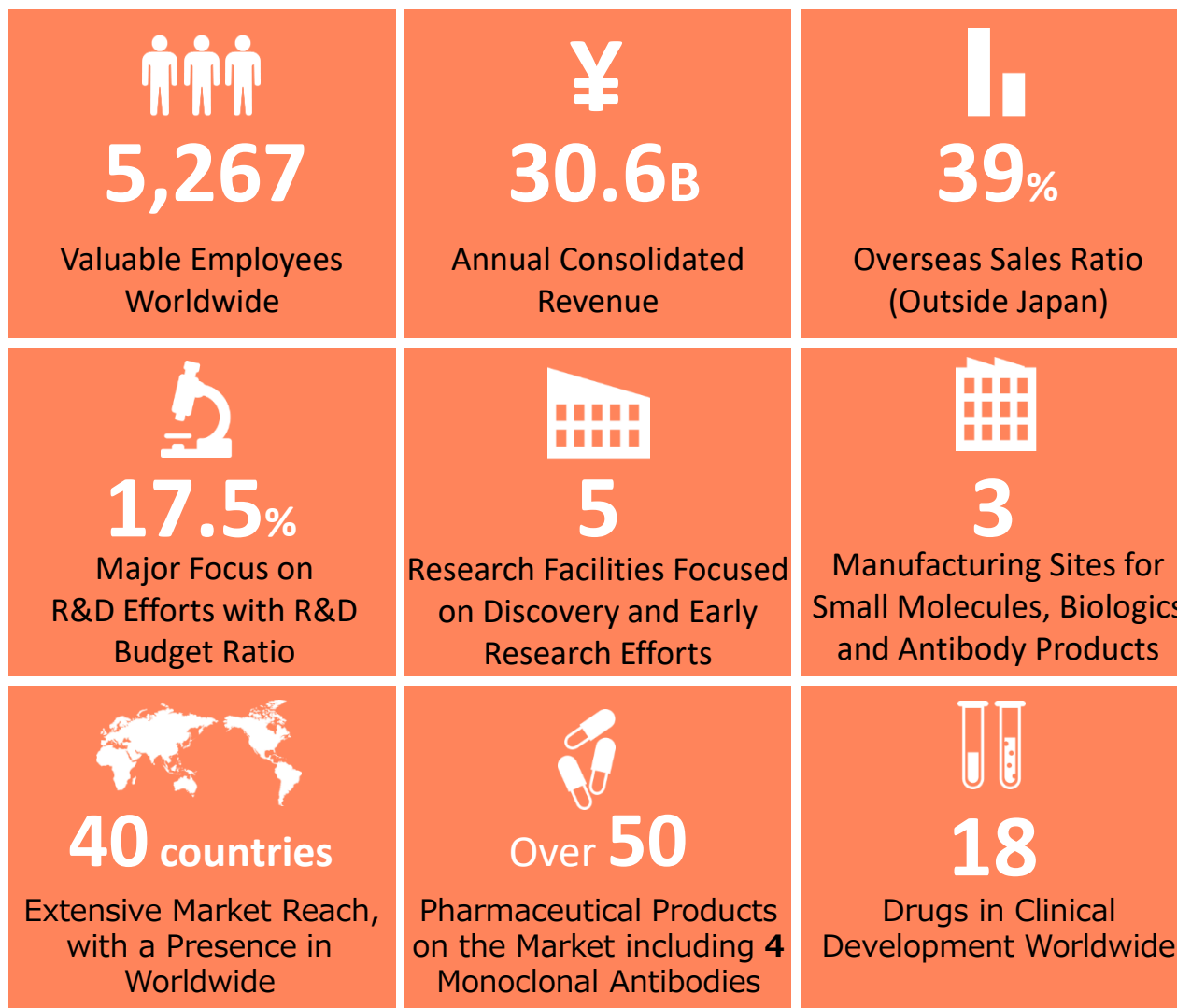


# Leaping Forward for a Global Specialty Pharmaceutical Company (GSP)

Kyowa Kirin Co., Ltd.



# In Numbers



# History of Kyowa Kirin



Making the leap to a Global Specialty Pharmaceutical Company (GSP)

○ Kirin    ○ Kyowa Hakko    ○ Kyowa Hakko Kirin

**1885**

Japan Brewery Company founded, forerunner company of Kirin Brewery Co., Ltd.



**1949**

Kyowa Hakko Kogyo Co., Ltd. established



**1951**

First volume production of streptomycin in Japan using technology from US drug firm Merck & Co.



**2003**

BioWa's mission is the out-licensing of Kyowa Kirin's Therapeutic Antibody Technologies, POTELLIGENT® and COMPLEGENT®



**BioWa**

**1988**

Supported the establishment of the La Jolla Institute for Immunology in the US



**2008**

Kyowa Hakko Kirin Co., Ltd. starts operations



**2012**

Established FUJIFILM KYOWA KIRIN BIOLOGICS Co., Ltd., a joint-venture with FUJIFILM Corporation, to develop, make and sell biosimilars

**KYOWA KIRIN FUJIFILM**

Joint venture with shared strengths

Fujifilm Kyowa Kirin Biologics

**2011**

Acquired UK company ProStrakan Group plc., making it a subsidiary (now Kyowa Kirin International plc.)

**ProStrakan**

**2014**

Acquired UK company Archimedes Pharma Ltd., making it a subsidiary



**2016-2020**

**Midterm Business Plan**

Laid the foundations for the leap to a GSP



➤ Crysvita is a treatment for patients with XLH and sells in US/EU/JPN



➤ Poteligeo is a treatment for patients with MF and SS, and sells in US/JPN.



