

Gene Techno Science Co.,Ltd.

**Results of Operations
for the Fiscal Year Ended March 31, 2015 (FY3/15)**

May 21, 2015

Gene Techno Science is the Leader in the Field of Biosimilars

At the forefront of global progress with biosimilars



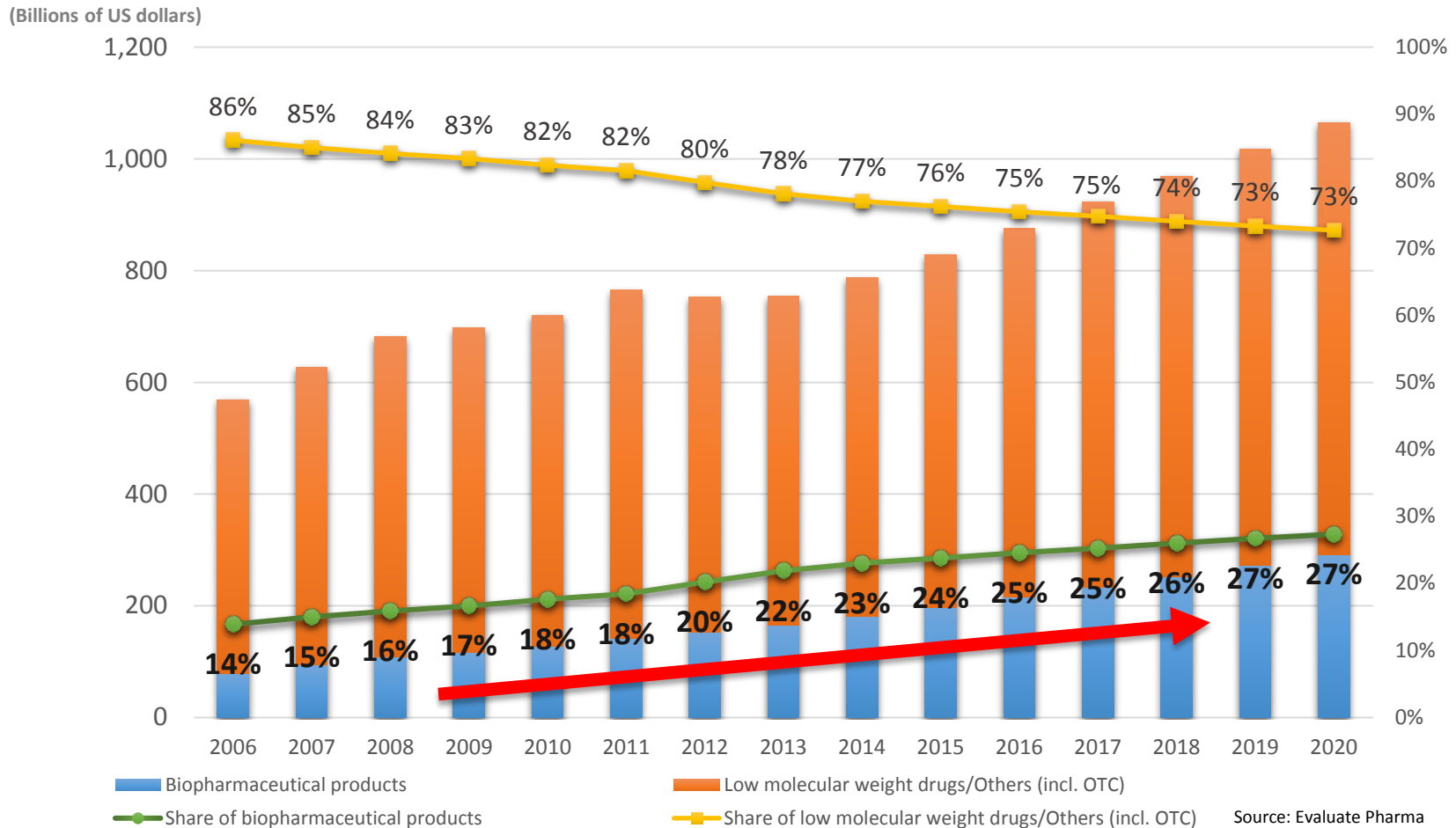
Biosimilars

GENE TECHNO SCIENCE

- ✓ Started selling Japan's first biosimilar, using Japanese biosimilar guidelines
- ✓ Working on the development of second and third biosimilars following the filgrastim biosimilar

