

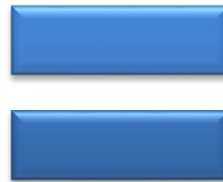
# Gene Techno Science Co., Ltd.

Results of Operations  
for the 2<sup>nd</sup> Quarter (April to September) of the FY 2015

November 18, 2015

Stock Code: 4584

**Gene Techno Science leads biosimilars in the world**



**Biosimilars**

GENE TECHNO SCIENCE

- ✓ **Launched the first biosimilar in Japan in accordance with the Japanese guidelines for biosimilars**
- ✓ **Started the development of series of biosimilar following Filgrastim biosimilar**

# Highlights of Operating Results

## 2Q (April – September 2015) of FY 2015 Operational Results

	Net Sales (Million Yen)	Operating Income (Million Yen)	Ordinary Income (Million Yen)	Net Income (Million Yen)	Net Income per share (Yen)
2014 (Apr - Sep) Actual results (A)	145	△396	△369	△370	△155.51
2015 (Apr - Sep) Actual results (B)	791	△116	△99	△100	△41.21
Difference (B-A)	+646	+280	+270	+270	-

**More than 5 times sales compared to the previous year**

- Strong sales of Filgrastim biosimilar
- Upfront payment from Mochida Pharmaceutical

# Revised Forecast of Operational Results

## ◆ Revised Forecast of FY 2015 (ending March 31, 2016)

	Net Sales (Million Yen)	Operating Income (Million Yen)	Ordinary Income (Million Yen)	Net Income (Million Yen)	Net Income per share (Yen)
Original Forecast as of May 14, (A)	1,022	△602	△573	△575	△232.62
Revised Forecast as of Nov.12 (B)	1,132	△1,045	△1,019	△1,021	△404.73
Result FY 2014 (Reference)	321	△824	△790	△792	△331.86
Difference (B-A)	110	△443	△445	△445	—

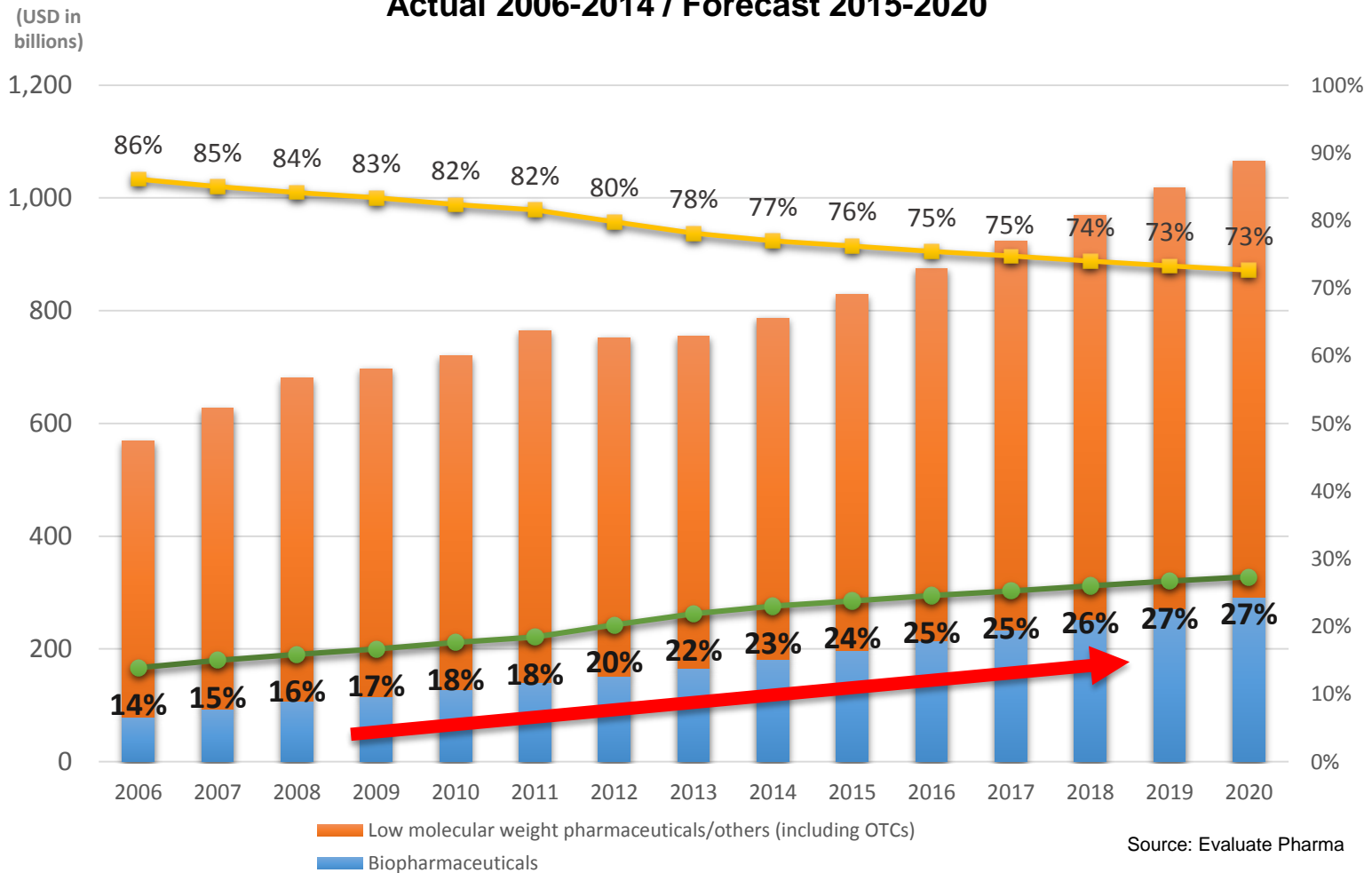
- Strong sales of biosimilar by Fuji Pharmaceutical and Mochida Pharmaceutical!
- Upfront payment by collaborations!
- ➔ **Expecting 4 times sales** compared to the previous year

