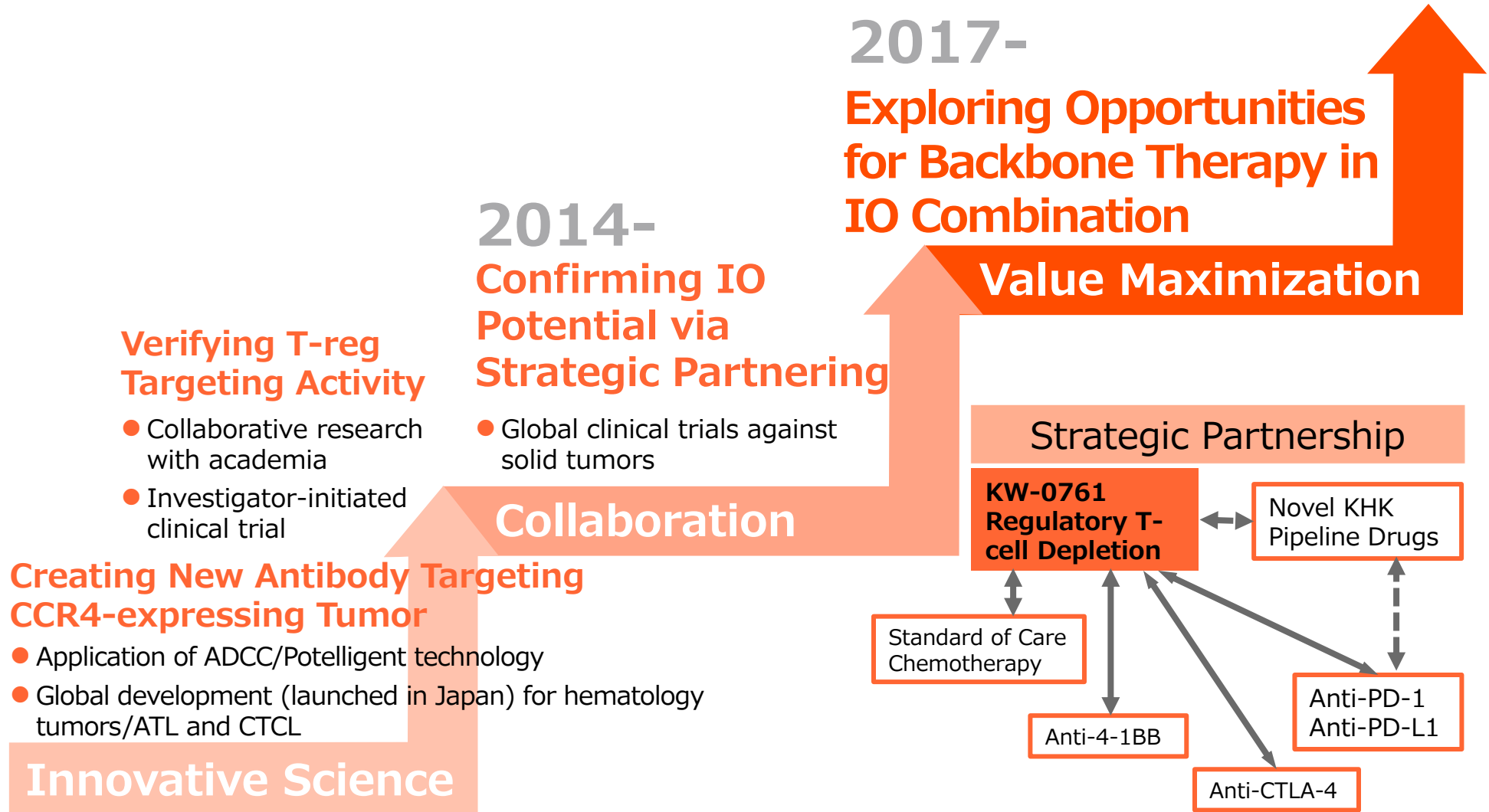


Note: The above sales expectations are preliminary and have been solely made by Kyowa Hakko Kirin.





# Expansion into Immuno-Oncology with KW-0761







## Two Approaches for the US Market

- **KW-6002**

**Driven through the MR sales force**

Resource-effective market penetration can be achieved through intensive promotion to the key prescribers

