

# Medium-term business plan FY 2013 to 2015

To become a global specialty pharmaceutical company

**January 31, 2013** 

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 tot eh 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 associated with the pharmaceutical industry's domestic and international operating environment, intellectual property risks, the risk of adverse reactions to pharmaceutical products, legal risks, risks arising from product manufacturing deficiencies, risks due to fluctuations in the market prices of raw materials, fuel and products, as well as exchange rate and financial market volatility.

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.

## **CONTENTS**



1.	FY 2010-2012 Medium-term business plan	4
2.	FY 2013-2015 Medium-term business plan and strategy	9
3.	Plans by business segment	
	1) Pharmaceuticals business	12
	2) Bio-Chemicals business	27
4.	Shareholder returns	30



FY 2010-2012 Medium-term business plan



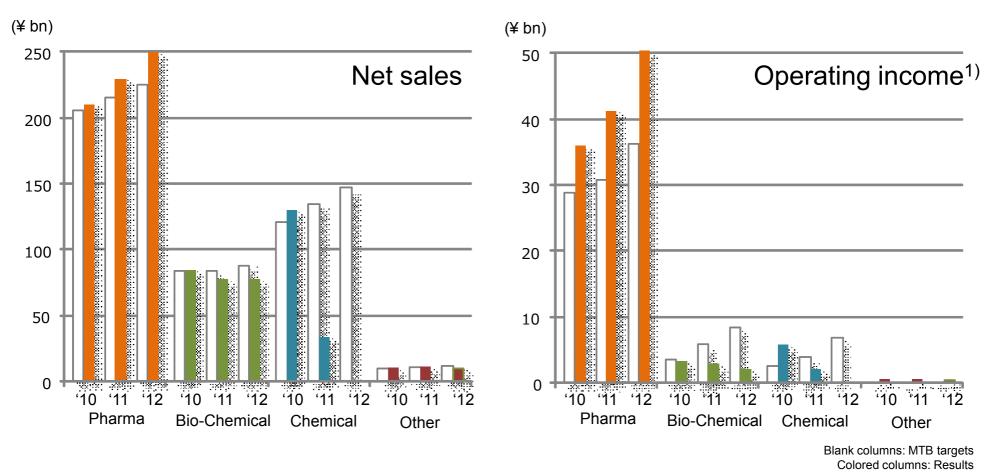
# Accelerated pipeline development through efficient use of management resources

- Selection and concentration of business portfolio
  - Divested Chemicals and other businesses
- Acquired ProStrakan, ensuring penetration of USA/Europe pharmaceutical markets
  - Entered biosimilars business through joint venture with FUJIFILM Corporation
- Strengthened profitability by reorganizing production facilities
  - Reorganized production facilities including those of the Bio-Chemicals business
  - Constructed new production facilities with automated equipments.
- Developed highest global standards for antibody technology business
  - Launched POTELIGEO, the world's first POTELLIGENT therapeutic antibody
  - Promoted out licensing and advanced therapeutic antibody through development stages

### Building a unique operating foundation worldwide

# 2010 -2012 Medium-term business plan: Results





2010 -2012 MTB<sup>2)</sup> FY2012 plan FY2012 results Difference between Achievement ratio (¥ bn) plan and results 454.0 333.0 333.1 +0.1 100% Net sales Operating 51.7 52.0 52.9 +0.9 102% income<sup>1)</sup>

<sup>1)</sup> Income after amortization of goodwill 2)2012 targets as set forth in the 2010 Medium-term business plan

# 2010 -2012 Medium-term business plan: Pipeline and product launches



# Entered 10 products into clinical trials, revealing the benefit of our integration synergies

Products newly entered into clinical trials\*: 10 compounds

KHK4563, KHK2866, LY2523355, CEP-37250/KHK2804, KHK2898, RTA 402, KHK4827, KHK6188, KHK4577, KHK7580

#### Products launched in Japan (new drugs, expanded applications, additional dosages/changes)

2010	2011	2012	
NESP subcutaneous	Romiplate	Apokyn	
ALLELOCK (infants)	ALLELOCK Powder	POTELIGEO	
ALLELOCK (OD)	NAUZELIN OD	Change to liquid volumes of NESP	
DESMOPRESSIN (Room temperature)		MINIRINMELT OD	
New drugs	Expanded applications	Additional dosages/changes	

Filed

KW-6002

KW-2246

NESP (infants)

TOPINA (infants)

Dacarbazine

Leunase

ACTIVACIN

Pasetocin

\*Phase1 as defined by FPI (First Patient In)

# Roadmap to

### **Global Specialty Pharmaceutical Company (GSP)**

**KYOWA KIRIN** 

# • Divested petro-chemical busing • Acquired ProStrakan Integrated two companies • Entered Biosimilars business Transferred Food business• Reorganized production sixts

•Transferred alcohol & livestoorelated business

- Maximize value of business in Japan
- Promote product development in US/EU
- Improve revenue & profitability of Bio-Chemicals business

### Leap to GSP

- Launch three products\* originated from KHK in USA/Europe
- \*KW-0761/KW-6002/KRN23
- Materialize global
   Biosimilars business
- Expand worldwide Bio-Chemicals business

STEP 1
Integrate strengths
2008~2009

STEP 2
Select and concentrate
2010~2012

STEP 3
Strive toward GSP

2013~2015

STEP 4
Realize our GSP model



FY 2013-2015 Medium-term business plan and strategy

### Become a global specialty pharmaceutical company

- Further strengthen competitiveness in Japan through our category-based strategy\*
- 2. Expand our business base in the USA, Europe and Asia and aim to become GSP
- 3. Strengthen the revenue base of our Bio-Chemicals business

<sup>\*</sup> Category-based strategy applies to the following four disease areas: Nephrology; Oncology; Immunology & Allergy; and Central Nervous System.