- Increase of R&D expenses by business collaboration with Senju Pharmaceutical for a biosimilar in the Ophthalmology field.
- ➔ **Acceleration of development of pipeline with higher probability of success**
- ➔ **Acceleration of monetization by milestone/royalty earnings, etc.**

# Overview of Global Pharmaceutical Market

## Global gross sales of pharmaceutical products and share of biologics

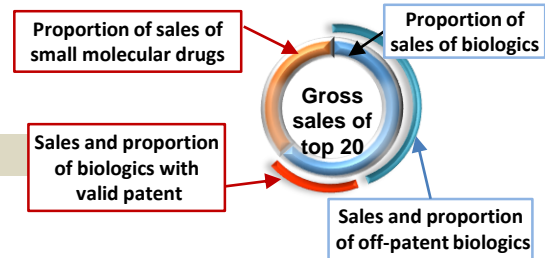
Actual 2006-2014 / Forecast 2015-2020



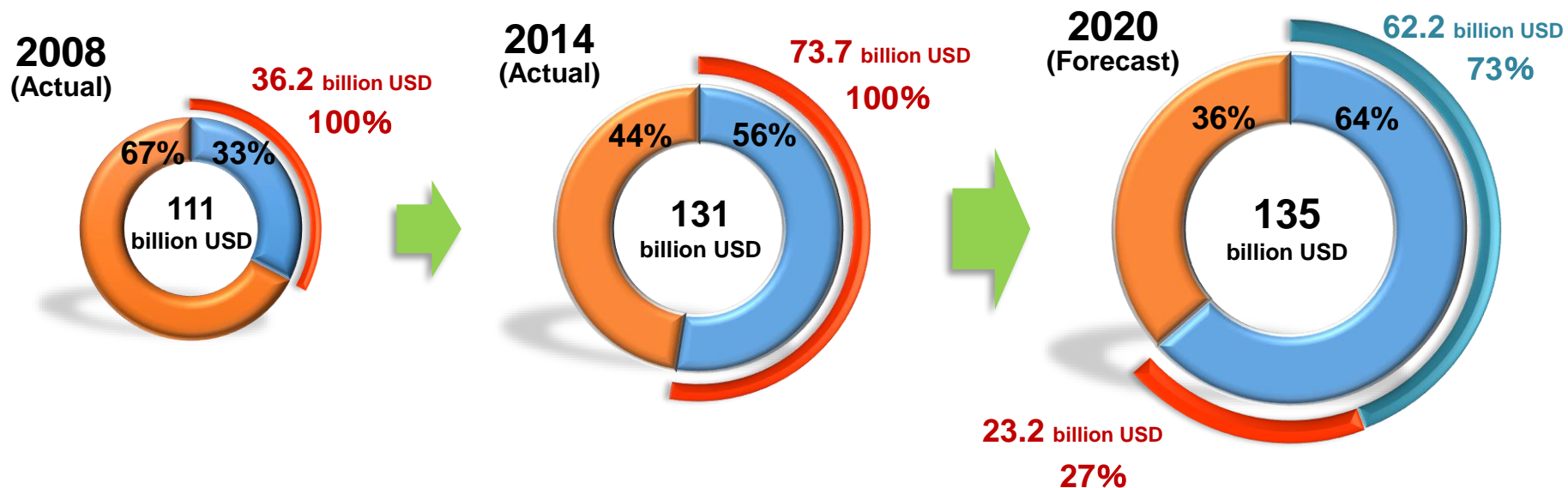
**Biologics market is steadily expanding**