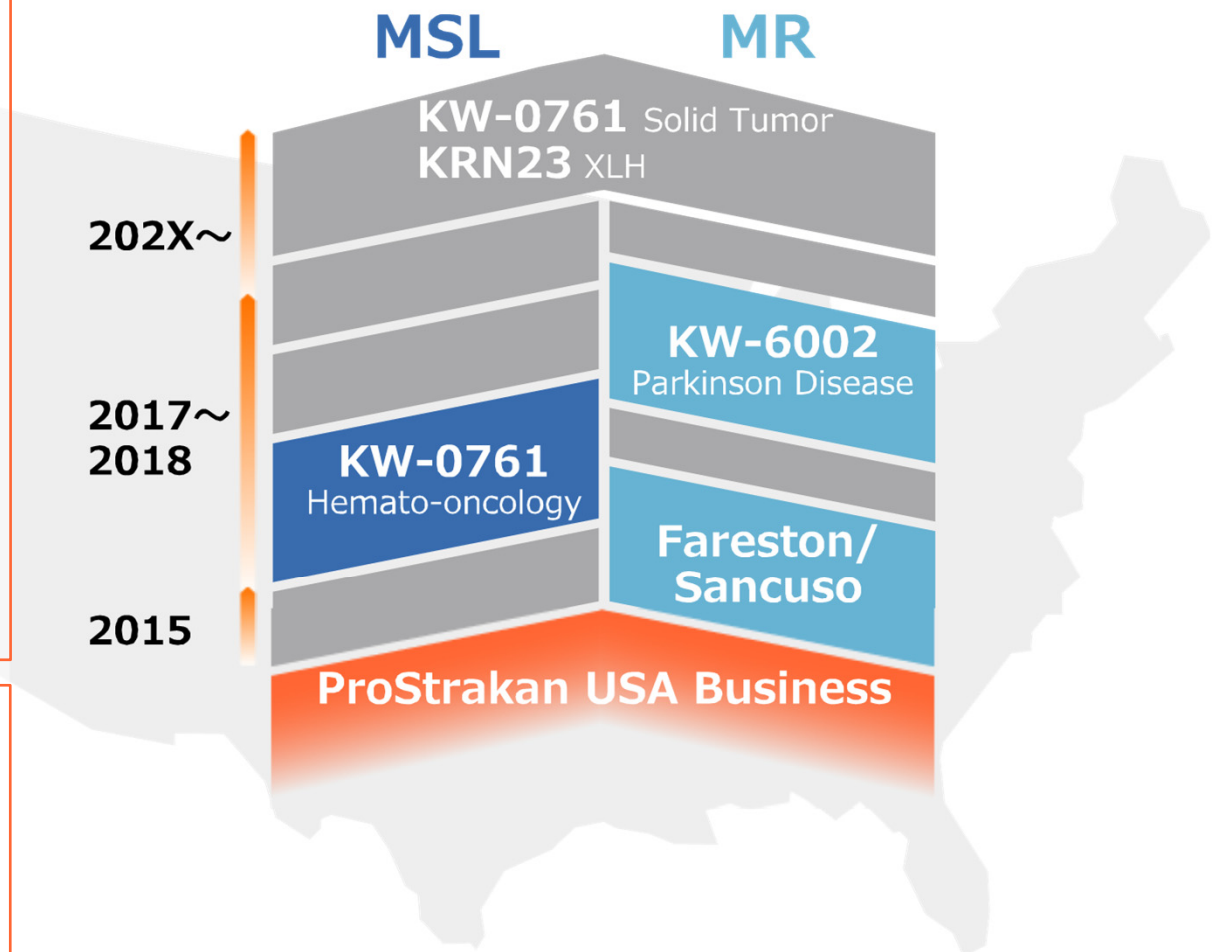
- **KW-0761 (for orphan disease)**

Provide fairly balanced scientific exchange and discuss disease state and all therapeutics through the MSL

(● KRN23 : Collaboration with Ultragenyx)

## Reinforcement of Supply Chain

Establish a global supply chain and quality assurance systems for the stable supply of products with excellent quality





## Company Name Change of Western Subsidiaries

Change the name of all Western pharmaceutical subsidiaries' names to a unified brand of "Kyowa Kirin"  
Pursue brand penetration and market expansion as a pharmaceutical company developing innovative medicines