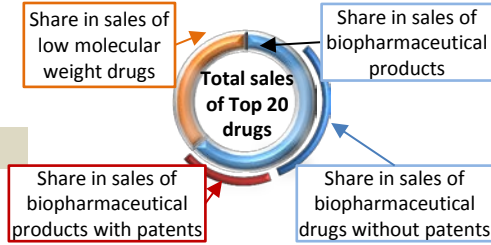
Growth of Global Pharmaceutical Sales

Worldwide Pharmaceutical Sales and the Share of Biopharmaceutical Products 2006 to 2013 sales and 2014 to 2020 forecast



The biopharmaceutical product market is expanding year after year

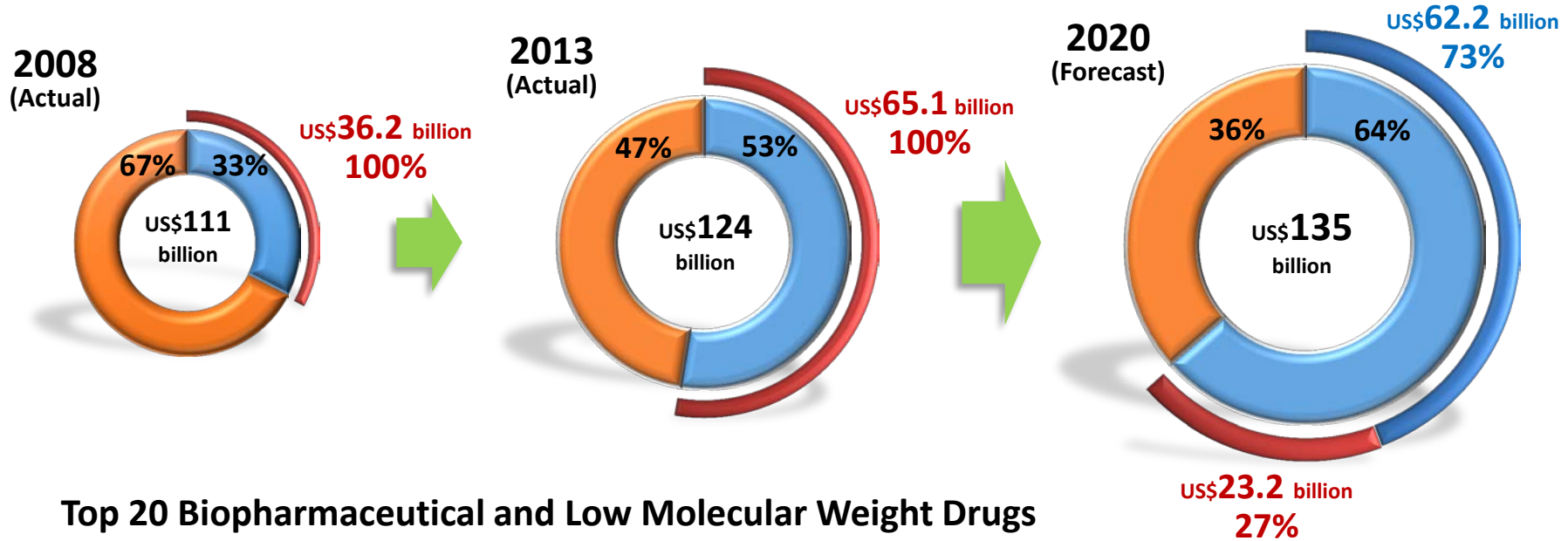
Growth of the Biopharmaceutical Product Market



