

# Press Conference

# Our Journey

**December 4, 2013**  
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**Astellas Pharma Inc.**



# Cautionary Statement Regarding Forward-Looking Information

This material includes forward-looking statements based on assumptions and beliefs in light of the information currently available to management and subject to significant risks and uncertainties.

Actual financial results may differ materially depending on a number of factors including adverse economic conditions, currency exchange rate fluctuations, adverse legislative and regulatory developments, delays in new product launch, pricing and product initiatives of competitors, the inability of the company to market existing and new products effectively, interruptions in production, infringements of the company's intellectual property rights and the adverse outcome of material litigation.

This material contains information on pharmaceuticals (including compounds under development), but this information is not intended to make any representations or advertisements regarding the efficacy or effectiveness of these preparations nor provide medical advice of any kind.

# Outline of Our Journey

- ❑ **Business environment and changes**
- ❑ **Challenges for changing tomorrow**



# Outline of Our Journey

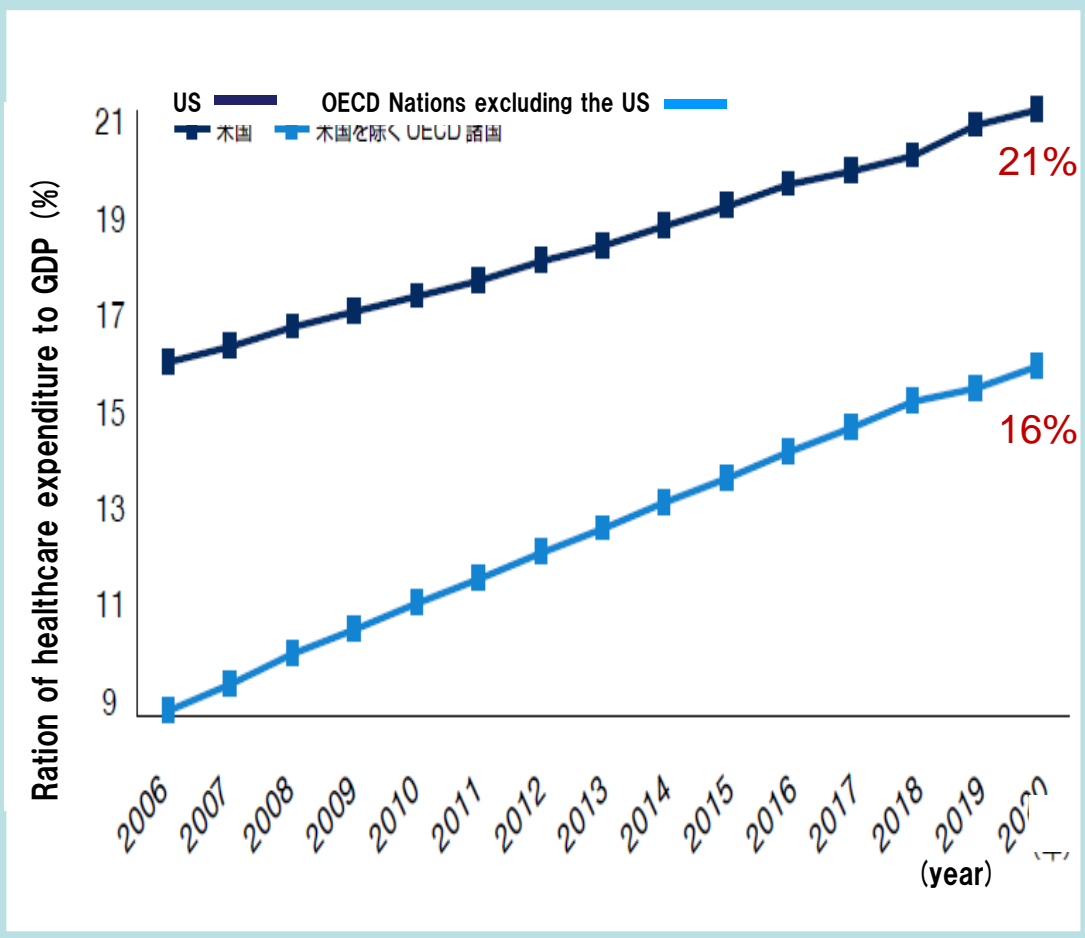


- ❑ **Business environment and changes**
- ❑ Challenges for changing tomorrow

# Growing market

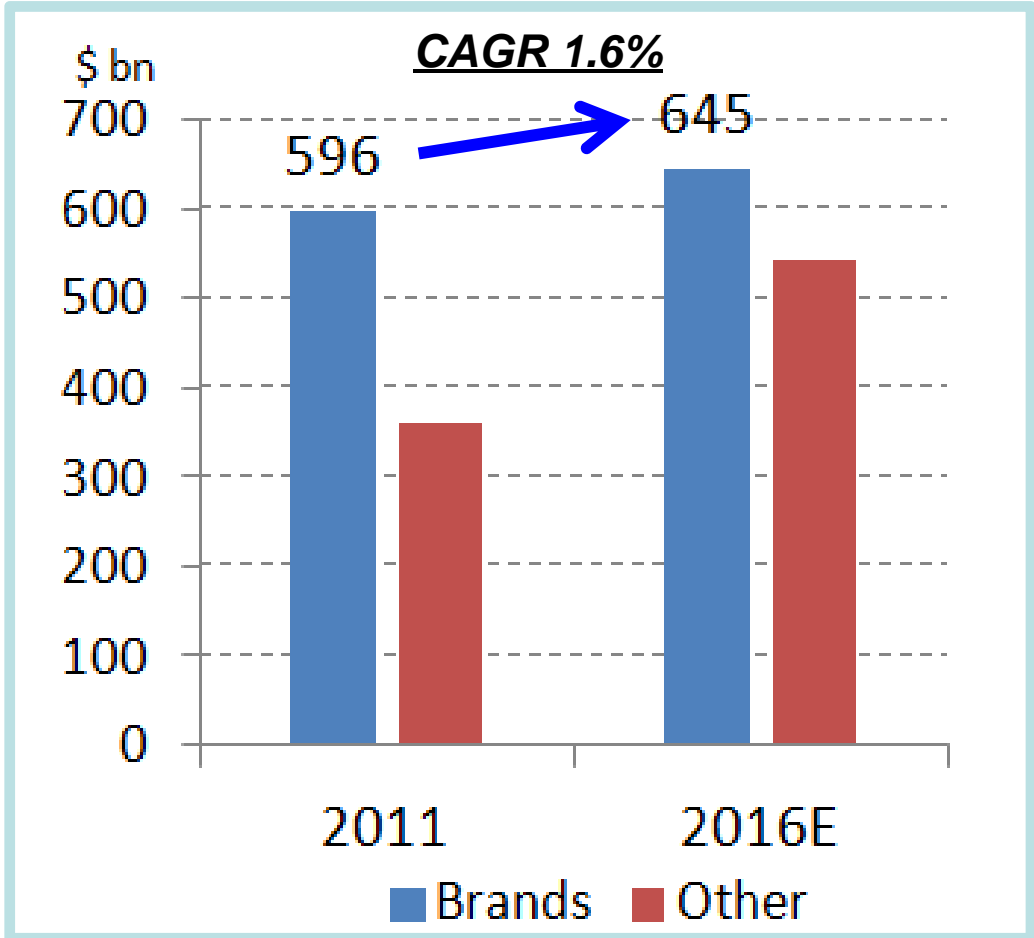
Pharma market is expected to continue growing steadily