➤ Nourianz is a treatment for patients with Parkinson's disease and sells in US/JPN

# Corporate Profile of Kyowa Kirin

## Key Marketed Products

### Nephrology

**NESP<sup>®</sup>**

Erythropoiesis Stimulating Agent  
Japan/Asia

**REGPARA<sup>®</sup>**

Calcium receptor agonist  
Japan/Asia

**オルケディア<sup>®</sup>**

Calcium receptor agonist  
Japan

### Oncology

**POTELIGEO<sup>®</sup>**  
(mogamulizumab-kpkc) Injection

Anti-CCR4 mAb  
Japan/US (approved in EU)

**Abstral<sup>®</sup>**  
SUBLINGUAL FENTANYL CITRATE TABLET

Sublingual fentanyl  
Japan/EU

**ジーラスタ<sup>®</sup>**  
**GRAN<sup>™</sup>**

Long-lasting G-CSF/G-CSF  
Japan/Asia

**リツキシマブ<sup>®</sup>BS**

Rituximab biosimilar  
Japan

### Immunology/ Allergy

**Allelock<sup>®</sup>**

Anti-allergic agent  
Japan/Asia

**パタノール<sup>®</sup>**

Ophthalmic Anti-allergic agent  
Japan

**LUMICEF<sup>®</sup>**

Anti-IL17R mAb  
Japan/Asia