### Leveraging Kyowa Hakko Kirin Group synergies to achieve sustainable growth by responding to environmental changes

(¥ bn)	FY 2012 Results	FY2013 Planned	FY2015 Guidance 1)	Compared to FY2012
Net sales	333.1	338.0	358.0	+24.9
Operating income <sup>2)</sup>	52.9	55.0	60.0	+7.1
(operating income to sales ratio)	(15.9%)	(16.3%)	(16.8%)	
Ordinary income <sup>2)</sup>	49.0	49.0	53.0	+4.0
Net income <sup>2)</sup>	24.1	30.0	30.0	+5.9
EPS 3) (¥)	61.0	71.7	71.7	+10.7

<sup>1)</sup> To be updated annually

<sup>2)</sup> Income after amortization of goodwill 3) EPS calculated using net income before amortization of goodwill



# To become a global specialty pharmaceutical company

FY 2013-2015 Medium-term business plan

= Pharmaceuticals business =

### Pharmaceuticals business: Consolidated targets



# Increase revenues by further strengthening competitiveness in Japan through category-based strategies and contributions from ProStrakan

(¥ bn)	FY 2012 Results	FY2013 Planned		FY2015 <sup>1)</sup> Guidance	Compared to FY2012
Net sales	249.8	251.0	N	260.0	+10.2
Operating income <sup>2)</sup> (operating income to sales ratio)	<b>50.3</b> (20.2%)	<b>49.0</b> (19.5%)		<b>52.0</b> (20%)	+1.7
R&D expense (Sales to R&D ratio)	<b>41.3</b> (16.6%)	<b>40.7</b> (16.2%)	- <b>y</b> -	<b>40.0</b> (15.4%)	(1.3)

<sup>1)</sup> To be updated annually

#### Core strategy

- Further strengthen competitiveness in Japan through our category-based strategy
- Enhance business foundations in USA, Europe and Asia aiming to become a global specialty pharmaceutical company
- Create a corporate culture and organization appropriate for a global specialty pharmaceutical company

<sup>2)</sup> Operating income after amortization of goodwill



# Implement PPM\* in each category from R&D to S&M Realize sustainable growth while enhancing productivity

#### Nephrology (Including diabetes/ hypertension)

#### **Enhance presence in CKD**

Maintain high NESP market share
 Expand REGPARA market
 Early launch/market
 penetration of Saxagliptin

### **Immunology & Allergy**

# Enhance presence in dermatology / otorhinology

- · Accelerate development of KHK4563, KHK4827
- . Address ALLELOCK/Patanol competitor products

# Global Specialty Pharma

Oncology

# Enhance position in hematology Enhance presence in cancer support therapies

- ·Establish POTELIGEO brand
- ·Early launch of KRN125, KW-2246
- ·Accelerate ARQ 197 development

# Central Nervous System

# Maximize synergy with existing products

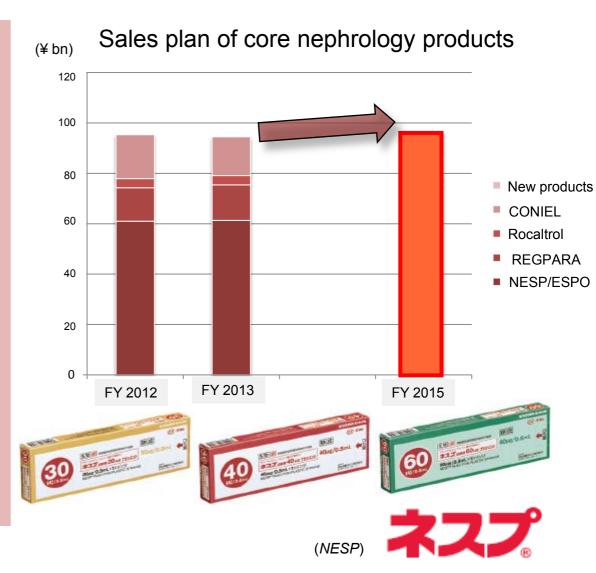
 Early launch/market penetration of Apokyn
 Early launch of KW-6002

\*PPM: Product Portfolio Management



### Strive to be a thought leader in chronic kidney disease (CKD) therapy

- Maintain leading share in renal anemia therapy, primarily through NESP
  - Enhance value of NESP through unified injection volume for predialysis chronic kidney diseases
- Utilize largest renal specialist MR structure
  - Promote sales through 400 MRs
- Create product line-up to broadly cover CKD market
  - Respond to therapeutic needs
- Introduce antidiabetic agent
  - DPP4 inhibitor saxagliptin