Sales of Top 20 Drugs Worldwide and Share of Biopharmaceutical products

-Sales of biopharmaceutical products with expired patents and share of sales-

Source: Prepared by Gene Techno Science based on the document of Evaluate Pharma



Top 20 Biopharmaceutical and Low Molecular Weight Drugs Based on Sales (No. of drugs)

Source: Prepared by Gene Techno Science based on the document of Evaluate Pharma

	2008 (Actual)	2013 (Actual)	2020 (Forecast)
Biopharmaceutical products	7	9	12
Only biopharmaceutical products with expired patents	0	0	8
Low molecular weight drugs	13	11	8

Potential for growth of the biosimilars market will increase rapidly as many biopharmaceutical product patents expire between 2015 and 2020

The Biosimilars Market: U.S. is Emerging Following Japan and Europe

The U.S. market for biosimilars is finally open!



The FDA announced biosimilar guidelines in April 2015

In 2015, Sandoz, Inc. received approval to start manufacturing and selling Zarxio®



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

EU: Guidelines established

Since 2006, six biosimilars have been launched, starting with Somatropin (human growth hormone).



Ministry of Health, Labour and Welfare

Japan: Guidelines established

Since 2013, two biosimilars have been launched: filgrastim and Infliximab



U.S.: Market is open

Established the Biosimilars Forum in May 2015.
Health care insurance companies are supporting the use of biosimilars, too.

Most other countries permit the sale of biosimilars that have been approved by the U.S., EU and Japan. (Some countries require the approval two of these three regulatory authorities.)

The Biosimilars Market: Strong Support from the Japanese Government

The government is acting in many ways to increase the use of biosimilars.

Prime Minister Abe made a National Diet statement about promoting the use of biosimilars

At a meeting of the House of Representatives Committee on Financial Affairs on March 13, 2015, Prime Minister Abe, stated that biosimilars are an effective way to lower the cost of healthcare. In addition, he said he wants to increase the use of biosimilars by increasing the understanding of these drugs among health care professionals and others.

Formed the Parliamentary Association for Promoting Biosimilars, consisting of Diet members from many political parties

At the urging of ruling and opposition parties Diet members, a group of Diet members from many parties was formed on March 26, 2015 to increase the use of biosimilars. The objective is to submit bills for the purpose of creating an environment for increasing the use of biosimilars at medical institutions and biosimilar R&D at companies in Japan.

Proposal for measures to increase the use of generic drugs

At the Council on Economic and Fiscal Policy (chaired by Prime Minister Abe) on May 19, 2015, private-sector members proposed a system for increasing the use of generic drugs as part of measures to cut healthcare expenses, and thus government expenditures. The goal is raising the generic drug use rate target for the end of FY17 from 60% to 80% or 90%. Raising generic drug use from 60% to 100% would cut expenditures by an estimated ¥600 billion.

How will the Japanese government hold down healthcare expenditures?

The use of generic drugs is increasing, so why aren't healthcare expenditures falling?



The benefits of switching to generic drugs have been offset by the use of very expensive biopharmaceutical products.



In fact, biopharmaceutical products account for the majority of the largest drug purchases by major cancer treatment hospitals in Japan.

Biosimilars will be essential to holding down healthcare expenditures!

- ✓ Lowering these expenditures will produce benefits for even more patients
- ✓ A big reduction in pressure on financing for healthcare expenses



Financial Highlights

◆ FY3/15 Review of Operations

	Net sales	Operating income	Ordinary income	Net income	Net income per share
	(Million yen)	(Million yen)	(Million yen)	(Million yen)	(Yen)
Forecast announced on April 10, 2015 (A)	310	(970)	(946)	(948)	(397.47)
Results (B)	321	(824)	(790)	(792)	(331.86)
Change (B-A)	11	146	156	156	

Sales were slightly higher than forecast due to a small increase in the volume of filgrastim biosimilar deliveries.