**ドボベット<sup>®</sup>**

Vitamin D3/Corticosteroid  
Japan

### Central Nervous System

**NOURIANZ<sup>™</sup>**

Adenosine A<sub>2A</sub>R antagonist  
Japan/US

**デパケン<sup>®</sup>**

Antiepileptic agent  
Japan

**トピナ<sup>®</sup>**

Antiepileptic agent  
Japan

### Others

**CRYSVITA<sup>®</sup>**  
burosumab

Anti-FGF23 mAb  
Japan/US/EU

**Romiplate<sup>®</sup>**  
Romiplostim

Thrombopoietin R agonist  
Japan/Asia

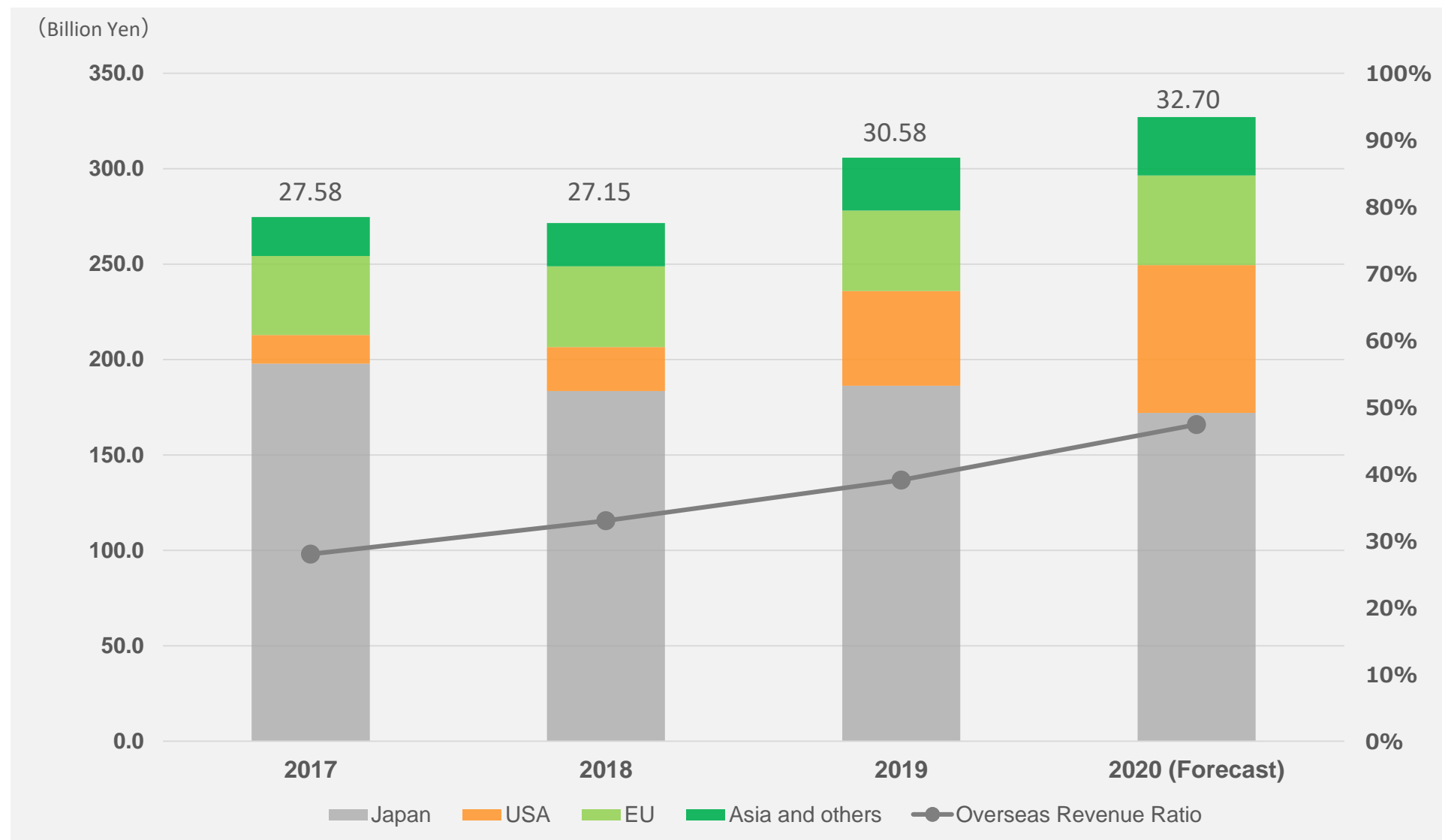
**Coniel<sup>®</sup>**

Calcium channel blocker  
Japan/Asia

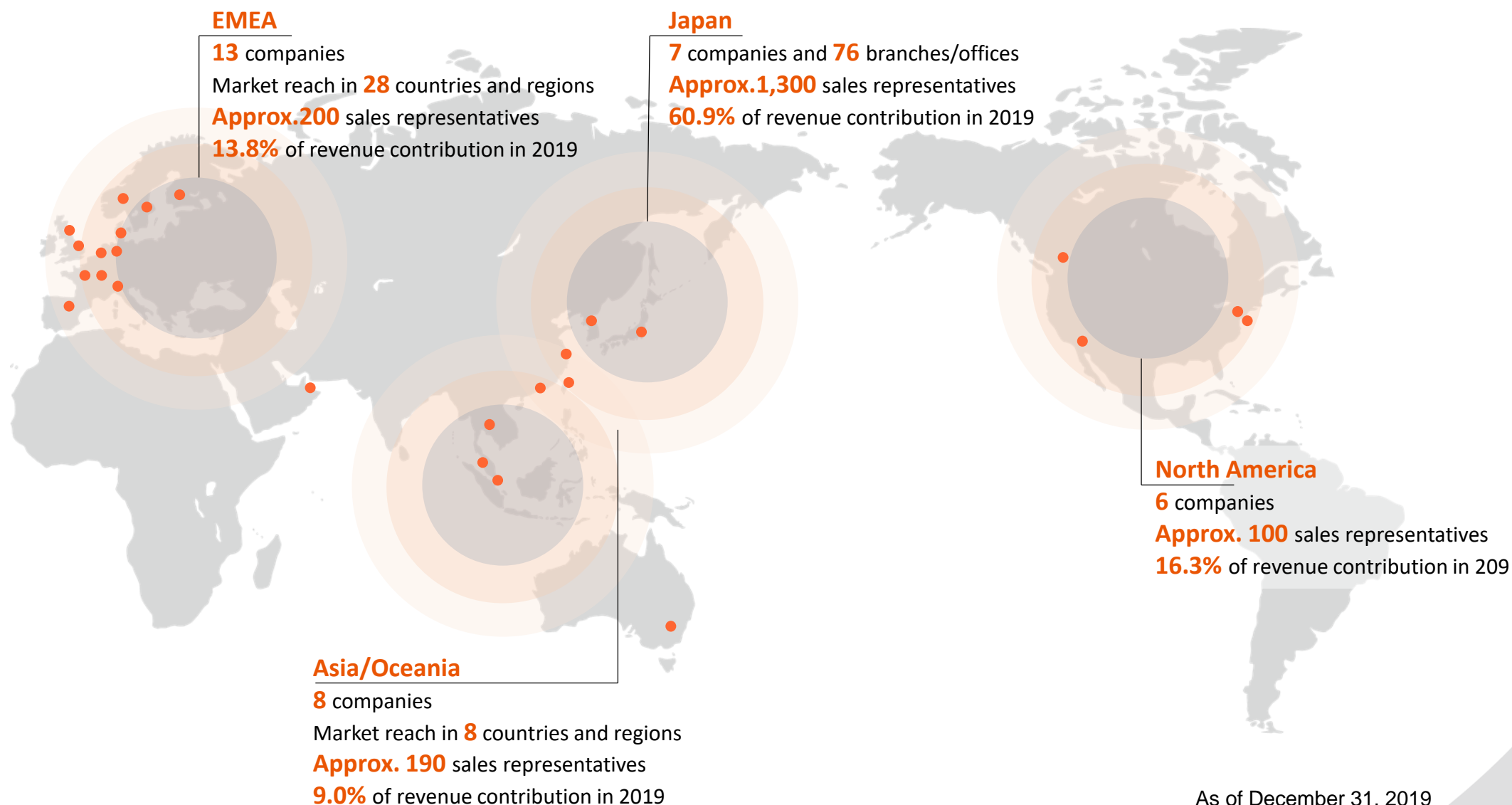
**オングリザ<sup>®</sup>**

DPP-4 inhibitor  
Japan

# Revenue by Region

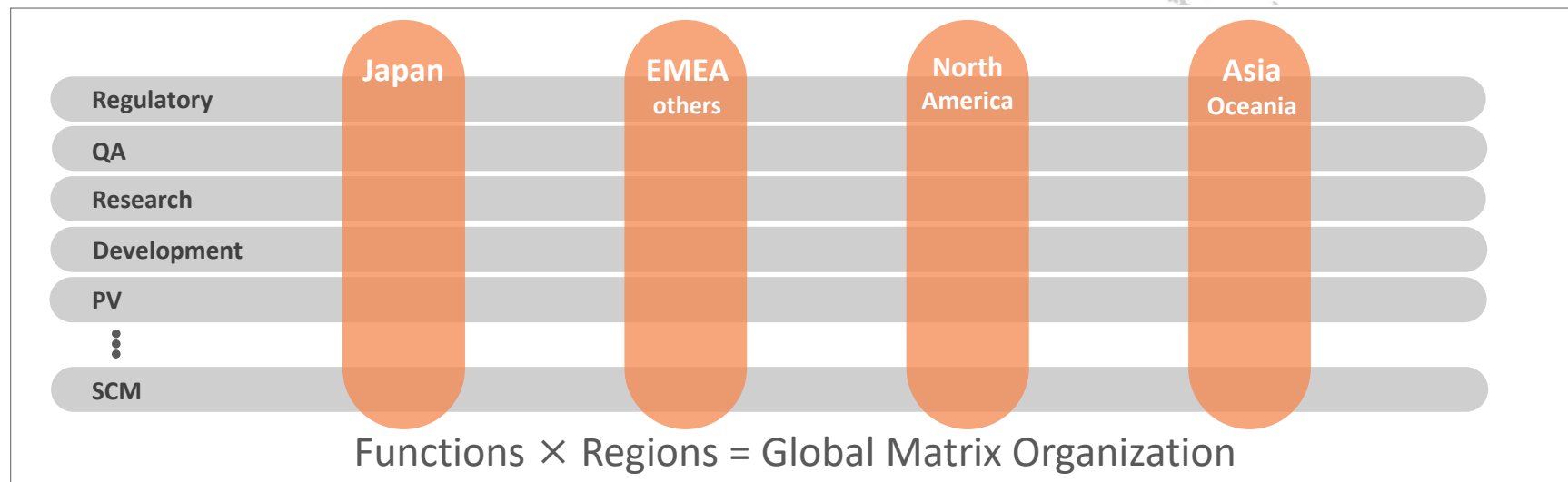


# Global Reach & Commercial Capability



# “One Kyowa Kirin” Organization

Global Management System from April 2019





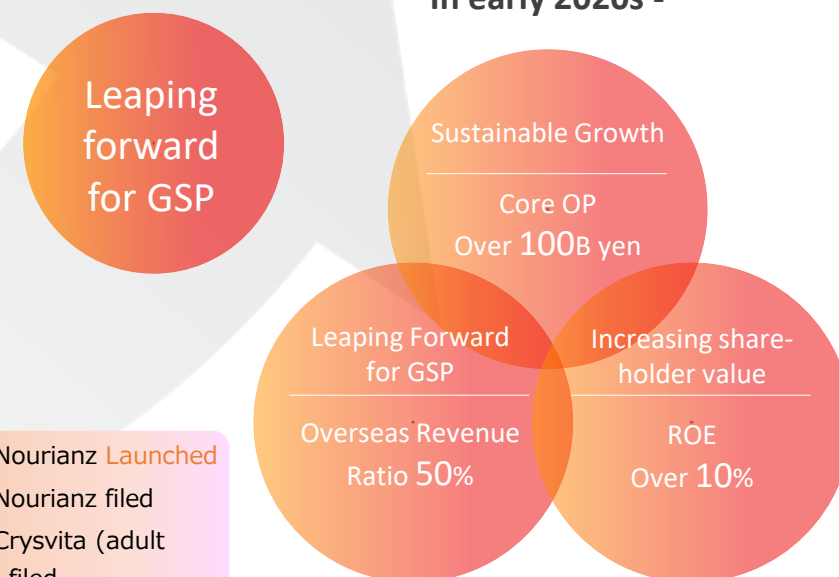
# 2016-2020 Mid-term Business Plan

## Achievements of the major targets in the Mid-term Business Plan (-2019)

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

<ul style="list-style-type: none"> <li>▶ US: Crysvita Designated Breakthrough Therapy</li> <li>▶ JPN: Lumicef <b>Launched</b></li> </ul>	<ul style="list-style-type: none"> <li>▶ EU/US: Crysvita filed</li> <li>▶ EU/US: Poteligeo filed</li> <li>▶ US: Poteligeo Designated Breakthrough Therapy</li> <li>▶ JPN: Orkedia filed</li> </ul>	<ul style="list-style-type: none"> <li>▶ EU/US: Crysvita <b>Launched</b></li> <li>▶ US: Poteligeo <b>Launched</b></li> <li>▶ EU: Poteligeo <b>Approved</b></li> <li>▶ EU: Hulio <b>Launched</b></li> <li>▶ JPN: RTA 402 Designated "Sakigake" and Ph3 Initiated</li> <li>▶ JPN: Orkedia <b>Launched</b></li> </ul>	<ul style="list-style-type: none"> <li>▶ US: Nourianz <b>Launched</b></li> <li>▶ EU: Nourianz filed</li> <li>▶ EU: Crysvita (adult XLH) filed</li> <li>▶ JPN: Crysvita <b>Launched</b></li> </ul>
2016	2017	2018	2019