Healthcare expenditure as a percentage of GDP in OECD countries



Source:Pricewaterhouse Coopers Pharma 2020 vision

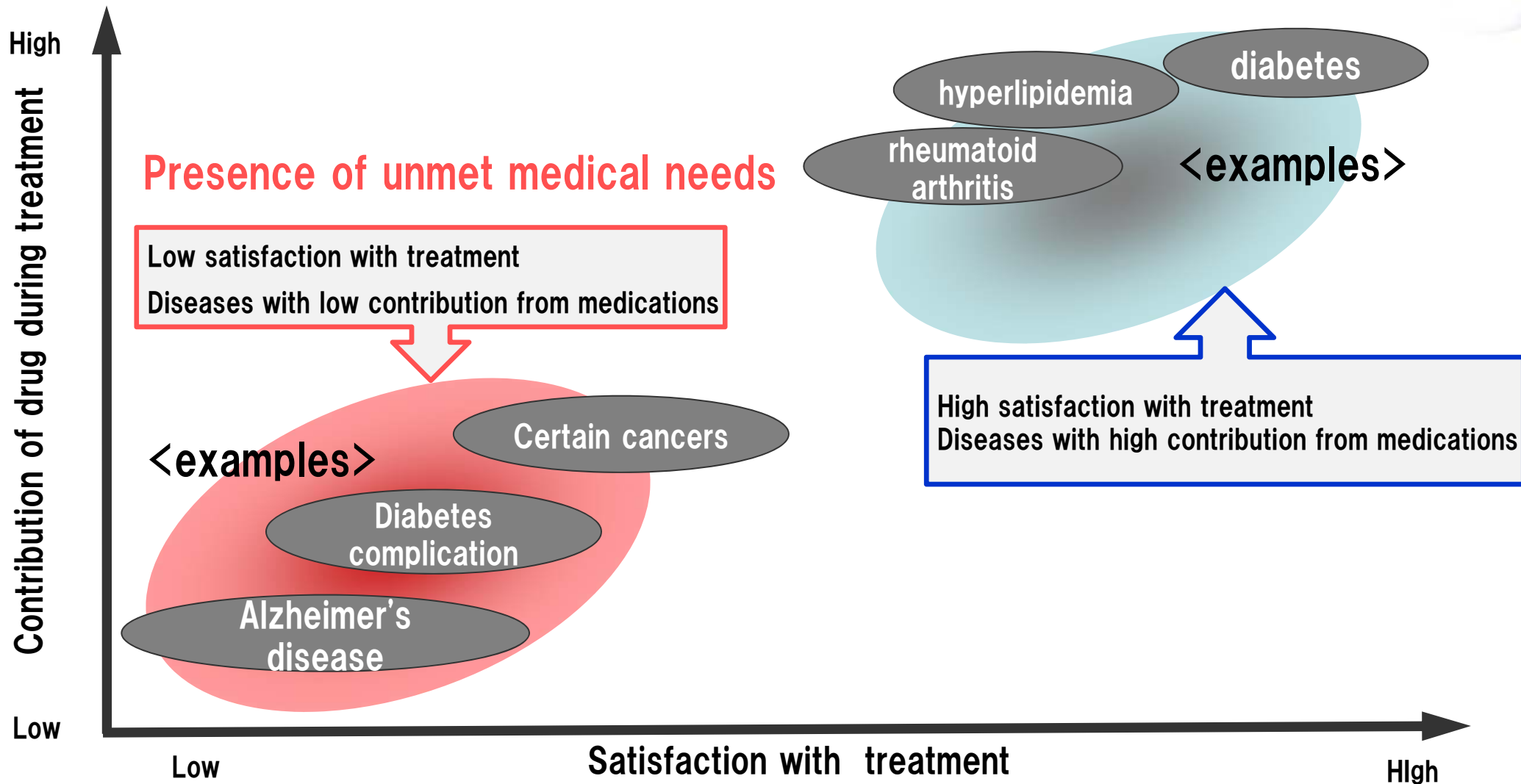
Global Pharma Market : 2011-2016



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# Unmet medical needs

With current treatment and medication, there are many diseases that lack sufficient treatment



# Drugs and advancement in biological sciences

Pharma market expansion with science evolution

To step up

⇒ **Innovation !!**

Vaccine  
Regenerative medicine  
etc

Molecular target drug, Biomedicine  
(Antibody, Protein drug etc)

Landing of Science?

Focus on  
molecular structure

H2 blocker  
b blocker

Focus on  
cell biology  
cell technology

Landing of Science?