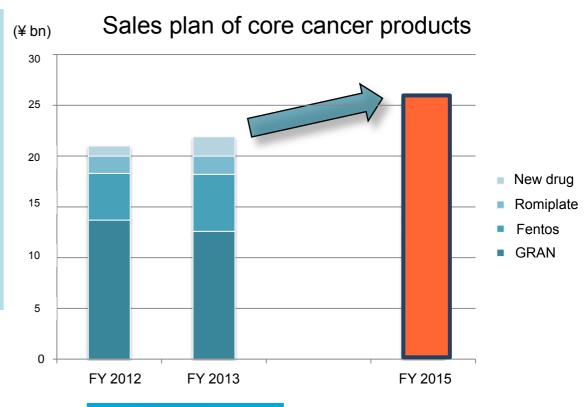
#### Enhance our position in oncology area primarily through POTELIGEO

- Replace GRAN with new product
- Continue activities to promote appropriate usage of proprietary therapeutic antibody POTELIGEO
- Continue to launch new investigational drugs
  - •KW-2246
  - •KRN125



#### **Expand indications of KW-0761**

- ·ATL 1st Line
- ·CTCL
- ·PTCL







# Continue to provide value in allergy drug market where competition is being intensified

- Anti-allergy drug
  - Continue to improve product value, primarily of ALLELOCK OD\*tablet/granules
- Anti-allergy eye-drops
  - Further strengthen its No.1 position in the category

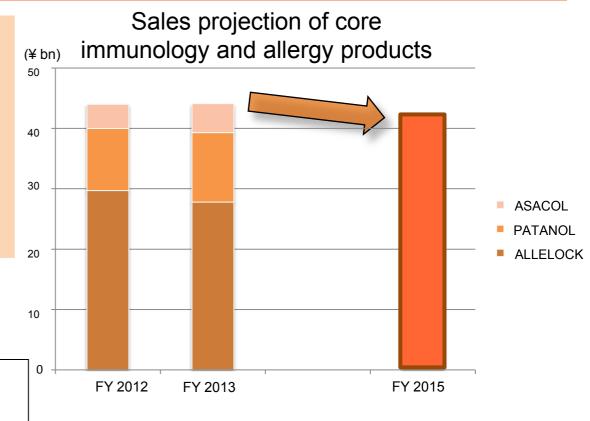
\*OD: Oral Disintegrant



# Accelerate development of new therapeutic antibodies

- ·KHK4563
- ·KHK4827

**Expand indications of Z-206 (ASACOL)** 









# Focus on expanding products for treatment of Parkinson's disease and penetrating markets with new drugs

(¥bn)

20

- Apokyn
  - Accelerate market penetration
- Launch proprietary investigational drug
  - KW-6002