## Mid-term Business Plan Forecasts - Aiming to achieve targets In early 2020s -

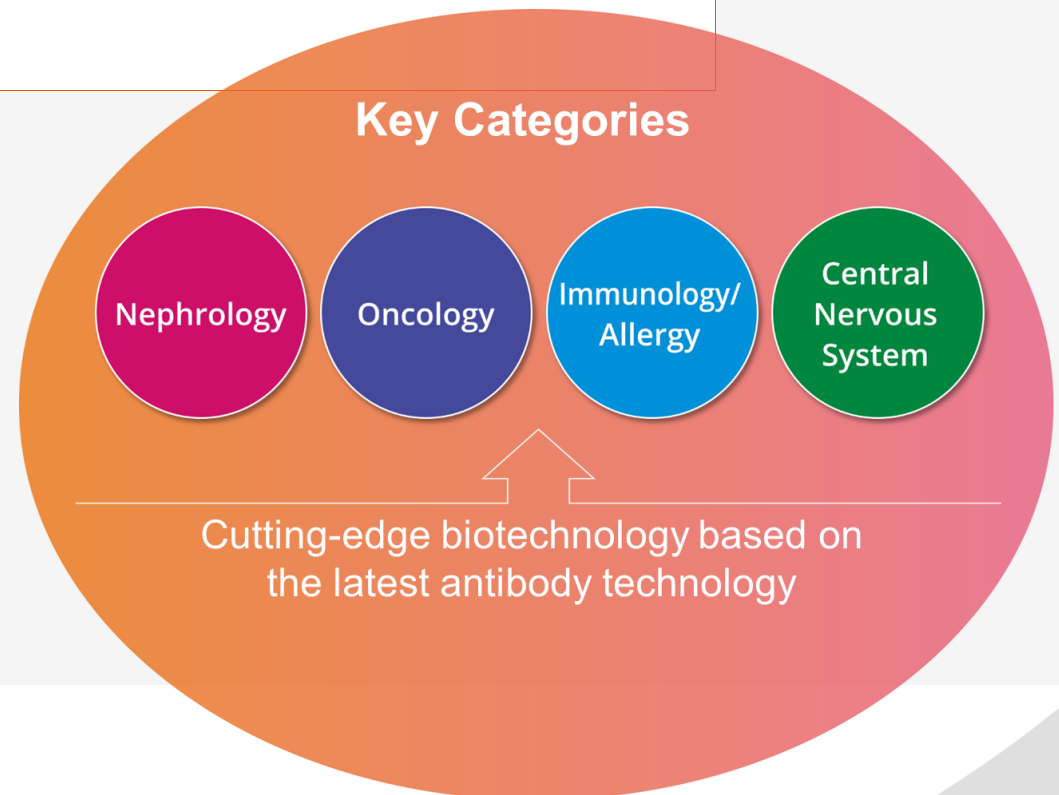


# Kyowa Kirin's R&D Activities

# Kyowa Kirin's R&D

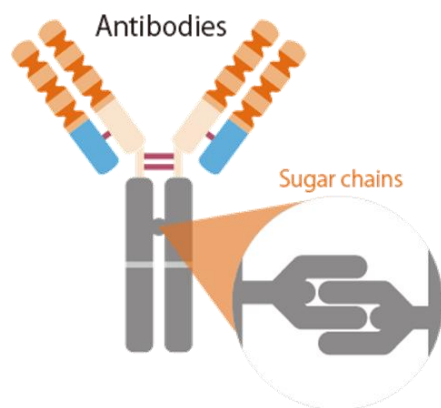
## VISION

Kyowa Kirin will be a Japan-based Global Specialty Pharmaceutical Company contributing to human health and wellbeing 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



# Biologics/Antibody Engineering Technology

## POTELLIGENT technology



The main feature of POTELLIGENT, originally developed by Kyowa Kirin, is its ability to remarkably increase the ADCC\* activity by reducing the amount of the fucose in the structure of antibodies, thus causing the extremely effective elimination of targets, such as cancer cells.

## Fully Human antibody-Producing Technology

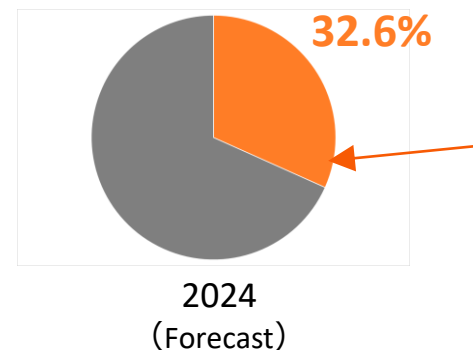
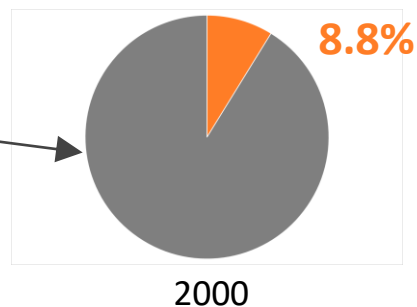
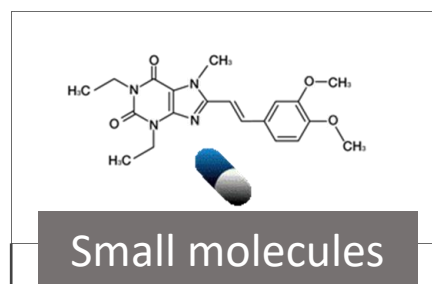
Kyowa Kirin pioneered an epochal technique of transferring a fragment of human chromosome containing a very large cluster of genes to cell nuclei that generate fully human antibodies. This technology enables us to generate fully human antibodies with the same diversity as naturally produced human antibodies.

## Takasaki Plant / Bio Process Research and Development Laboratories

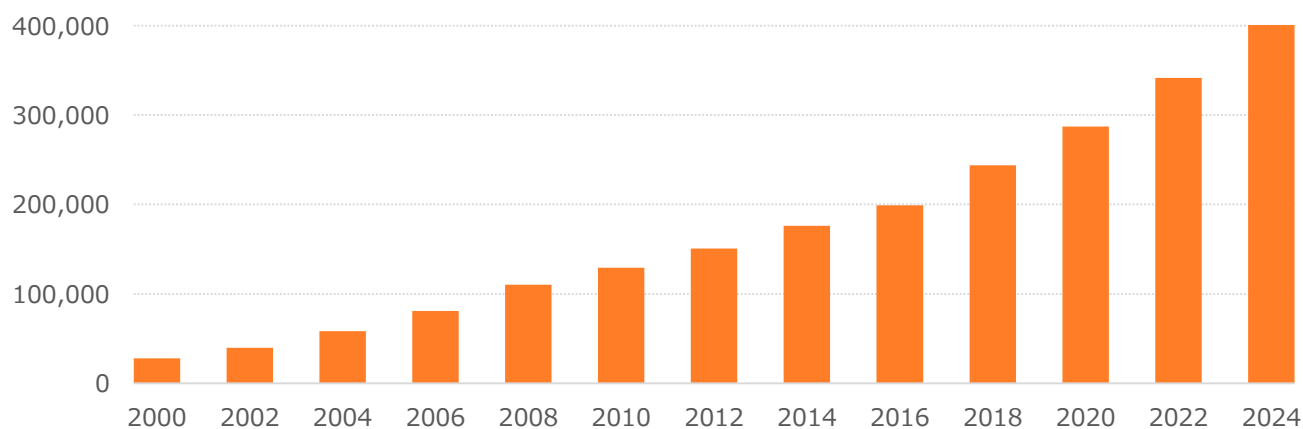


Drawing on Kyowa Kirin's unique technologies accumulated over more than 20 years which started with the production of erythropoietin, the Takasaki Plant produces and supplies high-quality pharmaceuticals to patients worldwide using a system that complies with GMP standards in JPN, the US and Europe. The Bio Process Research and Development Laboratories supports our production of biologics by combining advanced technologies with four key factors, -technology to create, visualize, preserve and refine.

