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

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

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.

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

**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®, Dovobet®, Onglyza®, and NOURIAST®, as well as our major product NESP®.

**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)

**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

<table>
<thead>
<tr>
<th>Year</th>
<th>KHK Consolidated</th>
<th>Pharmaceuticals</th>
<th>Bio-chemicals</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>Planned</td>
<td>Actual</td>
<td></td>
</tr>
<tr>
<td>2014</td>
<td></td>
<td></td>
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<tr>
<td>2015</td>
<td></td>
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</table>

*Disclosed on January 31st, 2013

### Operating Profit

<table>
<thead>
<tr>
<th>Year</th>
<th>KHK Consolidated</th>
<th>Pharmaceuticals</th>
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<td></td>
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</tr>
<tr>
<td>2015</td>
<td></td>
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<td></td>
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</tbody>
</table>

*Disclosed on January 31st, 2013

<table>
<thead>
<tr>
<th>Year</th>
<th>Sales (¥bn)</th>
<th>Operating Profit (¥bn)</th>
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<tbody>
<tr>
<td>2013</td>
<td>338.0</td>
<td>55.0</td>
</tr>
<tr>
<td>2014</td>
<td>340.6</td>
<td>51.8</td>
</tr>
<tr>
<td>2015</td>
<td>329.0</td>
<td>41.5</td>
</tr>
</tbody>
</table>

*Planned: FY2014=333.4, FY2015=364.3

*Actual: FY2014=36.2, FY2015=43.7*
FY2016-2020
Mid-term Business Plan
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
5-year Mid-term Business Plan (FY2016-2020)

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

FY2016-2020 Mid-term Business Plan


Further Growth

Consolidated Core Operating Profit*

53.5 billion JPY

39.0 billion JPY

Ex-Japan

Japan

Ex-Japan

Japan

Leaping Forward to US/EU Market

Investment for Future Growth

Operational Excellence

Success in Immuno-oncology field

Value Maximization of Global 3 products

Japan

Ex-Japan

2015

2016 → 2020

2025

*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)
First Strategic Pillar:

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

- 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)
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

Percentage of overseas sales (KHK Group Consolidated) 50%
First Strategic Pillar: Improvement of Global Competitiveness

Continuous Creation of Innovative Drugs

Major Pipeline Drugs Targeted for Approval

- **New Drug**
  - KW-0761 ATL (US/EU)
  - KRN23 XLH
  - KHK4827 Psoriasis
  - KHK4563 Asthma
  - KW-6002 Parkinson Disease (US)

- **New Geographic Area**
  - ARQ 197 HCC

- **New Application**
  - KW-0761 CTCL (US/EU)
  - KHK7580 SHPT
  - KHK4563 COPD

**2016**

**2020**

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
First Strategic Pillar: Improvement of Global Competitiveness

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.

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First Strategic Pillar: Improvement of Global Competitiveness

Expansion into Immuno-Oncology with KW-0761

2017-
Exploring Opportunities for Backbone Therapy in IO Combination

Value Maximization

2014-
Confirming IO Potential via Strategic Partnering

- Global clinical trials against solid tumors

Collaboration

Creating New Antibody Targeting CCR4-expressing Tumor

- Application of ADCC/Potelligent technology
- Global development (launched in Japan) for hematology tumors/ATL and CTCL

Innovative Science

Verifying T-reg Targeting Activity

- Collaborative research with academia
- Investigator-initiated clinical trial

Strategic Partnership

KW-0761
Regulatory T-cell Depletion

Standard of Care Chemotherapy

- Anti-4-1BB
- Anti-CTLA-4

Novel KHK Pipeline Drugs

- Anti-PD-1
- Anti-PD-L1
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
First Strategic Pillar: Improvement of Global Competitiveness

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)
Second Strategic Pillar:

**Creating Innovation**

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

Creating Innovation

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

New Value Creation

- Enrichment of pipeline

Global Development
Translational Research

Deep Insights in Focused Therapeutic Areas

- Identification of unmet medical needs through category-based strategy
- Formulation of development strategy following therapeutic trends

Pursuit of Technology Excellence

- Evolution and expansion of drug modality
- Effective implementation of open innovation

Build up Innovation-oriented Corporate Culture

*Four Categories
- Nephrology
- Oncology
- Immunology and Allergy
- Central Nervous System
Second Strategic Pillar: Creating Innovation