15
10
Permax
Apokyn
DEPAKENE

FY 2012
FY 2013
FY 2015

Sales plan of core CNS products



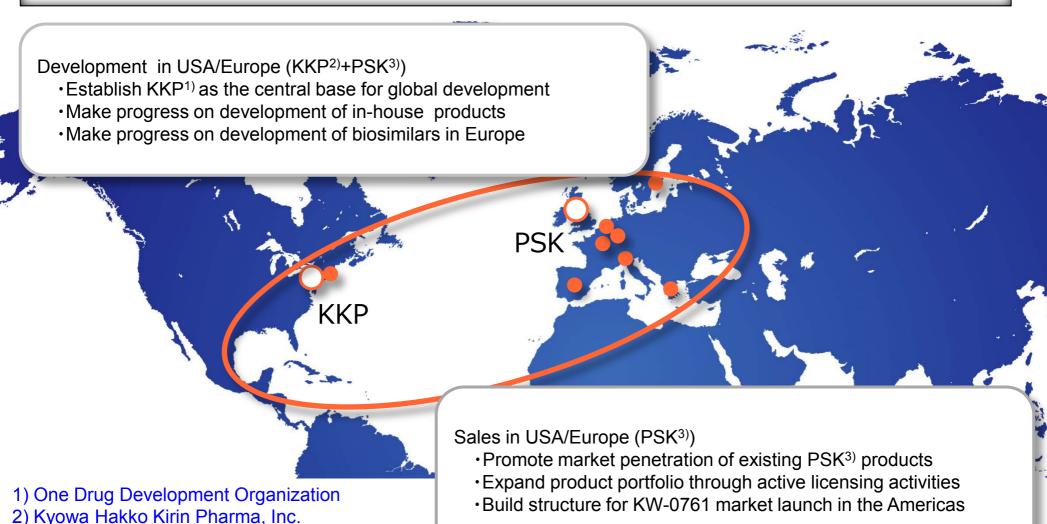
Develop new low molecular drug
•KHK6188



# Core Strategy 2. Overseas strategy Europe/USA: Development/sales structure



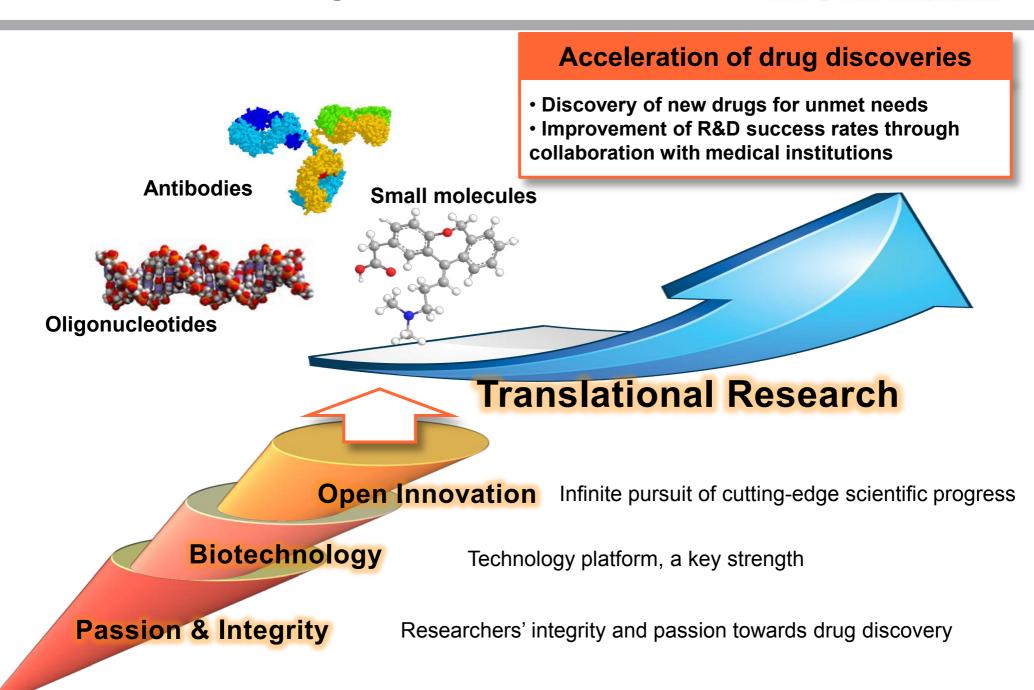
Development in USA/Europe: Promotion of ODDO<sup>1)</sup> centering on KKP<sup>2)</sup>
Develop robust sales structure for smooth transition to a global specialty
pharmaceutical company



3) ProStrakan, Inc.

## Acceleration of drug discoveries





### Global network-based drug discovery research



# **Japan**

Generation of candidate products using platform technologies including antibody

# San Diego

- Concept verification using clinical samples
- Access to cutting-edge scientific research progress
  - Promoting open innovation

Focus on translational research

Academia-industry alliances

# **Singapore**

Bench to bedside by using bioimaging technology

HAI

UC San Diego

# Late stage pipeline products



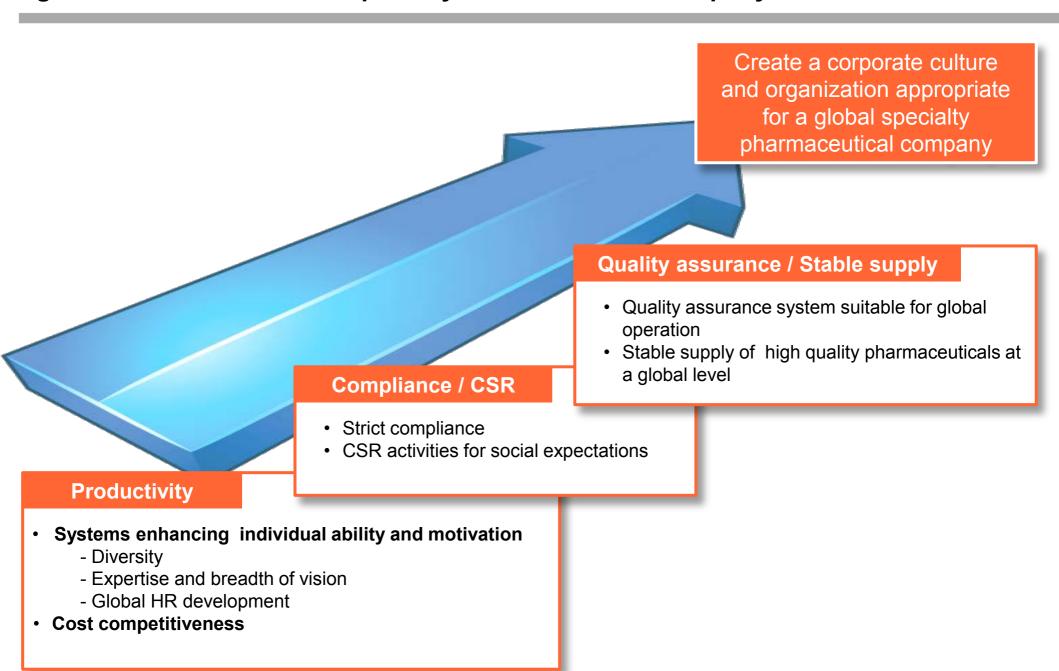
#### Core pipeline currently filed or scheduled for application

Name	Target	Region	Phase	Application schedule
KW-6002	Parkinson's disease	Japan	Filed	Mar. 2012
OPC-262 (Saxagliptin)	Diabetes	Japan	Filed*	Apr. 2012
KW-2246	Cancer pain	Japan	Filed	Dec. 2012
KRN125	Febrile neutropenia for chemotherapy patients	Japan	Phase 3	2013
KW-0761	ATL, 1st line combination therapy	Japan	Phase 2	2013
	PTCL & CTCL	Japan	Phase 2	2013
	ATL	USA/Europe	Phase 2	2015
	CTCL	USA	Phase 3	2016
KW-3357	Disseminated intravascular coagulation Congenital antithrombin deficiency	Japan	Phase 3	2014

\*: Filed by Otsuka Pharmaceutical; Launch scheduled for current period

# Core strategy 3. Improvement of corporate culture and organization toward Global Specialty Pharmaceutical company





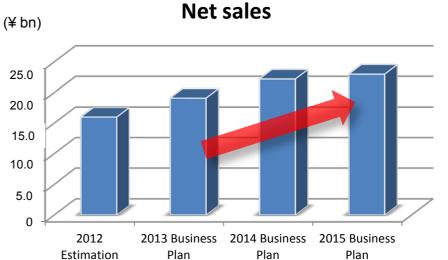
\*: Operating income after amortization of goodwill