Anti-inflammatory drug  
Antihypertensive drug

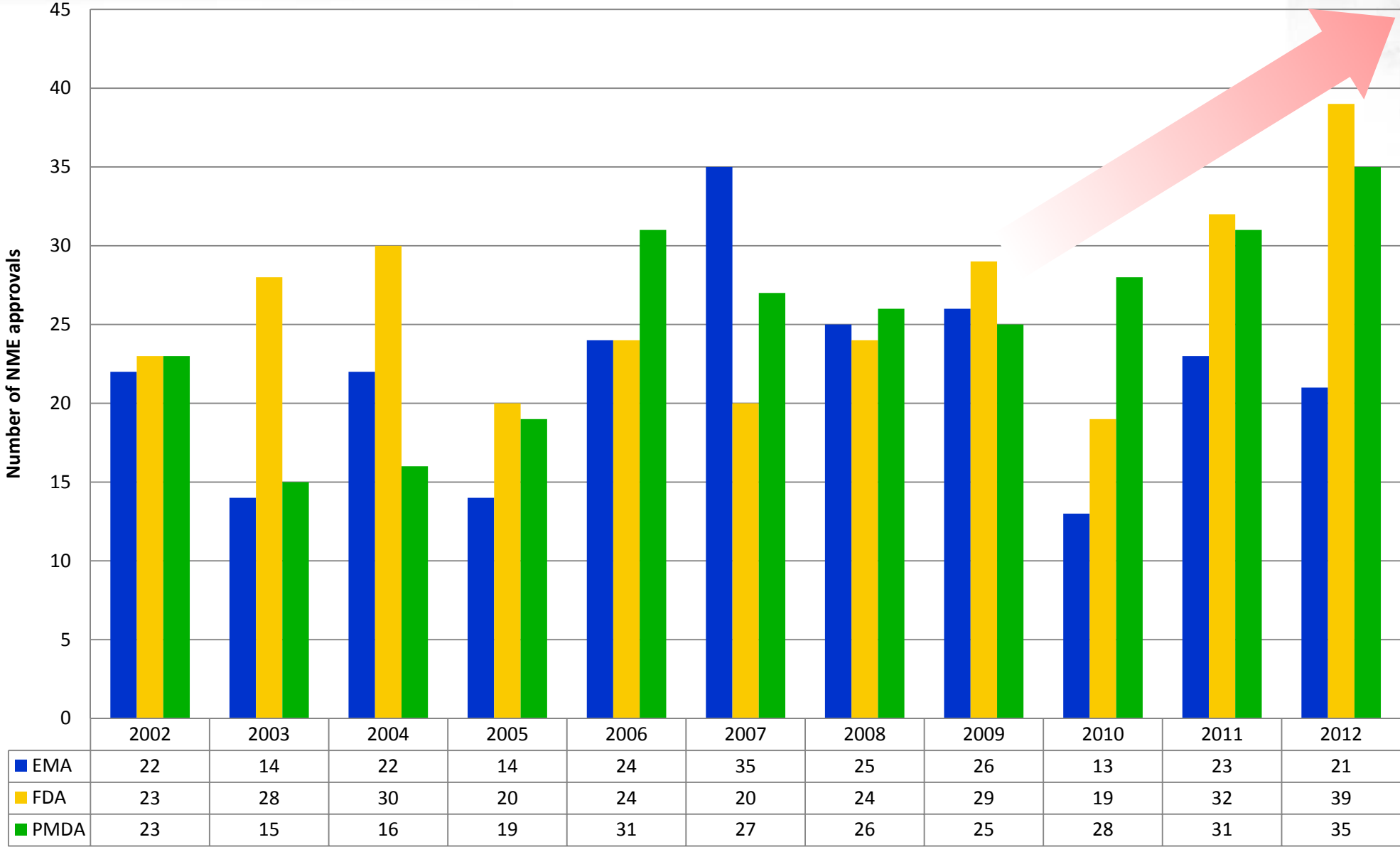
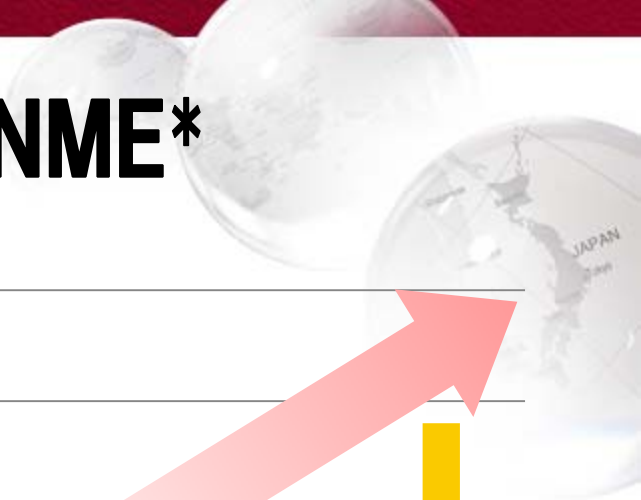
Aspirin

*Technological innovation  
supporting new drug discovery*

- Personal genomic medicine
- New generation sequencer
- Systembiology
- Bioimaging
- Bioinformatics etc