# Market Potential of Biopharmaceuticals



Biopharmaceutical share of the global drug market



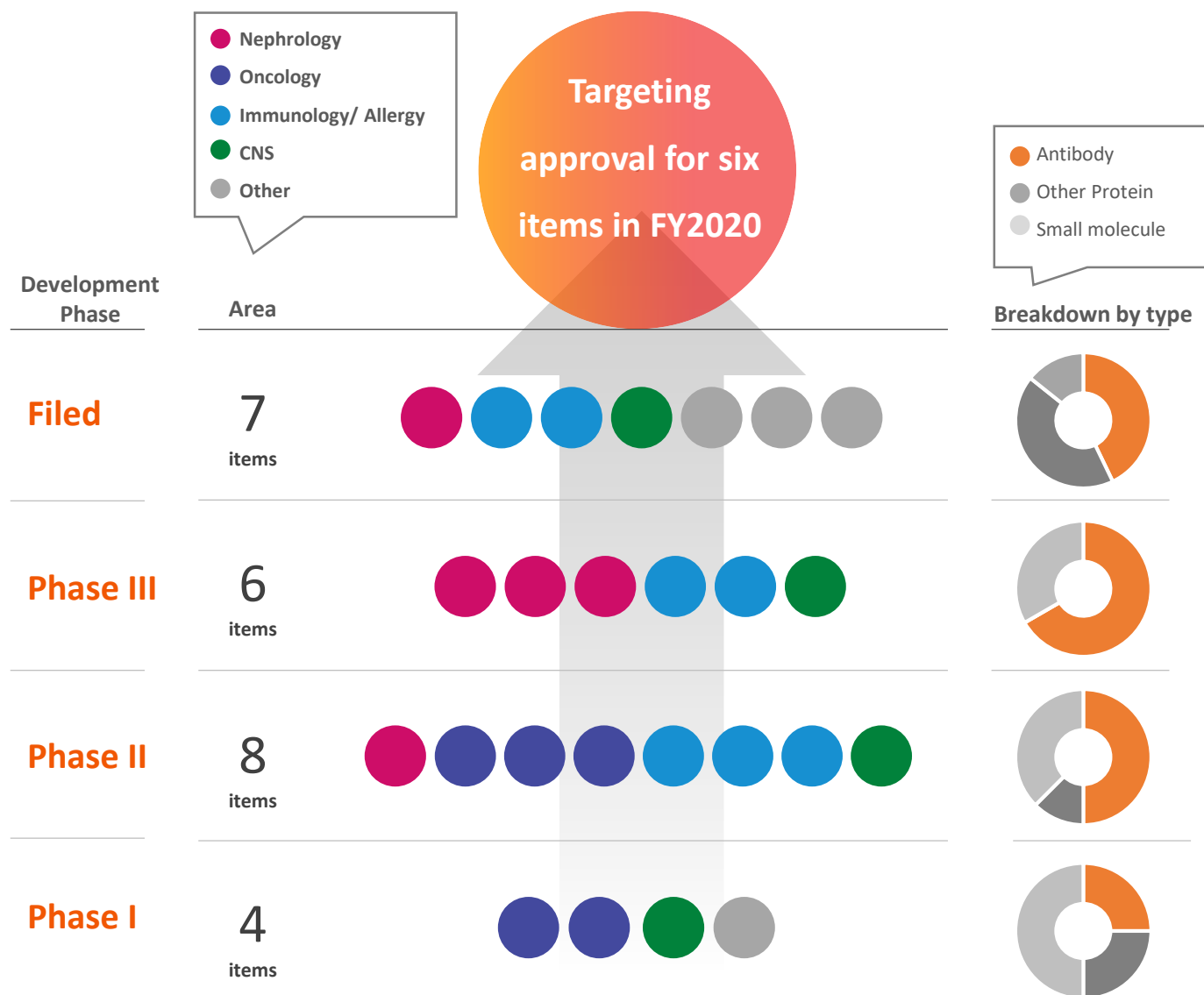
Global sales of biopharmaceuticals (Millions of USD)

# Innovative New Drugs into the World

Other	Oncology	CNS	Immunology/ Allergy
<div>J U E</div> <p><b>Crysvita</b></p> <p>FGF 23-related hypophosphatemic rickets/osteomalacia</p> <p>An antibody that inhibits the action of excess FGF 23 due to genetic abnormality, improves hypophosphatemia-related symptoms such as rickets/osteomalacia by improving urinary phosphate wasting.</p>	<div>J U</div> <p><b>Poteligeo</b></p> <p>Cutaneous T-cell lymphoma Peripheral T-cell lymphoma Adult T-cell leukemia/lymphoma</p> <p>Poteligeo is a POTELLIGENT antibody targeting CCR4 expressed on leukemic cells. By binding to CCR4 on malignant T-cells, Poteligeo elicits an antitumor activity mediated by ADCC.</p>	<div>J U</div> <p><b>Nourianz</b></p> <p>Parkinson's disease</p> <p>It has a new mode of action that blocks adenosine A<sub>2A</sub> receptor action. It has shown efficacy in patients with the wearing-off phenomenon, which is one of the motor complications.</p>	<p><b>benralizumab</b></p> <p>Asthma</p> <p>It is a monoclonal antibody utilizing our POTELLIGENT technology. It quickly removes eosinophil that is considered to be highly involved in inflammatory respiratory diseases by the ADCC activity.</p> <p><b>Sold by AstraZeneca.</b></p>

Global Strategic Products			Out-licensed to AstraZeneca
<p><b>WW Revenue</b></p> <p><b>32.6</b> Billion JPY (2019)</p> <p><b>60.1</b> Billion JPY (2020)</p>	<p><b>WW Revenue</b></p> <p><b>12.8</b> Billion JPY (2019)</p> <p><b>16.3</b> Billion JPY (2020)</p>	<p><b>WW Revenue</b></p> <p><b>9.8</b> Billion JPY (2019)</p> <p><b>13.3</b> Billion JPY (2020)</p>	<p><b>Tech-licensing Revenue</b></p> <p><b>8.9</b> Billion JPY (2019)</p>