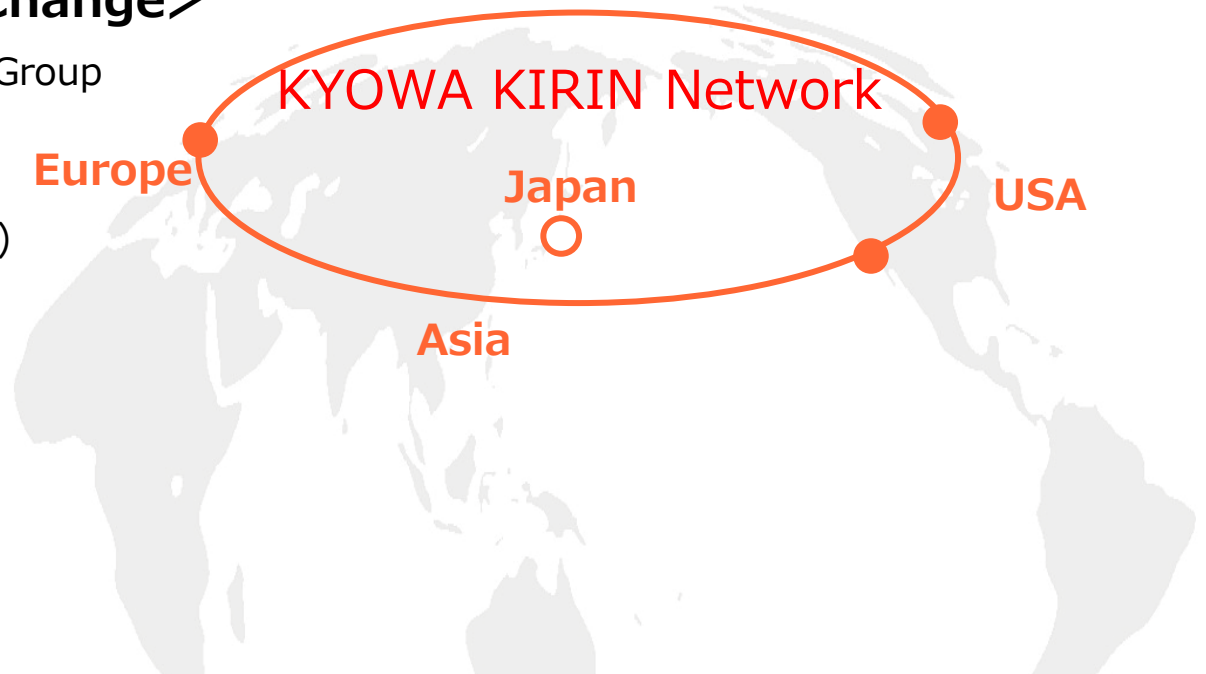
### <Scope of Company Name Change>

ProStrakan (PSK) all companies in PSK Group  
Kyowa Hakko Kirin America, Inc. (KKA)  
Kyowa Hakko Kirin Pharma, Inc. (KKP)  
Kyowa Hakko Kirin California, Inc. (KKC)

 ProStrakan



**KYOWA KIRIN**



Improvement of  
Global  
Competitiveness

(Leaping Forward to US/EU Market)

**Creating  
Innovation**

(Proactive Investment for R&D)

Continuous  
Improvement for  
Operational Excellence

(Group Management)

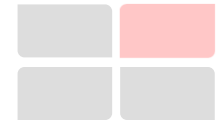
Contribution to  
Health and Well-being  
of People

(Creating Shared Value)