Extraction of active ingredient based on  
past experience / Discovery by luck

# Changes in the Number of Approved NME\*

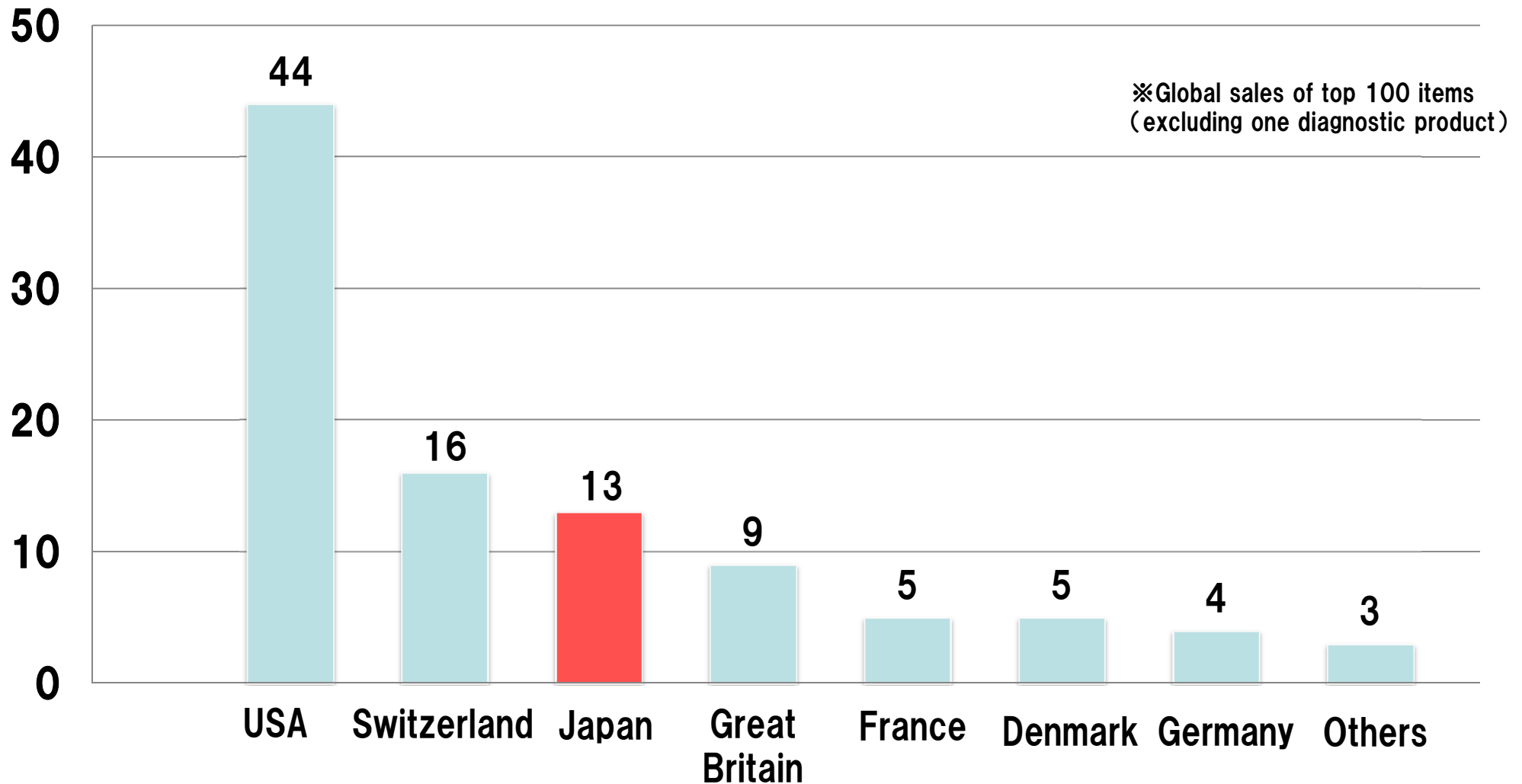


\*New Molecular Entity



# Country rankings based on new drug development (2010)

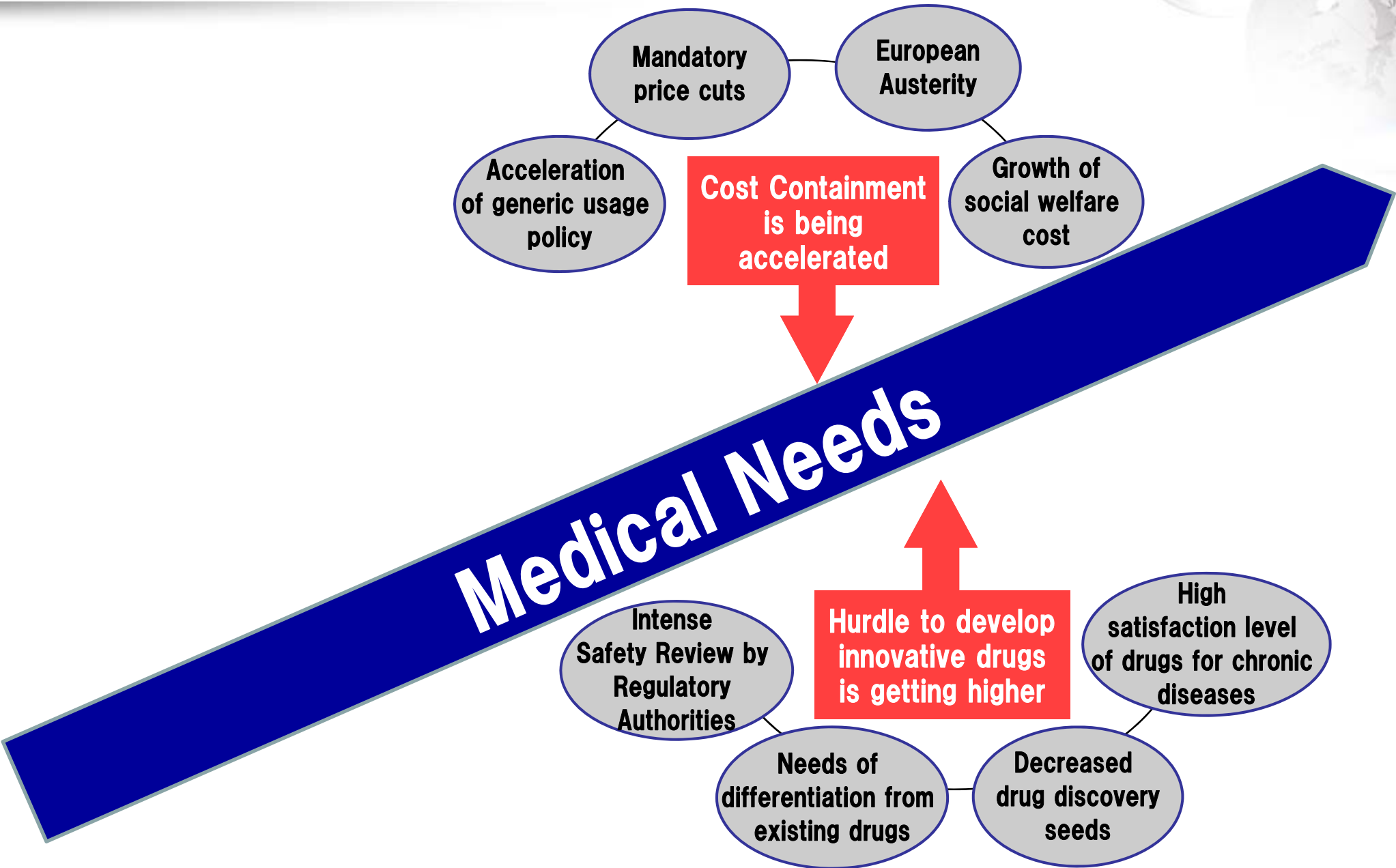
Japan is the 3rd best nation for innovative drug development