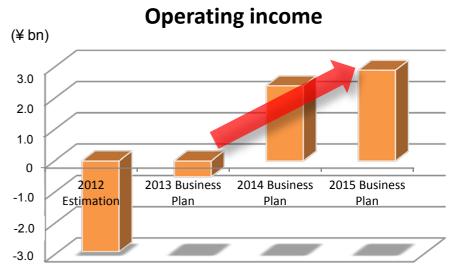
# Steady growth: Road to profitability\*

### ProStrakan

- Europe :
  - Sancuso: Launch
  - Abstral: Sales increase & profit improvement
- •USA:
  - Fareston (breast cancer product):Sales increase
  - Continuation of product licensing in oncology category







### Advancing to next stage using venture network

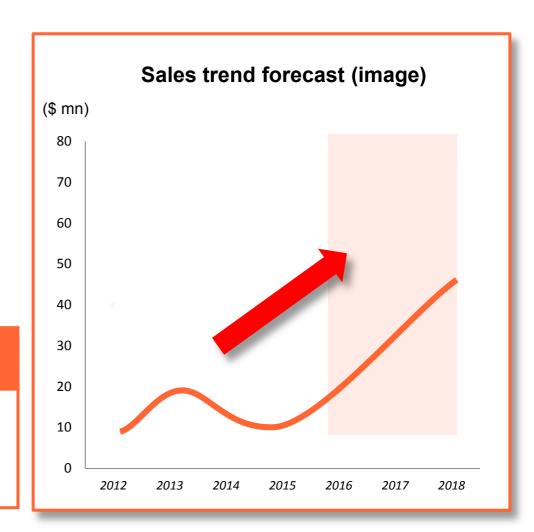
# **BioWa**

- Maximizing value of POTELLIGENT® and other technologies
  - Promoting licensing
  - Out licensing developed product



# Acquisition of promising seeds for drug discovery

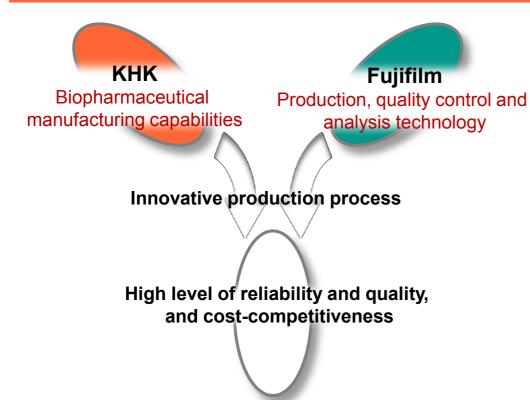
- Promotion of open innovation
- Accurate evaluation of seeds potential through collaboration with research base



### **FUJIFILM KYOWA KIRIN BIOLOGICS**



### Initiate adalimumab biosimilar clinical trials in Europe in 2013 H1



The concept of Interchangeable biosimilars is a valuable opportunity to demonstrate our strengths in biopharmaceutical manufacturing

- Development plan:
  - Development of four biosimilars
  - Clinical trials of one biosimilar per year from 2013
- Initial targets:
  - Adalimumab (clinical trials to begin in 2013)
  - Bevacizumab (clinical trials to begin in 2014)





# A strong presence in the pharmaceutical, medical and healthcare fields

FY 2013-2015 Medium-term business plan

= Bio-Chemicals business =



# Strengthen profitability through on-going business restructuring Reconstruct business foundation minimizing impact of exchange-rate fluctuations

(¥ 100 mn)	FY2012 Results	FY2013 Plan		FY2015 <sup>1)</sup> Guidance	Compared to FY2012
Sales	769	810	٨	910	+141
Operating income <sup>2)</sup> (operating profit ratio)	<b>21</b> (2.8%)	<b>58</b> ( 7.2%)		<b>80</b> (8.8%)	+59

<sup>1)</sup> To be updated annually 2) Operating income after amortization of goodwill

### Factors increasing profitability

- Cost reductions
- Volume increase of amino acids
- Production of tranexamic acid and APIs\*
- Expansion of healthcare business in Japan

\*\*: Active Pharmaceutical Ingredients

### **Bio-Chemicals business: Strategy to improve revenue**



# Meet strong demand for high Value-added amino acids

- Increase amino acids production through investment in existing overseas plants
- Maintain fair pricing and build/maintain a relationship of trust with customers through high quality products and services
- Significantly improve profitability utilizing manufacturing capacity of APIs at Daiichi Fine Chemical
- Reduce costs through introduction of new technologies

Reorganize business facilities and streamline production

#### **Expand healthcare business**

- Further improve public awareness of ornithine through active advertising
- Expand sales of original materials such as citrulline