# Biologics Market Expansion

## Top 20 sales and share of biologics in global market - Sales and its proportion of off-patent biologics -



Source: Modified based on the data in Evaluate Pharma



### Breakdown of top 20 sales of biologics / small molecular pharmaceuticals (# of products)

	2008 (Actual)	2014 (Actual)	2020 (Forecast)
Biologics	7	10	12
Off-patent biologics	0	0	8
Small molecular pharmaceuticals	13	10	8

Source: Modified based on the data in Evaluate Pharma

**Many biologics will go off-patent from 2015 to 2020 and potential biosimilar market will rapidly expand**

## U.S. biosimilar market finally opened!!



**Guidelines for biosimilars published in April 2015**

**Zarxio® developed by Sandoz was approved and launched in 2015.**



EUROPEAN MEDICINES AGENCY  
SCIENCE · MEDICINES · HEALTH

### EU: Guidelines are in place

Six biosimilars have been marketed starting with somatropin (human growth hormone) since 2006

1. Somatropin
2. Erythropoietin
3. Filgrastim
4. Insulin
5. Infliximab
6. Follitropin



Ministry of Health,  
Labour and Welfare

### Japan: Guidelines are in place

Biosimilars of filgrastim and infliximab have been marketed since 2013

1. Filgrastim
2. Infliximab
3. Somatropin
4. Erythropoietin
5. Insulin



### US: Market opened

Biosimilar forum was established in May 2015. Additional support by health insurers

Filgrastim  
(Approved May, 2015,  
sales started Sep, 2015)

Approval can be obtained in many countries other than US/EU/Japan, if the drug is approved in either of the three areas

(\*Some countries require approval in two or more countries among US, EU, or Japan)

# Significance of Biosimilar and Government Moves

Q: Why does not the social healthcare cost decline under the circumstance that use of generic is gradually expanding?

A: Use of expensive Innovator drugs off sets the effect of generics.

The key to healthcare cost reduction = **"Biosimilar"**

## Contribution to patients

- 1) Lower patient's cost
- 2) Available to a larger number of patients



## Contribution to society

- 3) Reduce financial pressure on healthcare cost significantly

Government move



PM Abe manifested his opinion that biosimilars would be effective for healthcare cost reduction, and the use of biosimilars should be promoted, at the Lower House Financial Committee on March 13, 2015



Supra-party federation of Diet Members launched for promotion of the use of biosimilars on March 26, 2015



Council on Fiscal and Economic Policy (Chairman: PM Abe) suggested the use of generic as an fiscal expenditure reduction plan on May 19, 2015



## Highlight 1

### Business collaboration with Mochida Pharmaceutical

- ✓ MOU signed for Oncology field biosimilar (Aug.11, 2015)
- ✓ Collaboration for commercialization of an Oncology field biosimilar

## Highlight 2

### Business and Capital collaboration with Senju Pharmaceutical

- ✓ MOU signed for Ophthalmology field biosimilar (Nov.12, 2015)
- ✓ Collaboration for commercialization of a Ophthalmology field biosimilar
- ✓ Senju has acquired Gene Techno Science stock (share 5.26%)