Enrichment of Immuno-Oncology Pipeline

<table>
<thead>
<tr>
<th>2016</th>
<th>2018</th>
<th>2020</th>
<th>2022</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Next Candidates</strong></td>
<td>● Maximize product value by taking options, including partnering strategy</td>
<td>● Accelerate non-clinical studies</td>
<td>● Aim for early entrance into clinical studies</td>
</tr>
<tr>
<td><strong>Drug Target Search</strong></td>
<td>● Promote open innovation</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>New Drug Discovery Platforms</strong></td>
<td>● Create drug candidates through continuous innovation in drug discovery platforms</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Drug Repositioning</strong> (Products on market and in pipeline)</td>
<td>● Search for potential candidates</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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Second Strategic Pillar: Creating Innovation

Evolution and Expansion of Drug Modality

Technology-driven drug discovery leveraging technological advantages and open innovation

Development of Four Major Modalities

**Our Core Strengths Established by R&D and Production of Biopharmaceuticals**
- Genetic engineering technology
- Protein/antibody engineering technology
- Excellence in analysis and control of carbohydrates
- Skills in cell culture and control of cell differentiation
- Technology for manufacturing of biologics

**Next Generation Therapeutic Antibodies**
- Immuno activating antibody
- Cell/tissue homing antibody

**New Small Molecule Drugs**
- Integrated approach with science of biologics
- Precise drug design and synthesis based on structural analysis of target molecule

**Nucleic Acid Drugs**
- Nucleic acid function-enhancing technology
- DDS technology using lipid nanoparticles

**Regenerative Therapeutics**
- iPS-T cell technology (collaboration with Kyoto University)
- Skills in stem cell culture and differentiation control

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KYOWA KIRIN

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

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

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®, Dovobet®, Onglyza®, NOURIAST®, 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.

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

<table>
<thead>
<tr>
<th>Code Name</th>
<th>Generic Name</th>
<th>Stage</th>
<th>Countries/Area</th>
</tr>
</thead>
<tbody>
<tr>
<td>FKB327</td>
<td>Adalimumab</td>
<td>Phase III</td>
<td>USA, others</td>
</tr>
<tr>
<td>FKB238 *</td>
<td>Bevacizumab</td>
<td>Phase I</td>
<td>UK</td>
</tr>
</tbody>
</table>

* 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.
Third Strategic Pillar: Continuous Improvement for Operational Excellence

Bio-Chemicals: The Best Production and Supply Systems

**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.

<table>
<thead>
<tr>
<th>Year</th>
<th>High-value-added amino acid market is growing at 6% per year</th>
</tr>
</thead>
<tbody>
<tr>
<td>2010</td>
<td>30,000 MT (KHB Share 35%)</td>
</tr>
<tr>
<td></td>
<td>16,500 MT</td>
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</tbody>
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Fourth Strategic Pillar:

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

(Creating Shared Value)
Fourth Strategic Pillar:
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

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

CSV Management based on Our Unique Business Structure

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
Fourth Strategic Pillar: Contribution to Health and Well-being of People

Contribution to Preventive and Presymptomatic Care

Challenge for value expansion of the products and development of new materials

1. Value Expansion
   Sales of substances ⇒ supply of products and services

   Branding*: Consent to use our trademark for substances and differentiation of our products from competitor substances.
   Foods with functional claims
   Aggressive exercise our intellectual property rights
   Evidenced Nutrition: Provision to customers with evidence of efficacy
   Mail-order**: Expansion and increased awareness of products useful for the preventive and pre-symptomatic stages

2. New Challenges in R&D
   Partnering with academia and other entities to develop new businesses

   Development of cell culture media that contribute to regenerative therapy
   Development of new substances in the pharmaceutical and nutrition fields
Fourth Strategic Pillar: Contribution to Health and Well-being of People

Contribution to Preventive and Presymptomatic Cares

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, compliments diagnosis
     - Self-Medication
       OTC business
Financial Strategy
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
Financial Strategy:
Action to Achieve ROE of 10%

\[ \text{ROE} = \frac{\text{Return (R)}}{\text{Assets (A)}} \times \frac{\text{Debt(D) + Equity(E)}}{\text{Equity(E)}} \]
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=Days Inventory Outstanding(DIO)+Days Sales Outstanding(DSO) – 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.
Financial Strategy:

Action to Achieve ROE of 10%

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

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

<table>
<thead>
<tr>
<th>Core Operating Profit</th>
<th>Overseas Sales</th>
<th>ROE</th>
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<tbody>
<tr>
<td>over 100 billion JPY</td>
<td>50%</td>
<td>over 10%</td>
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KYOWA KIRIN