 Develop new materials in pharmaceutical, medical and healthcare areas

Promote development of new products and materials



# FY 2013-2015 Medium-term business plan

= Shareholder returns =

### **Shareholder returns**



#### Targeting a consolidated dividend ratio of 40% before goodwill amortization

#### **Basic policy**

Dividend

Stable dividend policy

Consolidated dividend payout ratio

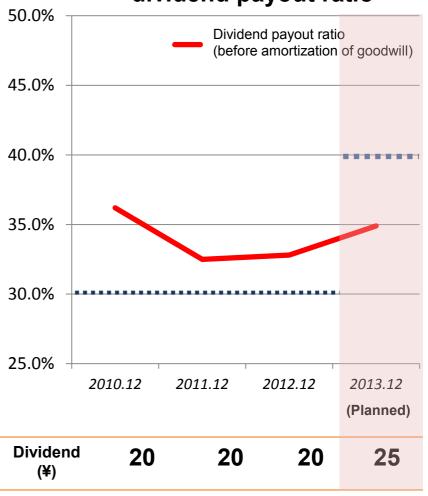
2010 MTB: targeted 30% or more

2013 MTB: Targeting 40% or more

Share repurchase

Fast and flexible response

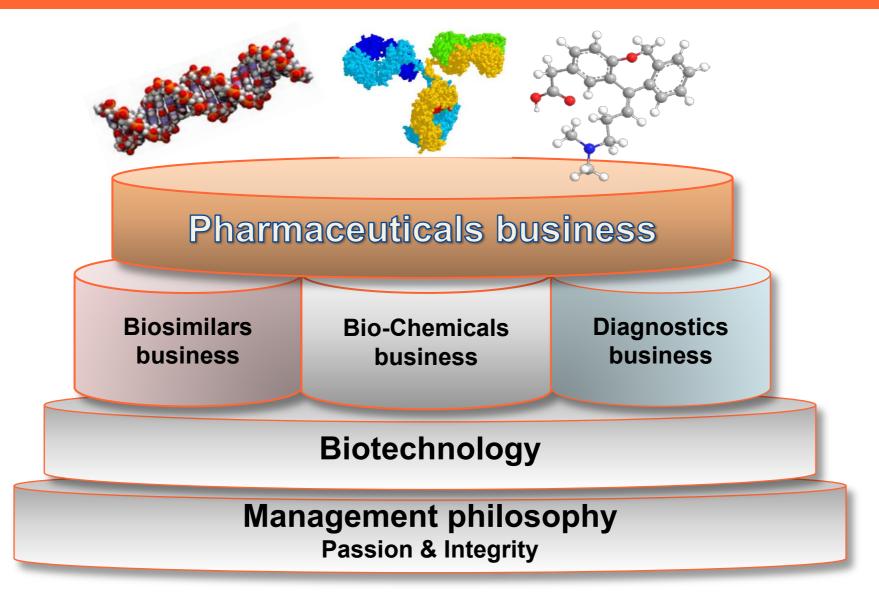
# Consolidated dividend and dividend payout ratio



## KHK Group's unique business structure



### Leap to a Global Specialty Pharmaceutical company





# **KYOWA KIRIN**

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### **APPENDIX**

### 2013 Medium-term Business Plan Management targets by business segment



(¥ bn)	FY2012 Results	FY2013 Planned		FY2015 Guidance <sup>1)</sup>	Compared to FY2012
Net sales	sales 333.1 338.0			358.0	+24.9
Pharmaceutical	249.8	251.0		260.0	+10.2
Bio-Chemical	76.9	81.0		91.0	+14.1
Others	6.3	6.0		7.0	+0.7
Operating income <sup>2)</sup>	erating income <sup>2)</sup> 52.9			60.0	+7.1
Pharmaceutical	50.3	49.0		52.0	+1.7
Bio-Chemical	2.1	5.8		8.0	+5.9
Others	0.3	0.2		1.0	(2.0)
1) To	be updated annually 2) (	Operating income after an	nortization of	goodwill	
R&D expense	<b>44.8</b> 13.4%	<b>44.0</b> 13.0%		<b>43.0</b> 12.0%	(1.5)

40.7

16.2%

3.3

4.1%

Net sales to R&D expense ratio figures have been italicized

41.3

16.6%

3.4

4.5%

40.0

15.4%

3.0

3.3%

(1.3)

(2.0)

Pharmaceutical

**Bio-Chemical** 

# To become a global specialty pharmaceutical company



### Aims for 2015



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.

### 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 which brings out individual abilities and organizational strengths

Dusiness vision

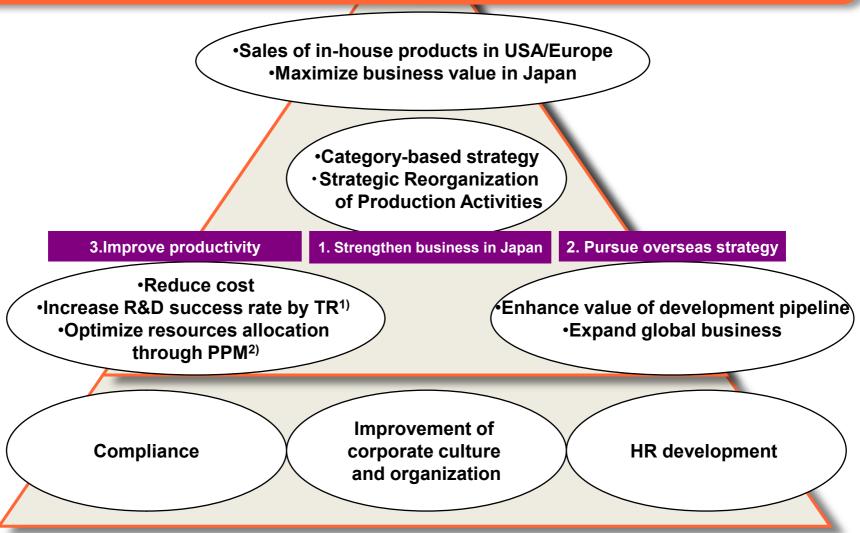
Aims for 2015

Slide no. A-3

## Strategy map



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.