Source: IMS World Review, Pharmaprojects (reprint/replication prohibited)

Created by: Japan Pharmaceutical Manufacturers Association and Office of Pharmaceutical Industry Research

# Growing Pharmaceutical Market and Changing Environment



# Outline of Our Journey



- Business environment and changes
- **Challenges for changing tomorrow**

# Challenges for changing tomorrow

## - Three Strategic Issues for Sustainable Growth -

1

Maximizing the Value of New Products

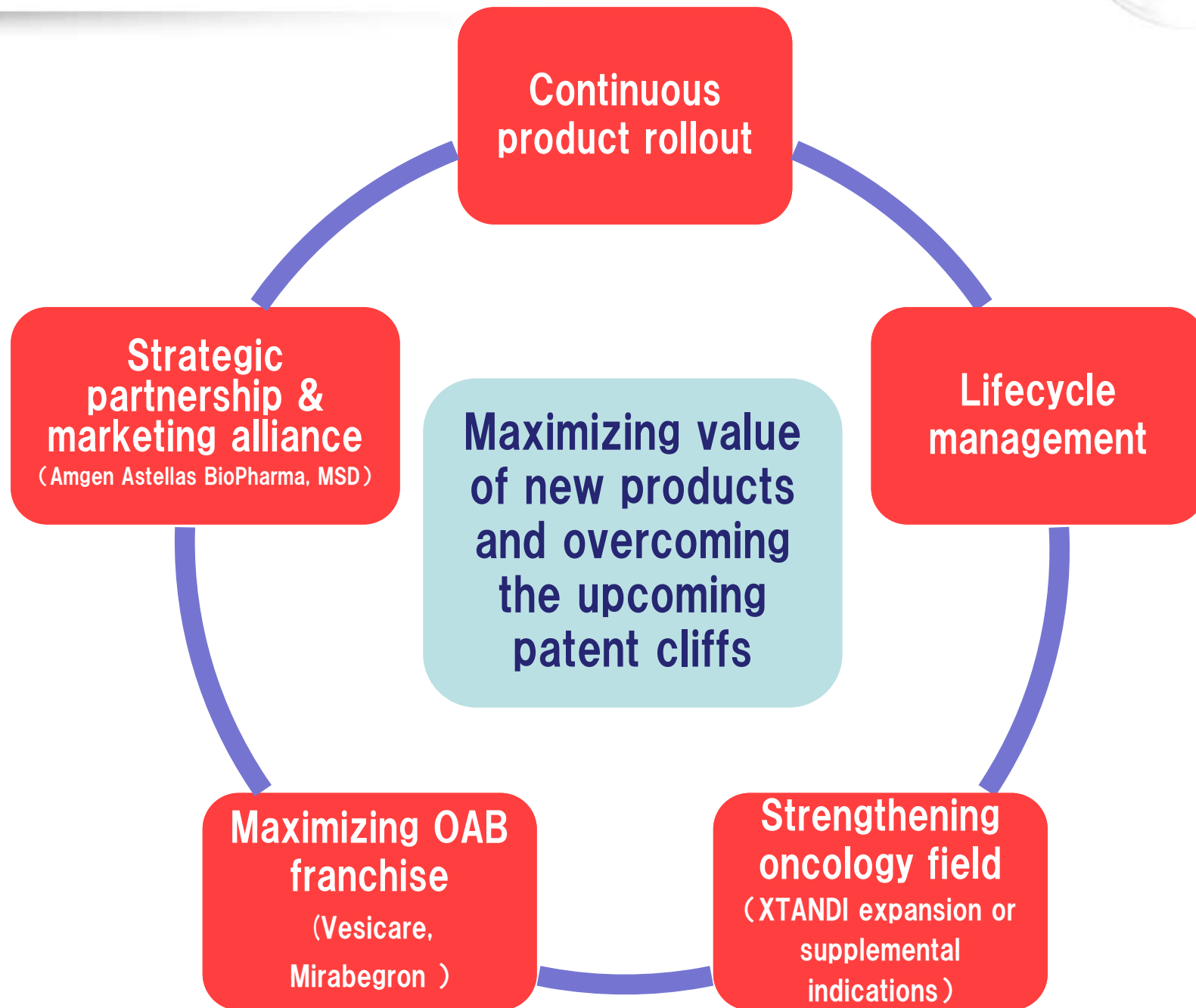
2

Enhancing Ability to Generate Innovative Drugs  
(Reshaping Research Framework)