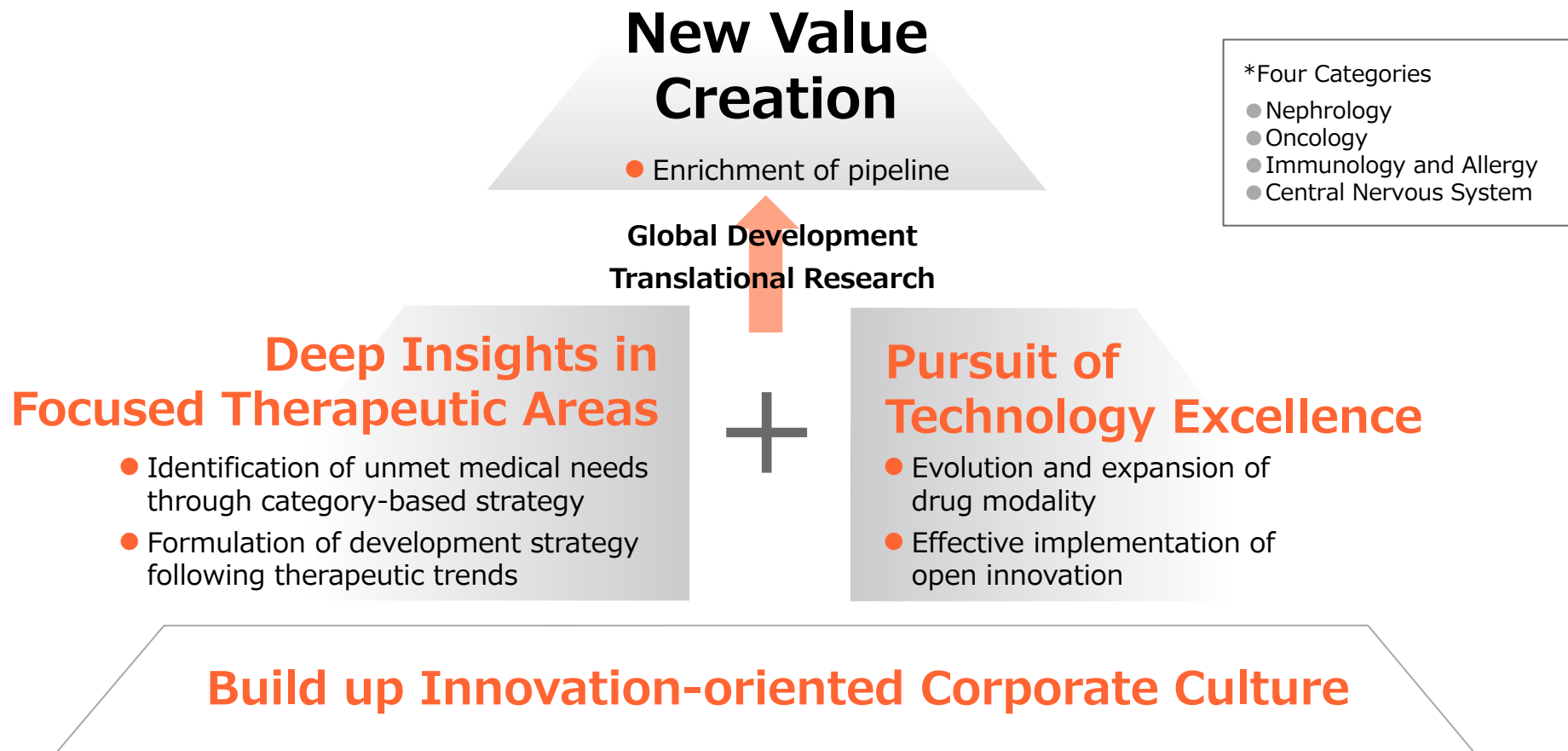


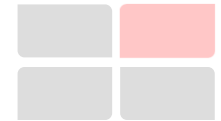
Second Strategic Pillar:  
**Creating Innovation**  
(Proactive Investment for R&D)