1) TR: Translation research 2) PPM: Product portfolio management

# Core strategy 1. Strengthen business in Japan: Background of category-based strategy



#### To win in an increasingly challenging external environment

Increase in new drug creation hurdles

Further restriction of medical expenses

#### KYOWA KIRIN

To become a global specialty pharmaceutical company

Strengthen competitiveness in focused categories

Complexity of information and high level of expertise demanded by medical front

Change from competition on scale to era requiring intelligence, network and internal and external collaboration

Emergence of new medical technologies

Change from competition by individual item to competition by comprehensive strengths

# Core strategy 2. Overseas strategy Asia: Development/Sales structure

#### **KYOWA KIRIN**

- Promote development centering on KHK with utilization of local subsidiaries, etc.
- Introduce new products in each country under sales and marketing scheme adapted to respective healthcare environment

#### **Kyowa Hakko Kirin China Pharmaceutical**

- Accelerate development (NESP and others under multinational developments)
- Improve sales by strengthening sales-force capabilities
- Initiate in vitro diagnostics business

#### **Kyowa Hakko Kirin (Hong Kong)**

- Strengthen sales capabilities for targeted clinical departments and improve sales of existing products
- Launch new products and promote market penetration (Sancuso, Nplate)

#### Kyowa Hakko Kirin Korea

- Build strong presence in targeted treatment area for cancer, nephrology and hematology
- Accelerate multinational studies by strengthening development capability

#### **Kyowa Hakko Kirin (Taiwan)**

- Launch new products and promote market penetration (Sancuso, Nplate)
- Reorganize sales structure corresponding to upcoming biosimilar entry

#### **Kyowa Hakko Kirin (Thailand)**

- Launch new products and promote market penetration (Regpara)
- Enhance presence in Nephrology

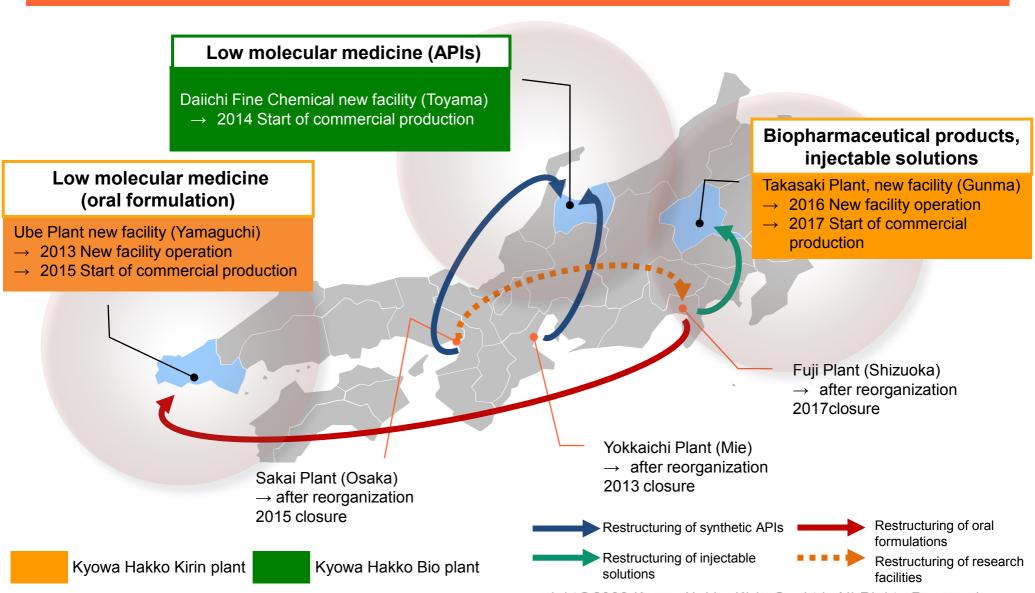
#### Kyowa Hakko Kirin (Singapore)

- Promote sales in Malaysian market
- Launch new products and penetrate market (Regpara, Sancuso, Nplate)

# Progress of reorganization plan of production and research facilities



Reorganization and consolidation of each function is proceeding as planned



### **Development progress with outlicensed compounds**



Name	Partner	Phase		Phase		Remarks
Nume	rannor	I	II	III	Application	Remarks
Tivozanib (KRN951)	AVEO Astellas				FDA	Cancer (VEGF receptor inhibitor)
KW-2871 (Low-fucose antibody)	Life Science				Cancer (Anti-GD3 antibody)	
MEDI-563 (KHK4563:POTELLIGENT®)	Medlmmune				Asthma (Anti-IL-5R antibody)	
KRN5500	DARA				Peripheral neuropathy	
LY2523355	Eli Lilly				Cancer (Mitotic kinesin Eg5 inhibitor)	
AMG 761 (KW-0761:POTELLIGENT®)	Amgen					Asthma (Anti-CCR4 antibody)
RGI2001	REGIMMUNE	Phas	se1/2	Immunosuppressive		Immunosuppressive
SAR252067	Sanofi			Inflammatory bowel diseas (anti-LIGHT antibody)		