3

Achieving Operational Excellence

# 1. Maximizing the Value of New Products



## 2. Enhancing Ability to Generate Innovative Drugs - GCL: Business Model of Astellas -

— Concentrate Resources —

Proprietary Ethical  
Pharmaceutical  
Business Approach

Innovative  
Pharmaceutical  
Business Approach

### Global Category Leader (GCL)

Current GCL

Urology

Transplantation

Third GCL

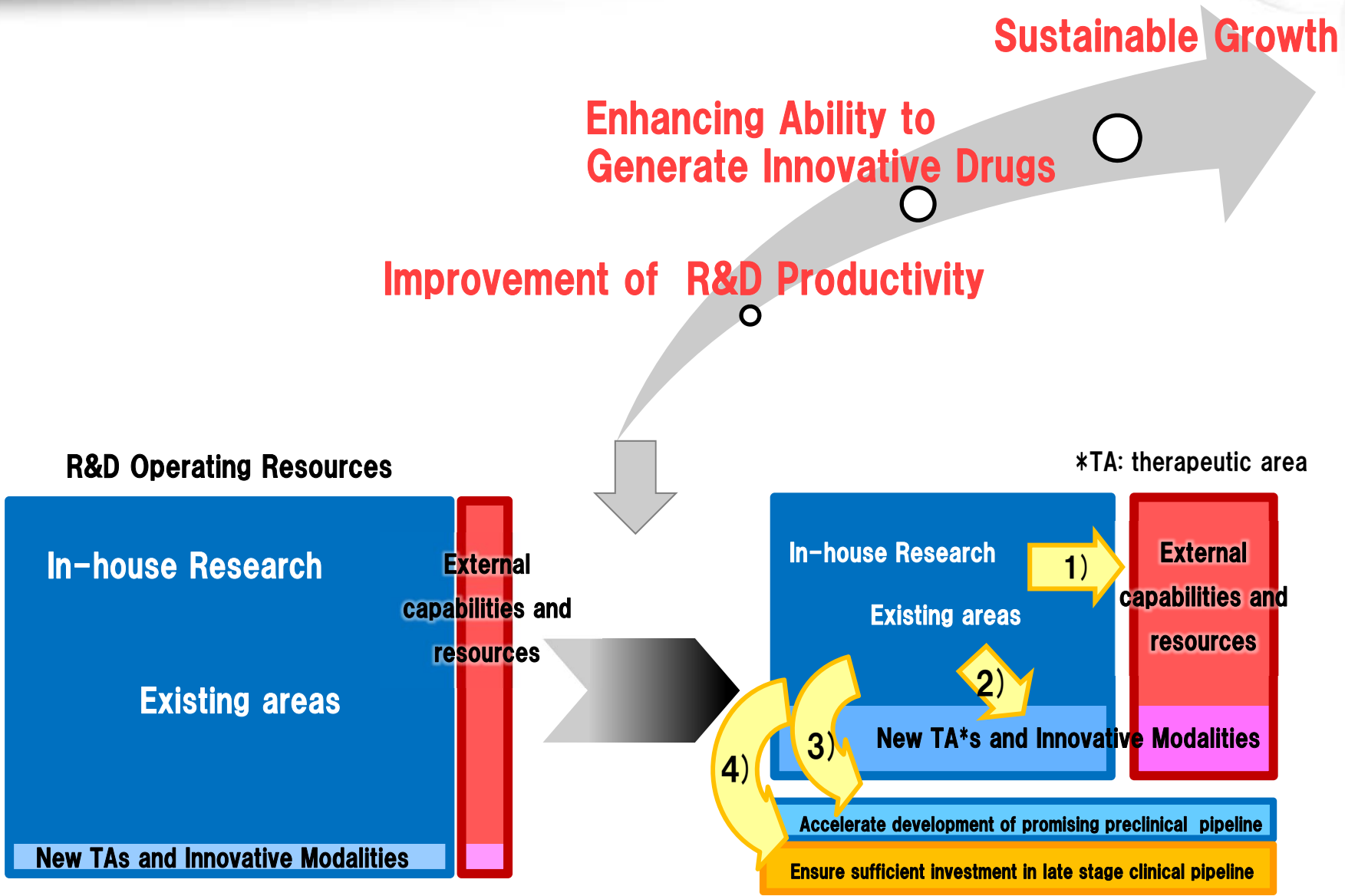
Oncology

Future GCL

- Immunology & Infectious Diseases
- Neuroscience
- DM Complications & Kidney Diseases, etc.