## Creating Innovation

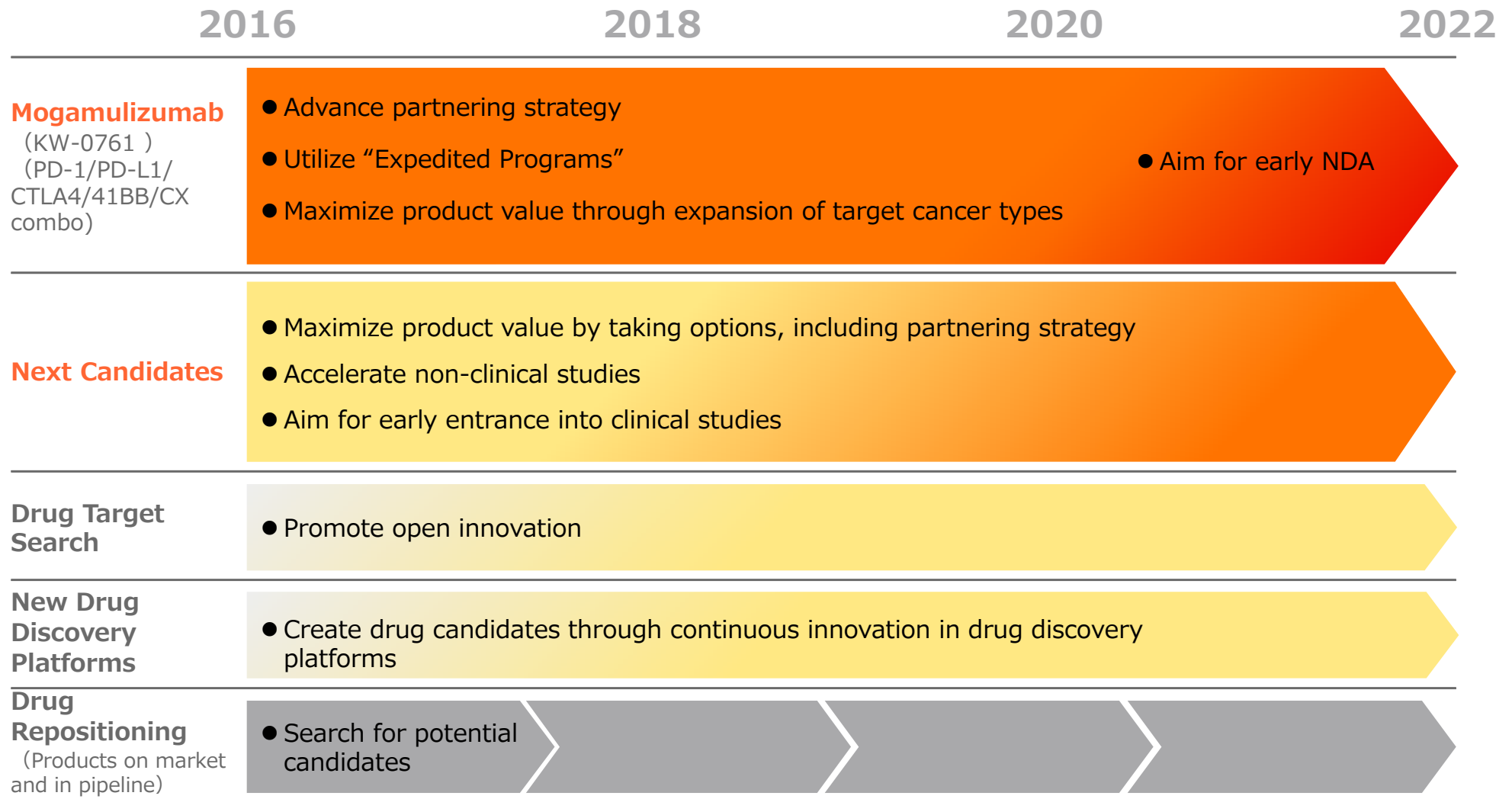


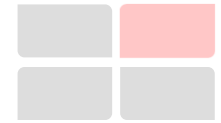
Address the creation of new value, combining innovative technologies with deep insights of diseases in the “Four Categories”\*.





# Enrichment of Immuno-Oncology Pipeline

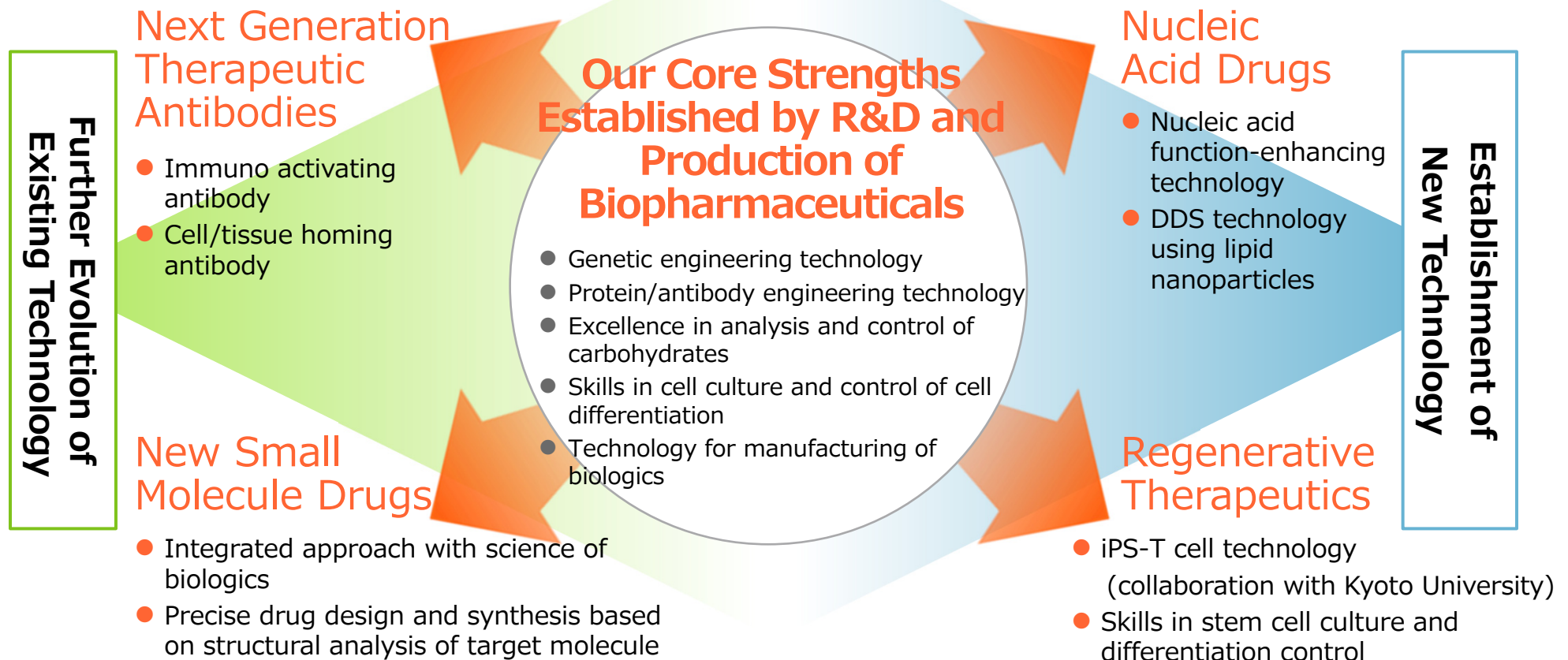




# Evolution and Expansion of Drug Modality

Technology-driven drug discovery leveraging technological advantages and open innovation

## Development of Four Major Modalities



Improvement of  
Global  
Competitiveness  
(Leaping Forward to US/EU Market)

Creating  
Innovation  
(Proactive Investment for R&D)

**Continuous  
Improvement for  
Operational Excellence**  
(Group Management)

Contribution to  
Health and Well-being  
of People  
(Creating Shared Value)