\*as of Nov.13

## Highlight 3

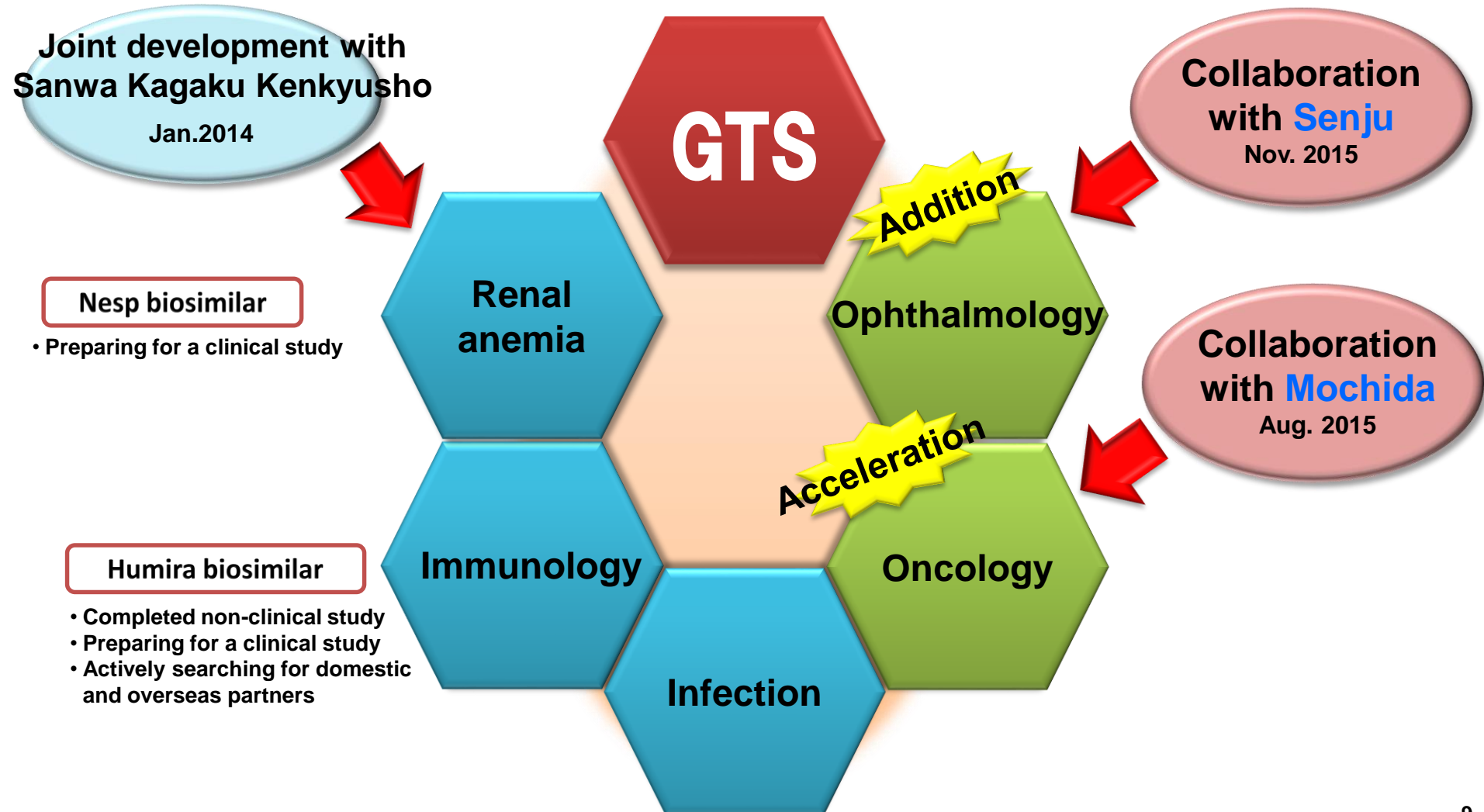
### Capital alliance with Dydo Drinco

- ✓ MOU signed for capital alliance (Jul.15, 2015)
- ✓ Management advice based on experience in the pharmaceutical industry for mutual business expansion
- ✓ Acquiring of Gene Techno Science stock by Dydo Drinco (share 3.79%)

\*as of Nov.13

# Wider Range of Biosimilar Pipeline

- 1) Addition of Ophthalmology field biosimilar!!
- 2) Acceleration of Oncology field biosimilar!!



# Market Size of the Key Pipeline of Gene Techno Science

Major pipelines have a potential market of **90 Billion JPY in Japan / 1,200 Billion JPY in the world**