# 2. Enhancing Ability to Generate Innovative Drugs

## - Sustainable Growth by improvement of R&D Productivity -

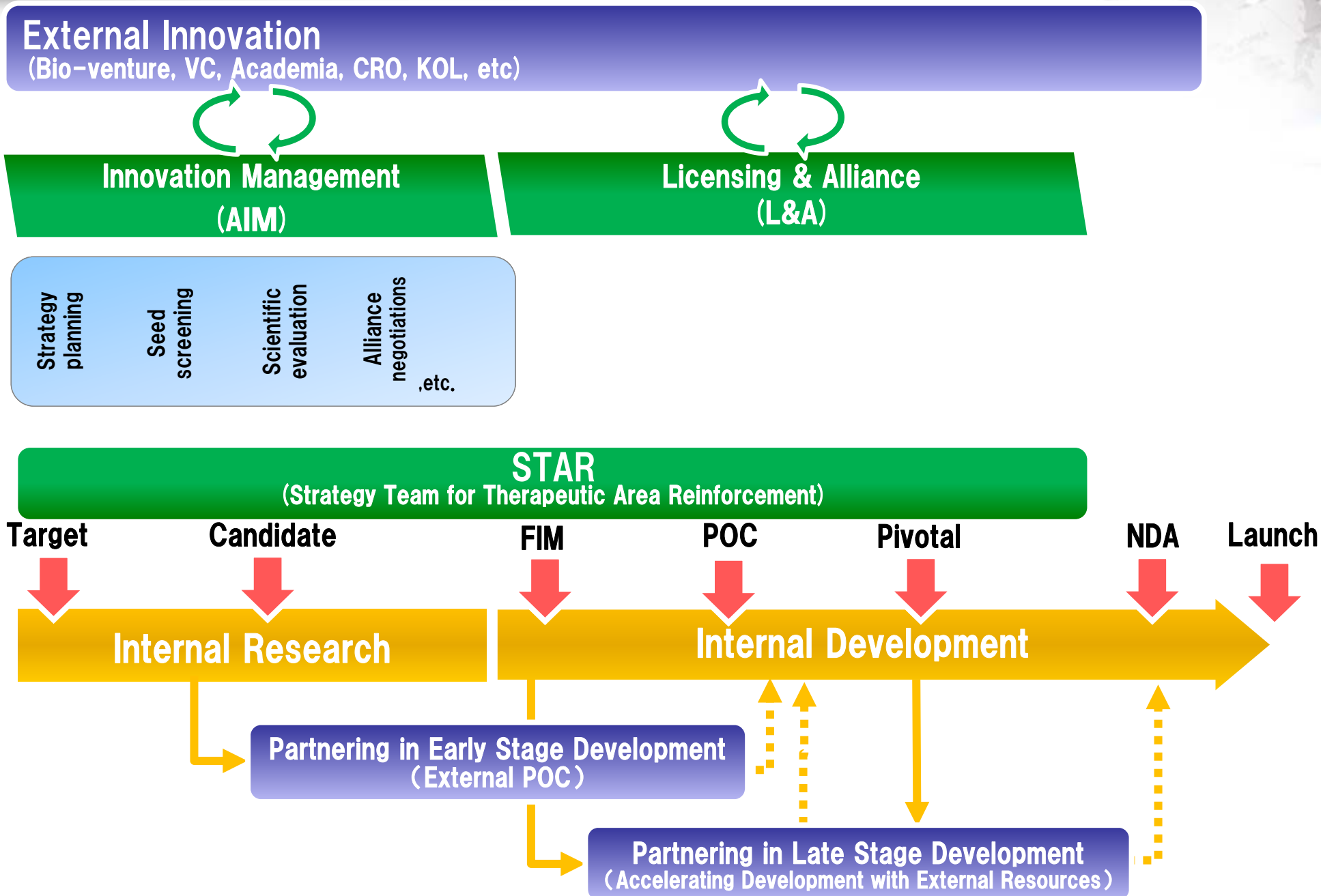


Review R&D Resource Allocation in order to Resiliently Respond to the Changing Environment