(as of January 24, 2013)

# **Kyowa Medex**



# Contribute to the advancement of personalized medicine through companion diagnostics

#### **Group synergy**

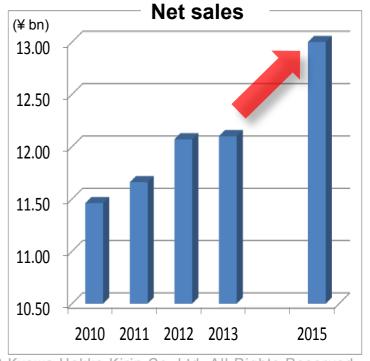
Development of companion diagnostics can be synchronized with new drug development at Kyowa Hakko Kirin from early stage





### Basic strategy

- Challenge as a pioneer in companion diagnostics
- Pursue business synergy through integrated strategy for diagnostic reagents and instruments
- Strengthen market access capabilities through its subsidiary in China
- Enhance cost competitiveness and increase production capacity through facility investment



### **Bio-Chemicals business: Aims for 2015**



Kyowa Hakko Kirin Group management philosophy

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

**Business vision** 

We will utilize innovative fermentation and synthesis technologies and continue to supply superior quality, high value-added functional materials that satisfy needs in the pharmaceutical, medical and healthcare fields to become the world's premier biochemical manufacturer.

#### Aims for 2015

#### Product value enhancement

Increase product value by further strengthening collaborations with Group companies to stably supply safe and secure products under solid quality assurance system and strong branding

#### **Profitability improvement**

Achieve high profitability structure by steadily implementing restructuring plan for higher productivity and low cost operation

#### **Growth strategy**

Achieve sustainable growth in the pharmaceutical, medical and healthcare fields through creation of new materials and new business development

#### Compliance

Realize steady business operations from CSR points of view, environmental conservation/protection and compliance, by working together with other group companies

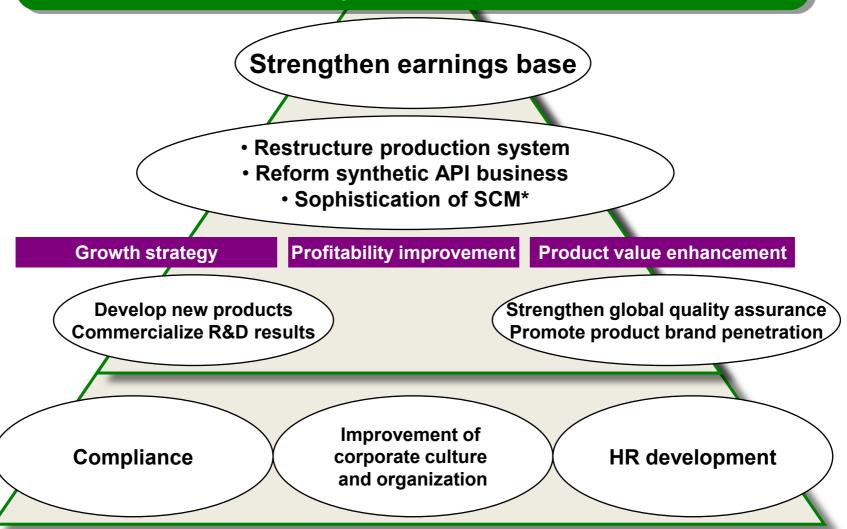
#### **HR / Organization**

Achieve vigorous corporate culture with high-productivity in which individual abilities and organizational strengths can be exercised as global enterprise

# **Bio-Chemicals business: Strategy map**



We will utilize innovative fermentation and synthesis technologies and continue to supply superior quality, high value-added functional materials that satisfy needs in the pharmaceutical, medical and healthcare fields to become the world's premier biochemical manufacturer.

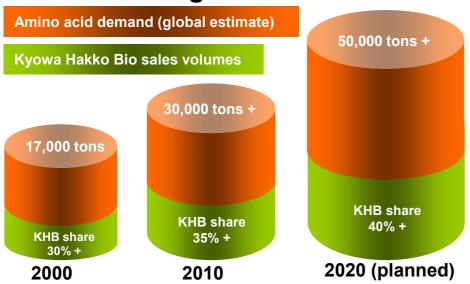


<sup>\*</sup> SCM: Supply chain management

#### **Expansion and new construction of production facilities**



#### Trends in the high value-added amino acid market

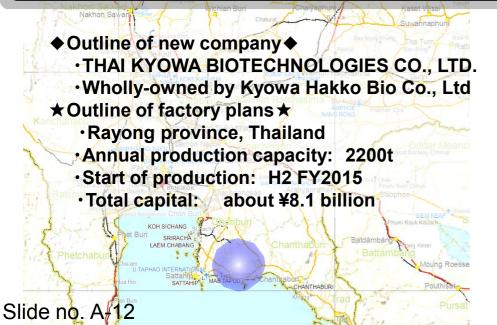


Targeting value-added amino acid market for pharmaceuticals, medical treatment and healthcare:

- √High growth globally
- ✓ Rapid market expansion, particularly in Asia, in recent years
- √ Forecasting similar growth in overseas markets

Bolstering production capacity to secure market share and capture opportunities in a growing market

#### Established subsidiary in Thailand—new production facility for amino acids



New facilities in resource-rich South East Asia, close to markets High-quality amino acids by advanced production technology and quality management

Customer assurance and satisfaction through steady supply of high-quality products

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