Third Strategic Pillar:  
**Continuous Improvement  
for Operational Excellence**  
(Group Management)



**Improve our business processes to make our asset management more efficient, and ensure the cash flow for aggressive and strategic investments**

### **Pursuing Continuous Improvement of Operational Efficiency**

- Manufacturing cost reduction by advanced production technology
- Improvement of business processes with the ROA as an indicator
- Effective resource management through collaboration with Kirin/KHK Groups

### **Reorganization and Reinforcement of Functions Responding to the Domestic Business Environment Change**

- Implementation of an “Area Strategy” and strategic allocation of sales resources
- Implementation of “Category-based Strategy”
- Appropriate creation and provision of evidences by the MSL

### **Development of Reliable Business Processes**

- Rigorous rules on compliance and risk-sensitive culture
- Application of a Corporate Governance Code
- Participation in the KENKO KIGYOKAI corporate community: “Healthy employees and healthy companies”



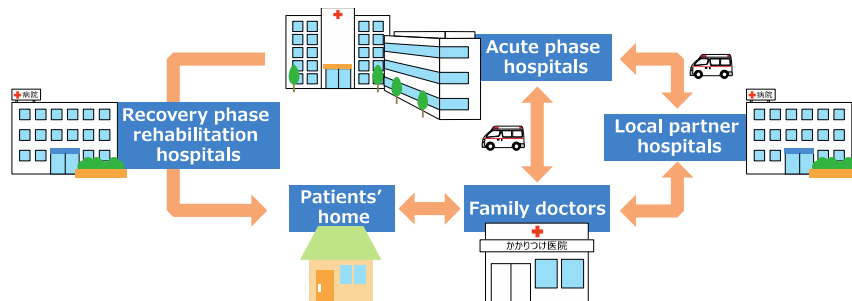


## Core Strategies for Japanese Business

### 1 Implementation of an Area Strategy

Responding to the community health initiative, alter the franchise of the sales offices from GPs and HPs to regional health communities

#### Scheme of "Secondary Medical Area" covered by each sales office



Adapted from the meeting materials from the 2nd National Council on Social Security System Reform

### 2 Strategic Allocation of Sales Resources

Ensure the market penetration of new products by leveraging the intensive resource allocation and appropriate information services for G-Lasta<sup>®</sup>, Dovobet<sup>®</sup>, Onglyza<sup>®</sup>, NOURIAST<sup>®</sup>, and new products to be launched in 2016-2020

### 3 Implementation of a Category-based Strategy

Further strengthen our core therapeutic areas by fostering our original products and exploring in-licensing opportunities



## Biosimilar Business

### Fujifilm Kyowa Kirin Biologics

**Contribute to the social pressure for medical cost containment through the stable supply of high-quality products at a low cost produced by innovative technology**

#### Biosimilar Pipelines Scheduled for Approval in 2016-2020

Code Name	Generic Name	Stage	Countries / Area
<b>FKB327</b>	Adalimumab	Phase III	USA, others
<b>FKB238 *</b>	Bevacizumab	Phase I	UK

\* Fujifilm Kyowa Kirin Biologics has entered into an agreement with AstraZeneca plc. to establish a joint venture; Centus Biotherapeutics for the development and commercialization of FKB238 in development for the treatment of multiple solid tumors.