# Research & Development Capability



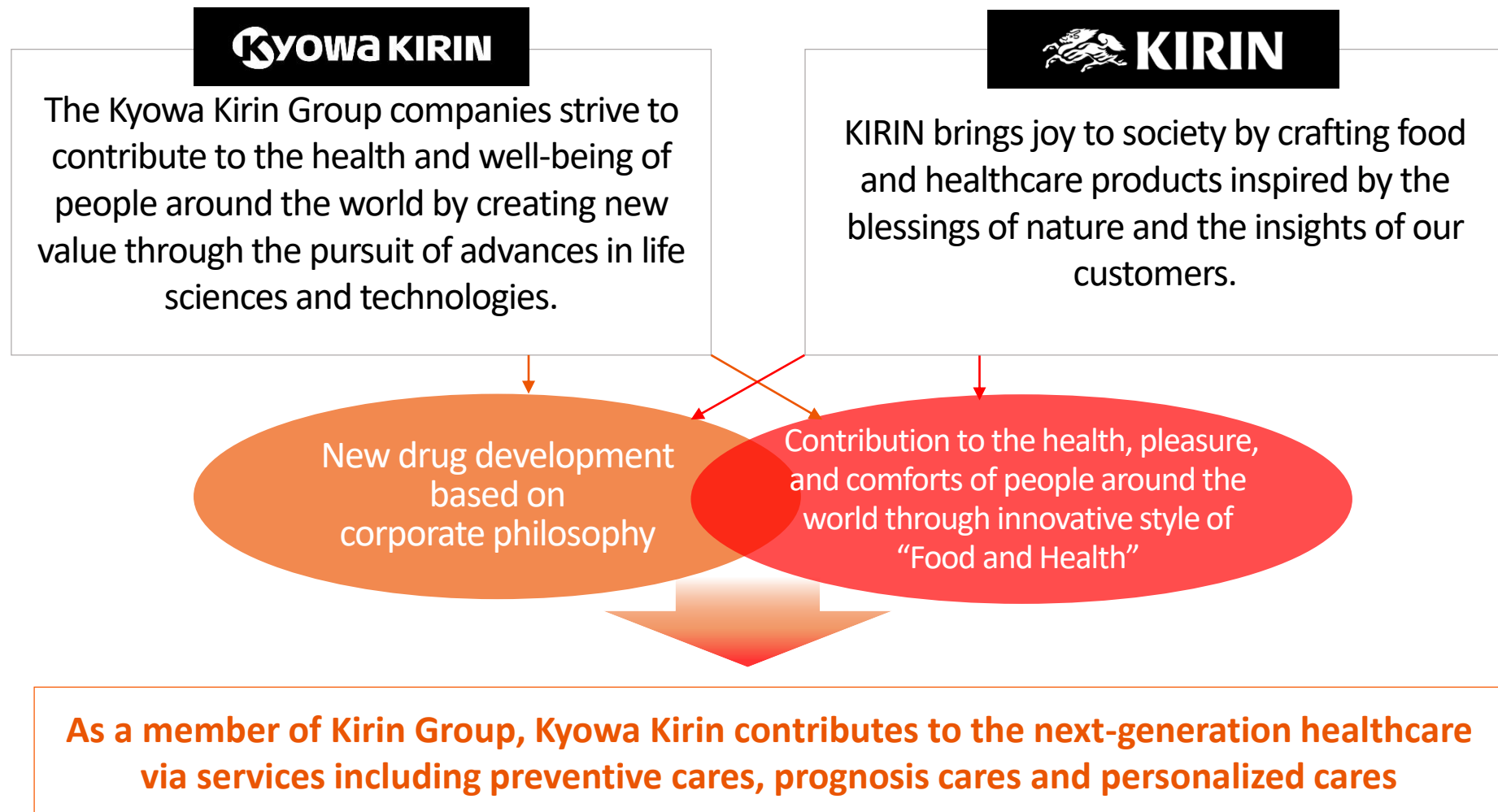
As of December, 31 2019

**Kyowa Kirin is developing innovative drugs using cutting-edge biopharmaceutical technology**

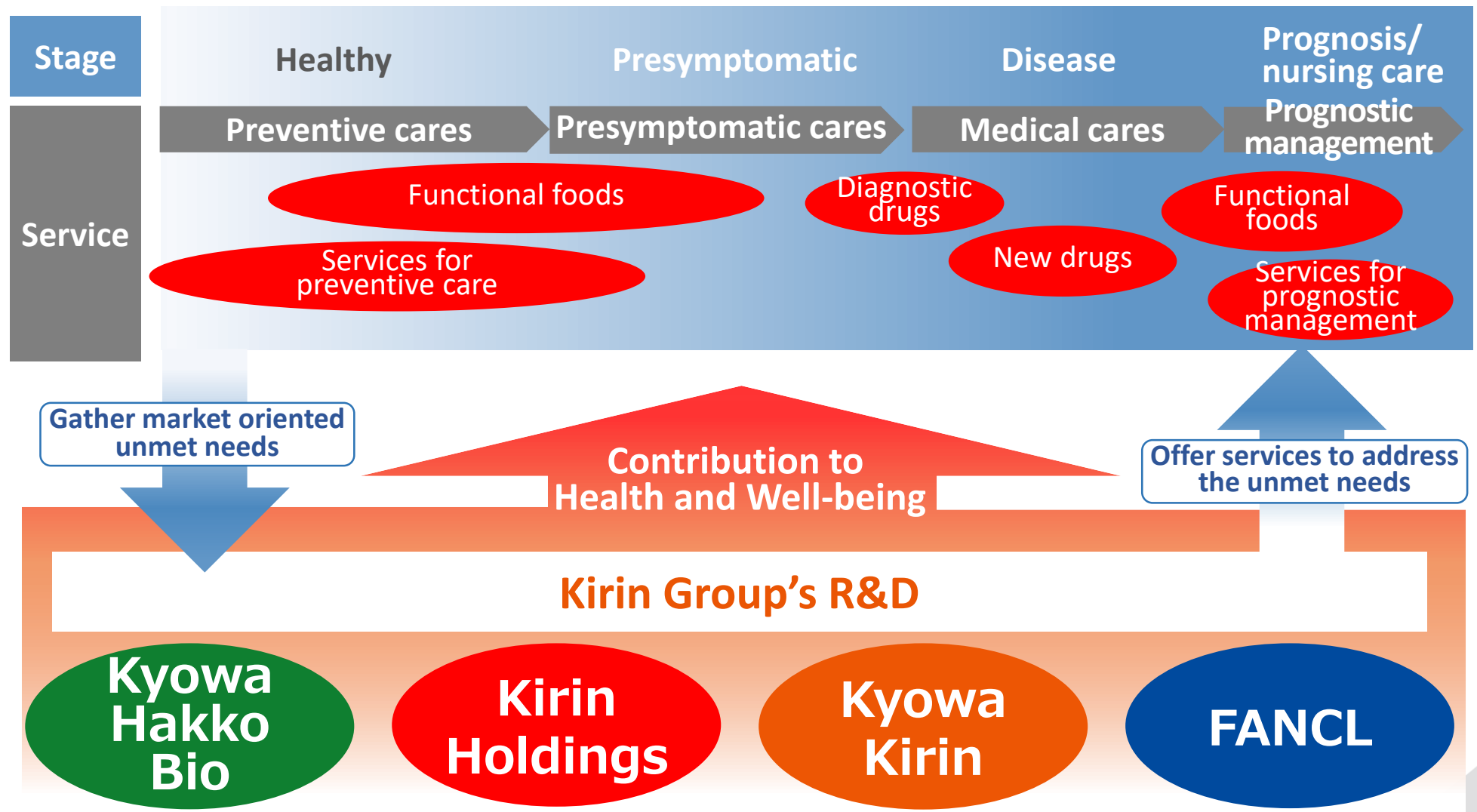
# **Kyowa Kirin - To Pursue Further Growth - Enhance Synergies within the Kirin Group**