## Biosimilar market\*

Japan

Global

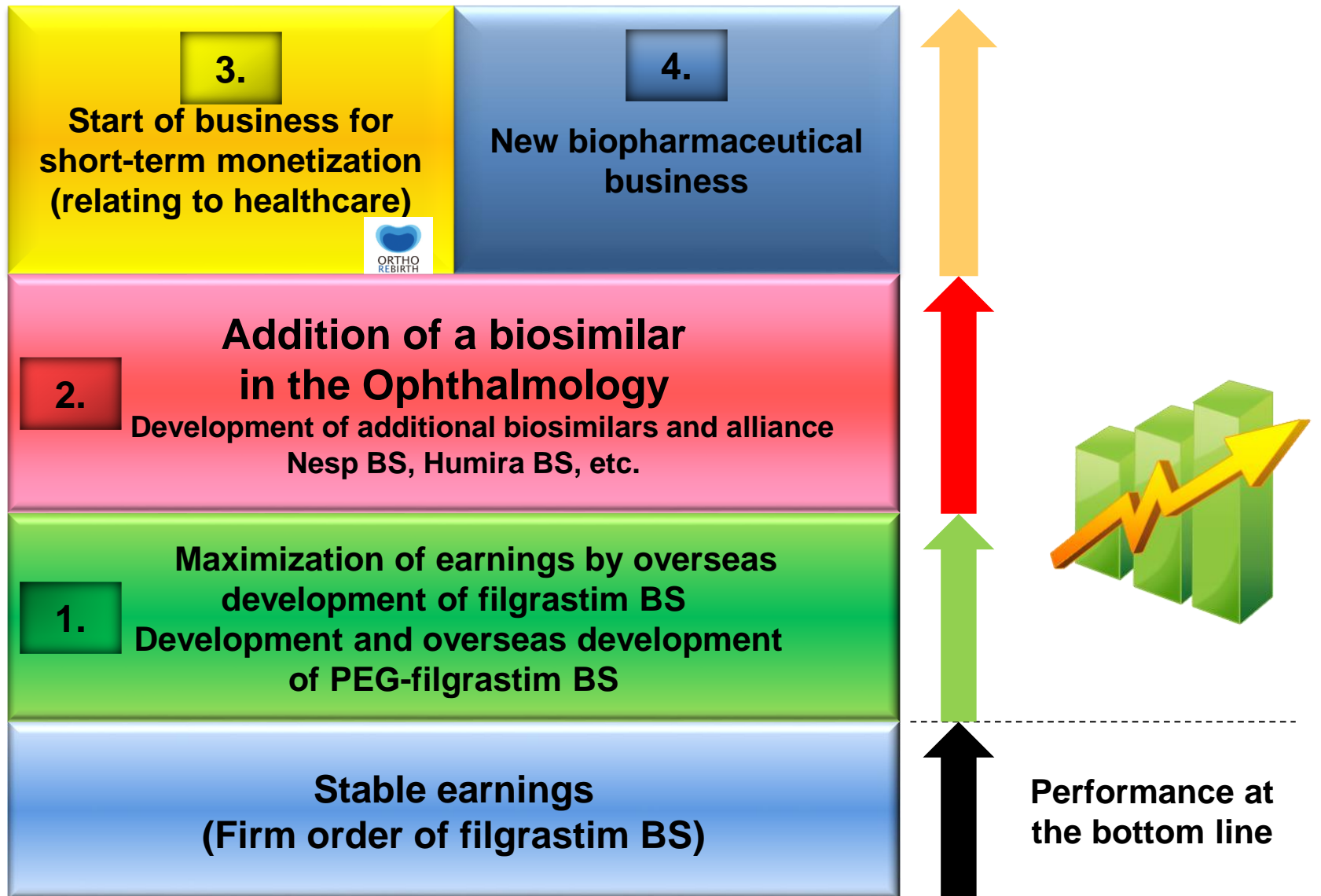
(Excluding Japan)

<p><b>Gran/Neupogen</b> (Neutropenia associated with chemotherapy) Innovator drug: 20B JPY (Japan) / 100B JPY (WW)</p>	8 B JPY	40 B JPY
<p><b>G-LASTA/Neulasta</b> (Neutropenia associated with chemotherapy) Innovator drug: 20B JPY (Japan**) / 520B JPY (WW)</p>	8 B JPY	208 B JPY
<p><b>Nesp/Aranesp</b> (Treatment for renal anemia) Innovator drug: 56 B JPY (Japan) / 230B JPY (WW)</p>	22.4 B JPY	92 B JPY
<p><b>Humira</b> (Treatment for rheumatoid arthritis) Innovator drug: 35B JPY (Japan) / 1,300B JPY (WW)</p>	14.4 B JPY	520 B JPY
<p><b>Biosimilars in the Ophthalmology field</b> (Treatment of Age-related macular degeneration AMD) Innovator drug: 60B JPY (Japan) / 730B JPY (WW)</p>	25.2 B JPY	307 B JPY
<p><b>Synagis</b> (Treatment of RS virus infection) Innovator drug: 35B JPY (Japan) / 140B JPY (WW)</p>	15.0 B JPY	59 B JPY
	<b>Total:</b>	<b>93.0 B JPY    1226 B JPY</b>