## Kyowa Hakko Bio

### Expansion of Worldwide Production Sites

- **Thai Kyowa (TK) Crude crystal ⇒ Shanghai Kyowa (SK) Final purification**

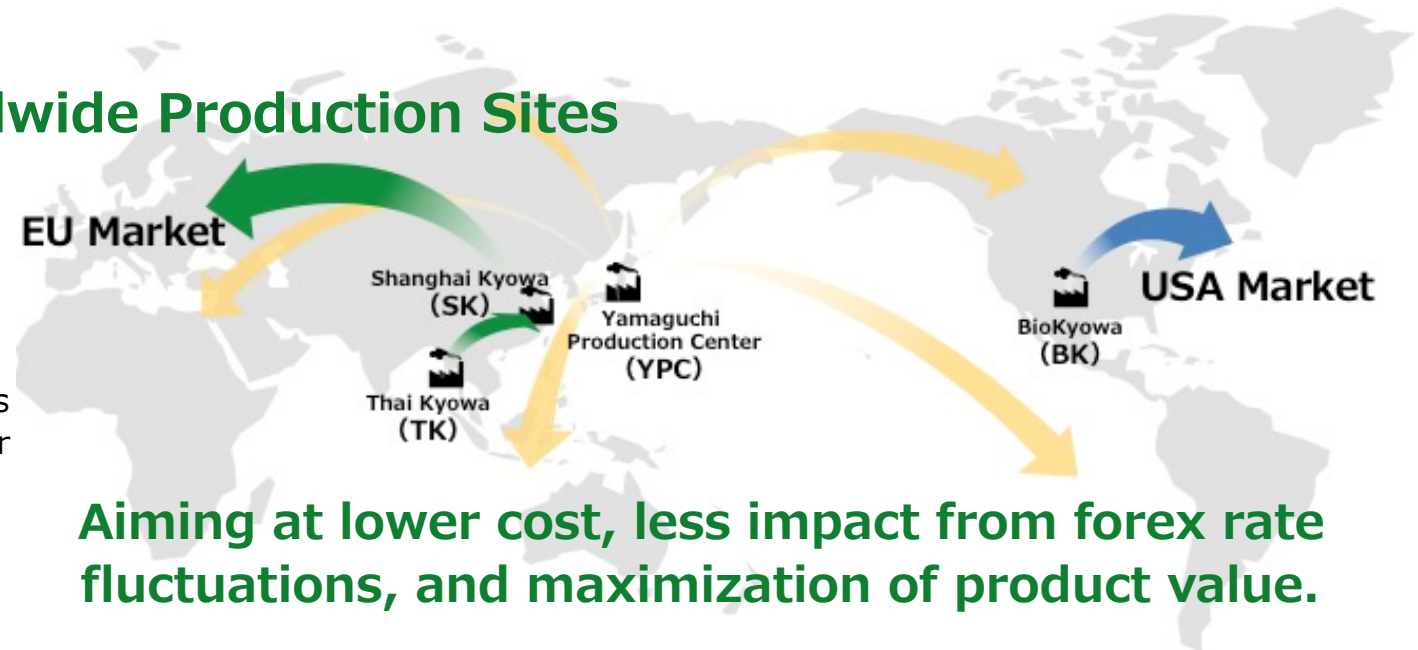
Invest in capacity expansion and supply pharmaceutical amino acids to the European market with lower production cost

- **Yamaguchi Production Center (YPC)**

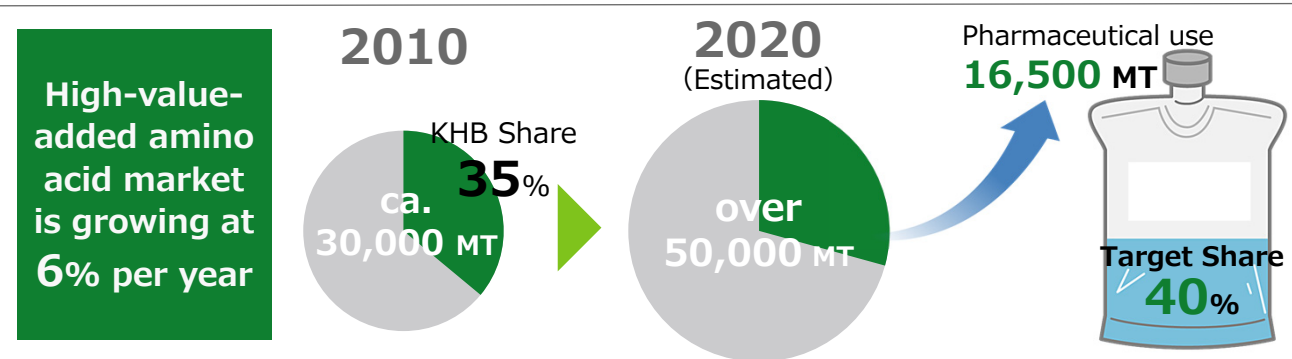
Supply high-value-added products such as peptides and nucleic acids to global market

- **BioKyowa (BK)**

Supply health food amino acids to the North American market with evidence of efficacy



**Aiming at lower cost, less impact from forex rate fluctuations, and maximization of product value.**



Improvement of  
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(Leaping Forward to US/EU Market)

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Contribution to  
Health and Well-being  
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(Creating Shared Value)

Fourth Strategic Pillar:

# Contribution to Health and Well-being of People

(Creating Shared Value)

## Contribution to Health and Well-being of People



Provide solutions responding to various medical needs, making use of our various business bases

### Provision of New Medical Value to Customers

- Creation of innovative new drugs that meet unmet medical needs
- Development of new indications and new formulations
- Providing stable supply of the products with excellent quality

### CSV Management based on Our Unique Business Structure

### Meet Social Demands for Medical Cost Containment

- Assessment of business feasibility for NESP® authorized generic drugs
- Production and supply of biosimilar products
  - FKB327 (Adalimumab BS)
  - FKB238 (Bevacizumab BS)
  - Rituximab BS

### Contribution to Kirin Group's CSV

### Contribution of Preventive and Presymptomatic Healthcare

- Expansion of health food business promoting "Evidenced Nutrition"
- Expansion and reinforcement of POCT and OTC in diagnosis business