# 2. Enhancing Ability to Generate Innovative Drugs

## 1) Utilize more External Capabilities and Resources

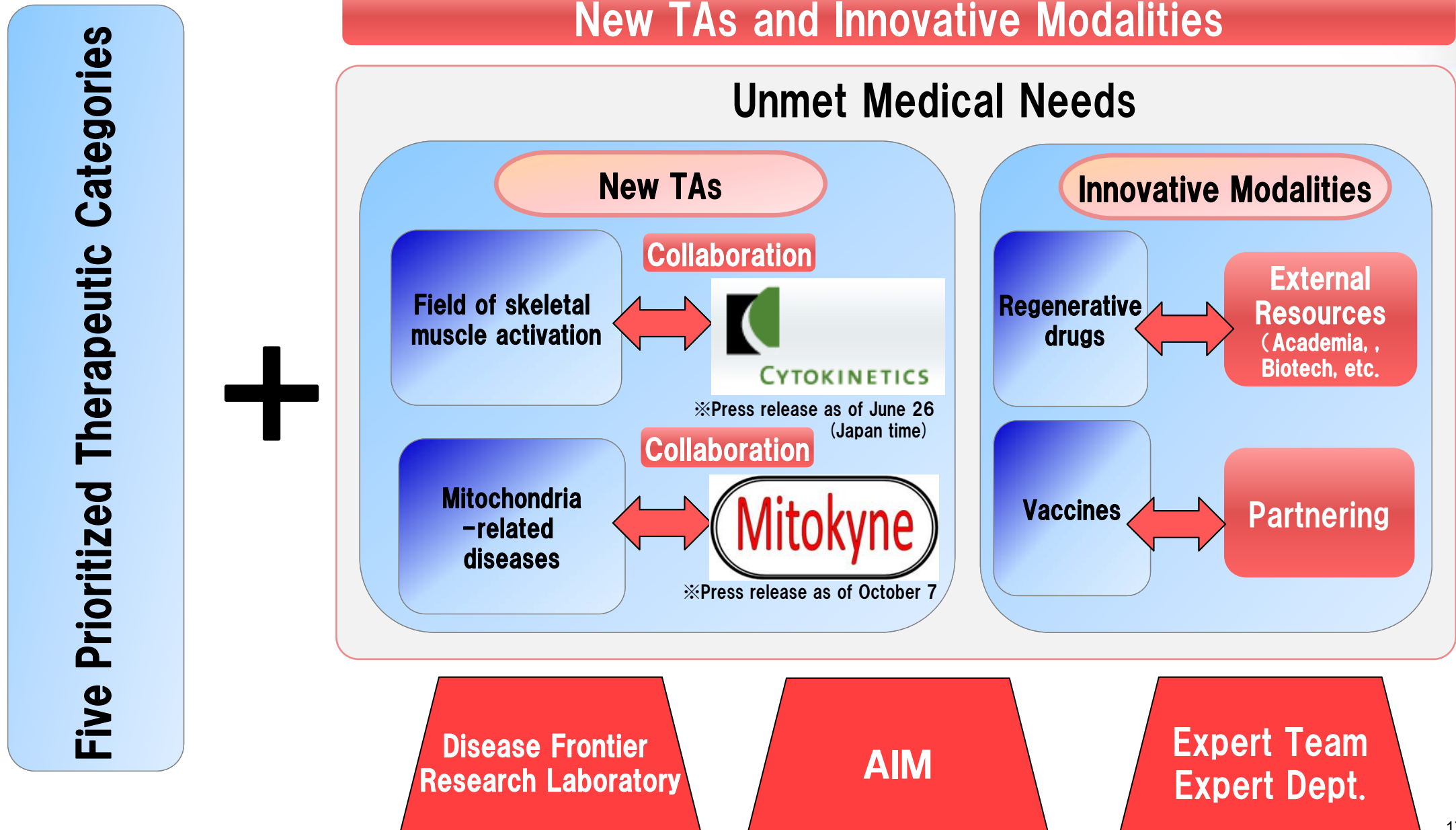
Multi-track R&D systems





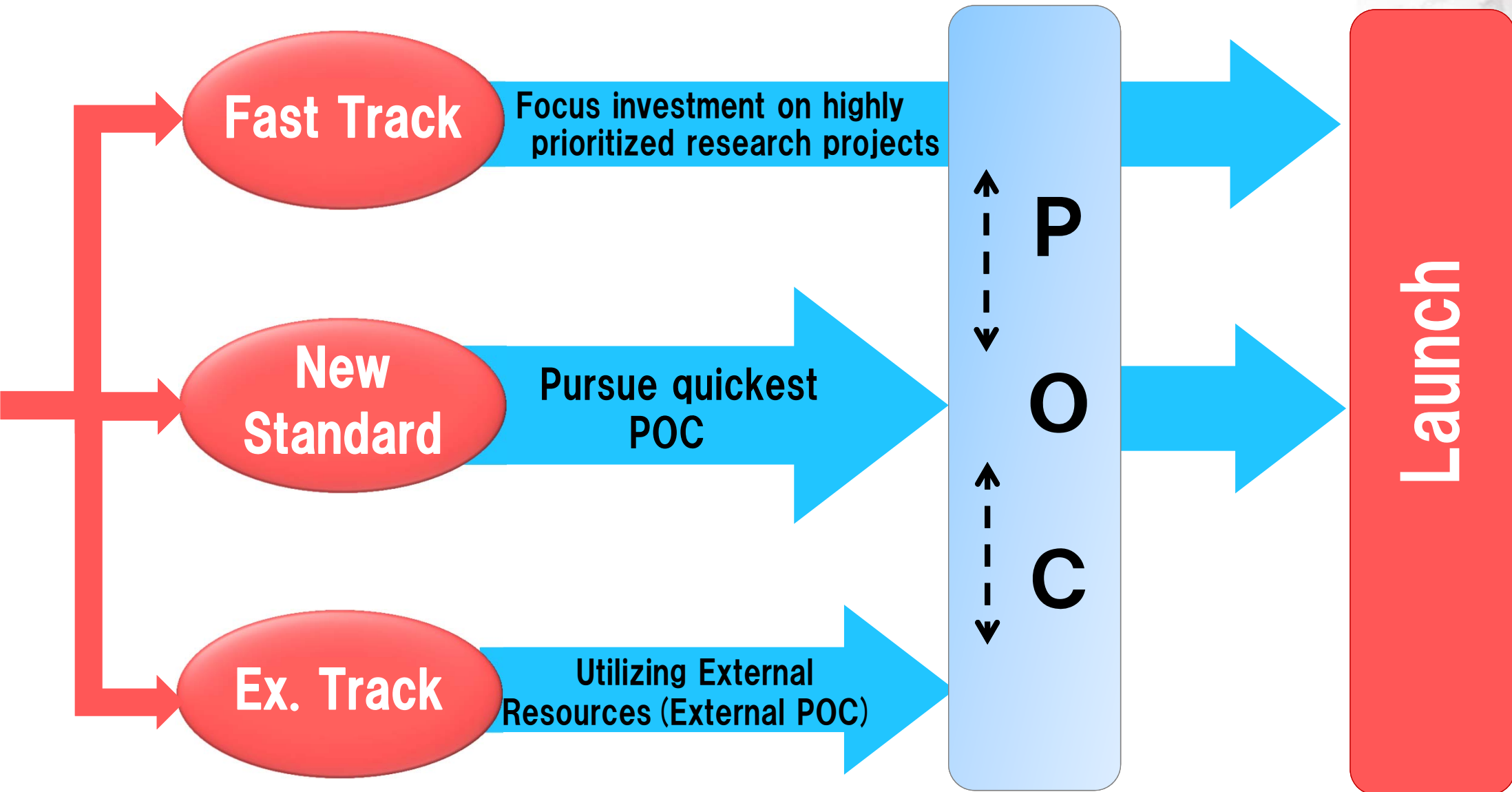
## 2. Enhancing Ability to Generate Innovative Drugs

### 2) Undertake Initiatives related to New Therapeutic Areas and Innovative Modalities



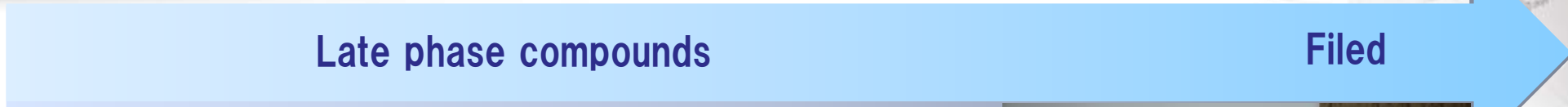
## 2. Enhancing Ability to Generate Innovative Drugs

### 3) Accelerate Development of Promising Preclinical Pipeline



# 2. Enhancing Ability to Generate Innovative Drugs

## 4) Ensure Sufficient Investment in Late-Stage Clinical Pipeline



|   | Late phase compounds   | Filed   |
|---|--|---|
| <b>Urology</b>  | <p>solifenacin/mirabegron<br/>urinary frequency, urinary incontinence or urgency associated with overactive bladder (OAB)</p> <p>solifenacin<br/>neuropathic bladder (pediatric)</p> |   |
| <b>Immunology (including transplantation) and infectious diseases</b> | <p>certolizumab pegol<br/>rheumatoid arthritis (pre-Methotrexate treatment)</p> <p>isavuconazole<br/>(Aspergillosis, candidemia)</p>   |   |
| <b>Oncology</b>   | <p>enzalutamide<br/>prostate cancer (pre-chemo treatment, non-metastatic)</p> <p>degarelix<br/>prostate cancer (3 month duration)</p>  | <p>erlotinib<br/>small cell lung cancer (supplemental)<br/>pediatric ependymoma</p> <p>enzalutamide *<br/>prostate cancer</p> <p><b>*Filed in Japan, available in the US and EU</b></p> |
| <b>Others</b>   | <p>AMG 145<br/>Hyperlipidemia</p> <p>romosozumab<br/>Osteoporosis</p>  | <p>roxadustat<br/>Anemia associated with CKD</p> <p>lpravgliflozin<br/>Type 2 diabetes</p> <p>midazolam<br/>conscious sedation in dentistry and dental surgery</p>                      |



※Press Conference on May 29 (Photograph: Edelman)



# 3. Achieving Operational Excellence





# Our Journey for Changing Tomorrow



# Changing tomorrow