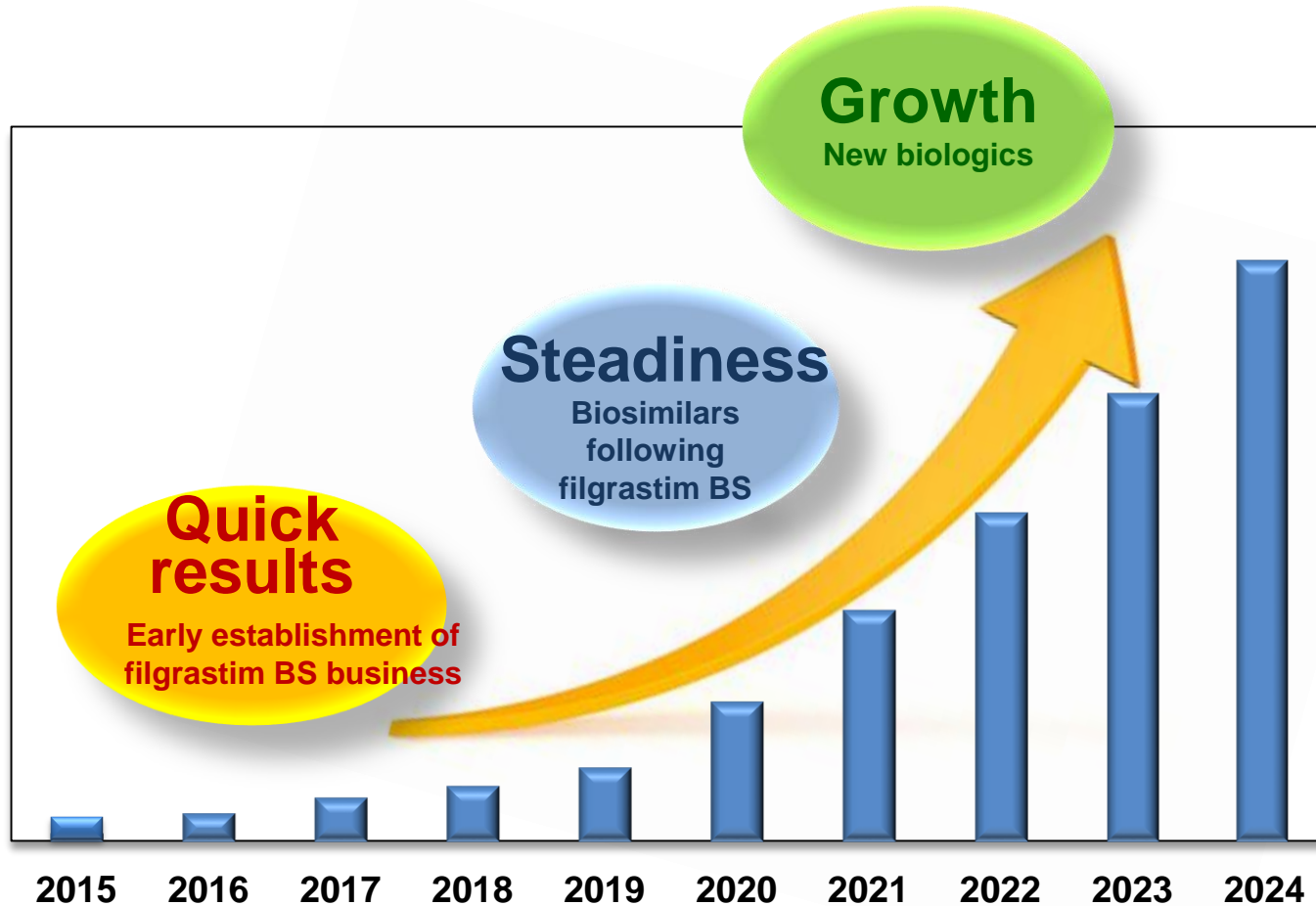
\* Assuming that approximately 40% of the innovator drug market is the biosimilar market in sales (The penetration rate of biosimilar [60%] x drug price [70% of the innovator drug] = 42%)

\*\* Used the peak sales described in the materials for determination of price of new drug (Central Social Insurance Medical Council, November 26, 2014) as a reference value since the innovator drug was launched in 2014.

# Secure Biosimilar Business & New Growth



# Middle to Long Term Sales Vision



**Sales of biosimilar drug product / drug substance and upfront and milestone revenue of new biologics**



**Thank you !!**