CSV: Creating Shared Value  
POCT: Point of Care Testing  
OTC: Over the Counter



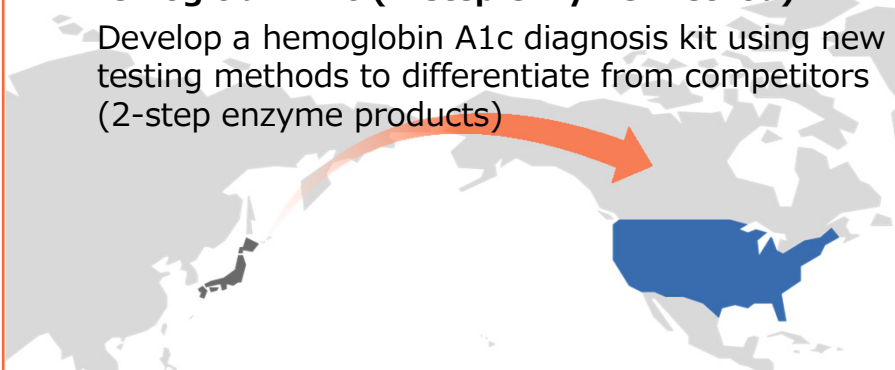


## Address two major strategic challenges as first-priority actions

### 1 Development of Overseas Markets

Accelerate global development, and achieve product launch in the US by 2020

- **FGF23 (XLH, CKD)**  
Develop own IVD kit (CKD indication) based upon the experience of LDT business with major US Laboratories.
- **Hemoglobin A1c (1-step enzyme method)**  
Develop a hemoglobin A1c diagnosis kit using new testing methods to differentiate from competitors (2-step enzyme products)



### 2 Creation of New Business Opportunities Based on the Perspectives of Healthcare Business

Create new healthcare businesses that tap into the global trend of healthcare cost containment

- **Preventive cares**  
Collaboration with other business fields
- **Presymptomatic cares**  
Expansion of POCT business and exploring new biomarkers
- **Personalized cares**  
Companion diagnosis, compliment diagnosis
- **Self-Medication**  
OTC business





FY2016-2020 Mid-term  
Business Plan  
**Financial Strategy**



## Management Targets 2020

# Aiming at outstanding growth toward 2020

### Sustainable Growth

Core Operating Profit\*

**100** billion JPY  
or more

\*Operating Profit + Amortization of goodwill  
+Share of profit/loss of entities accounted  
for using equity method

### Leaping Forward for GSP

Percentage of  
overseas sales

**50**%

### Increasing shareholder value

ROE\*

**10**%  
or higher

\* (Net Income + Amortization of goodwill )  
/ Shareholders' Equity

## Action to Achieve ROE of 10%

$$\text{ROE} = \text{ROA Management} \times \text{Financial Leverage}$$

**ROA Management**

**Financial Leverage**

$$\text{ROE} = \frac{\text{Return (R)}}{\text{Assets (A)}} \times \frac{\text{Debt(D) + Equity(E)}}{\text{Equity(E)}}$$

## Achievement of Core Operating Profit of 100 billion JPY

### **EU/USA: Expansion of overseas business**

- Launch of three global products (KW-0761, KRN23, KW-6002)
- Establishment of KHK brand

### **Biosimilar: Early payout of investment**

## More Efficient Utilization of Assets

### **Financial Efficiency: Shortening of Cash Conversion Cycle\***

- Streamlining of inventory and accounts receivable days

\* $CCC = \text{Days Inventory Outstanding(DIO)} + \text{Days Sales Outstanding(DSO)} - \text{Days Payable Outstanding(DPO)}$

### **Strategic Investment: Investment in continuous future growth**

- CAPEX for expansion of therapeutic antibodies and amino-acids
- Alliances including M&A / Investments to enrich product pipelines
- Additional investments in R&D for Immuno-Oncology etc.

## Funding Policy

**Funding Policy: Use of borrowings for investments exceeding cash on hand**

## Policies on Shareholder Returns

**Dividend Policy: Stable dividend**

Target 40% of “net income prior to amortization of goodwill”\* (From FY2016 to FY2018)

\* Net income + Amortization of goodwill

**Share Repurchases: Share repurchases will be considered, when deemed appropriate**

# Roadmap to Our Vision

Being a “Japan-based world-leading R&D type life science company”

STEP4

2016 → 2020

Leaping forward for GSP

- Improvement of Global Competitiveness
- Creating Innovation
- Continuous Improvement for Operational Excellence
- Contribution to Health and Well-being of People

Core Operating Profit

over  
**100**  
billion JPY

Overseas Sales

**50**%

ROE

over  
**10**%

STEP1

2008-2009

Integrate  
Strength

STEP2

2010-2012

Select and  
Concentrate

STEP3

2013-2015

Strive toward  
GSP

**KYOWA KIRIN**