## Enhance synergies within the Kirin Group - our shared philosophies -

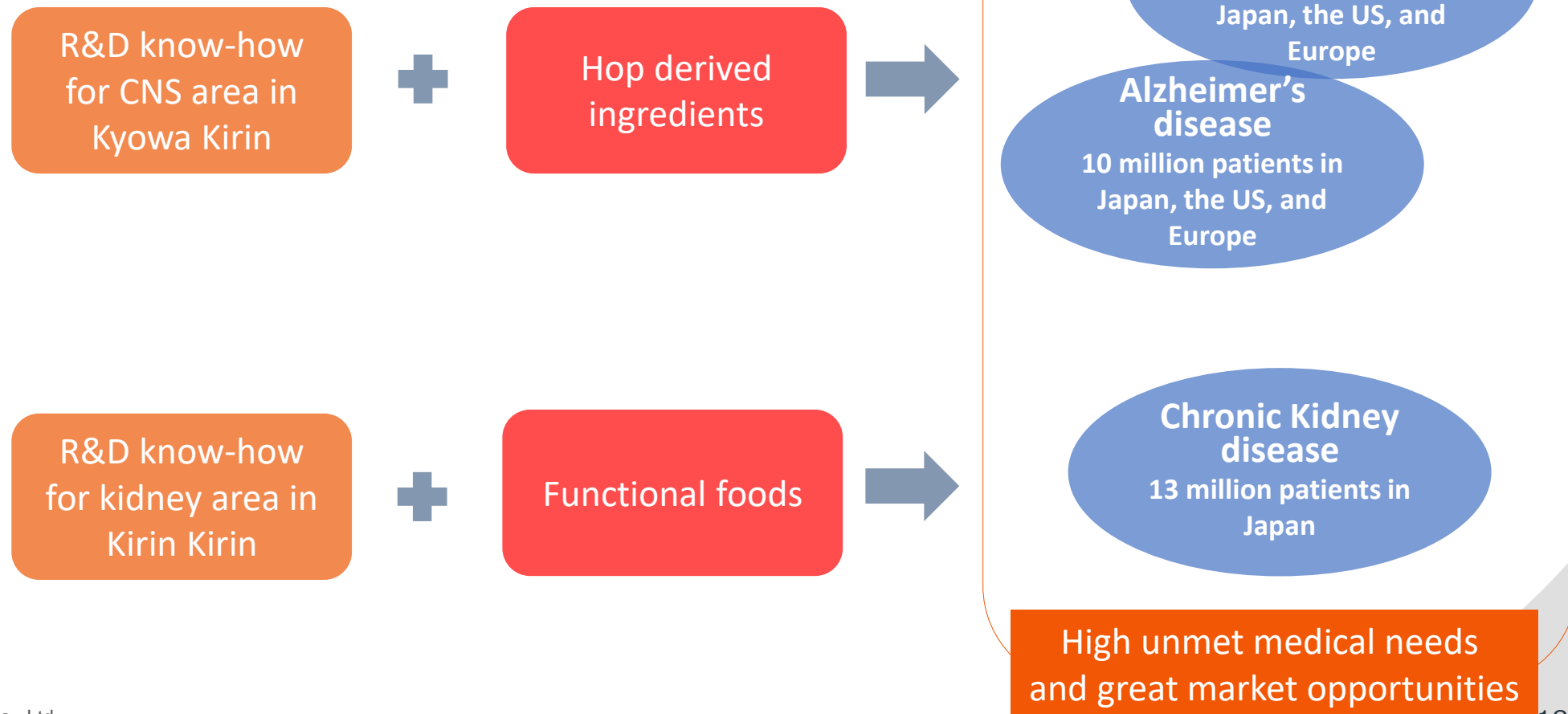


## Contributions to the next-generation healthcare -



## Enhance synergies within the Kirin Group

### ◆ Basic research collaborations targeting disease of brain, kidney, immune system, and intestine



## Enhance synergies within the Kirin Group

### ◆ Basic research collaborations targeting disease of brain, kidney, immune system, and intestine

- From 2016, research collaboration activities are conducted periodically to find new and cutting-edge approaches in healthcare services. (Kyowa Kirin, Kirin Holdings and Kyowa Hakko Bio)
- Initiate projects after making contract agreement in each case to create new business values and secure intellectual properties