Development expenses were dispersed and held down by improving development processes without any delays in projects.

FY3/16 Forecast

	Net sales (Million yen)	Operating income (Million yen)	Ordinary income (Million yen)	Net income (Million yen)	Net income per share (Yen)
FY3/15 Results (A)	321	(824)	(790)	(792)	(331.86)
FY3/16 Forecast (B)	1,022	(602)	(573)	(575)	(239.14)
Change (B-A)	701	222	217	217	

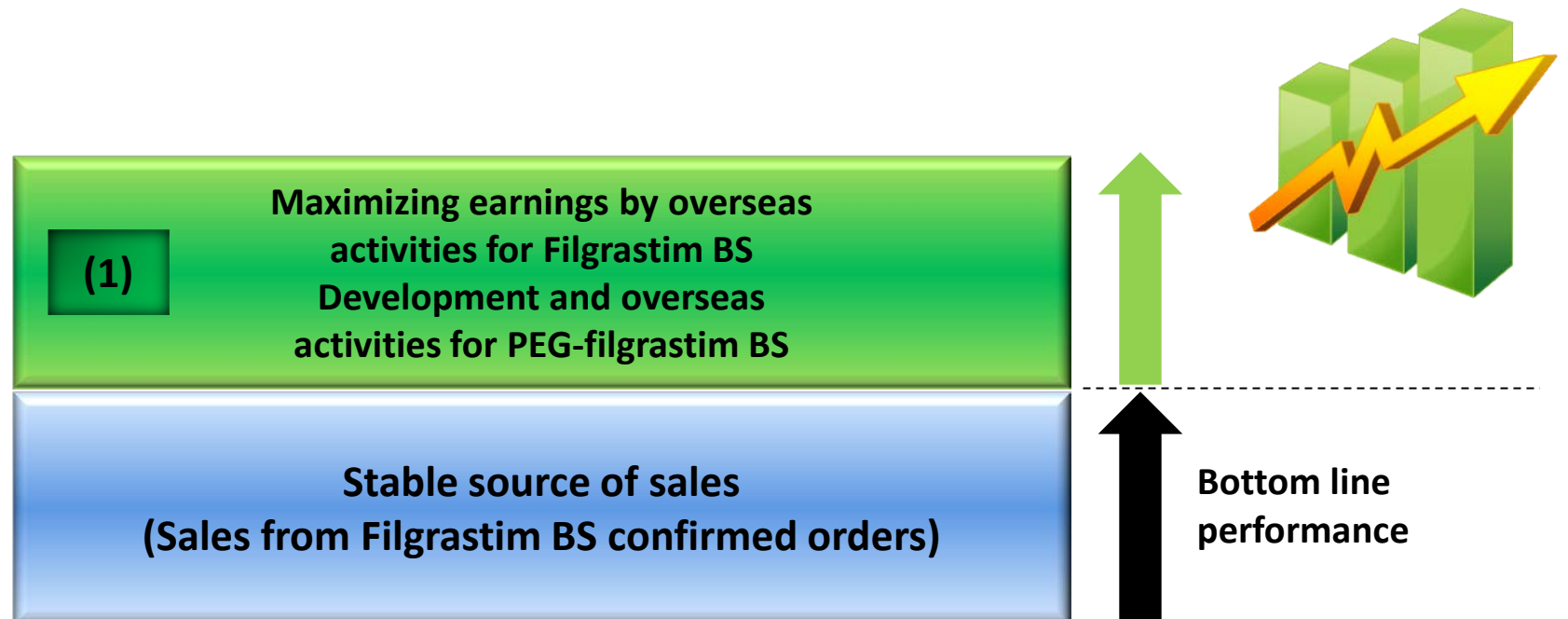
Anticipate strong sales of the filgrastim biosimilar by Fuji Pharma Co., Ltd. and Mochida Pharmaceutical Co., Ltd.

Forecast sales growth of **more than 3 times** in FY3/16

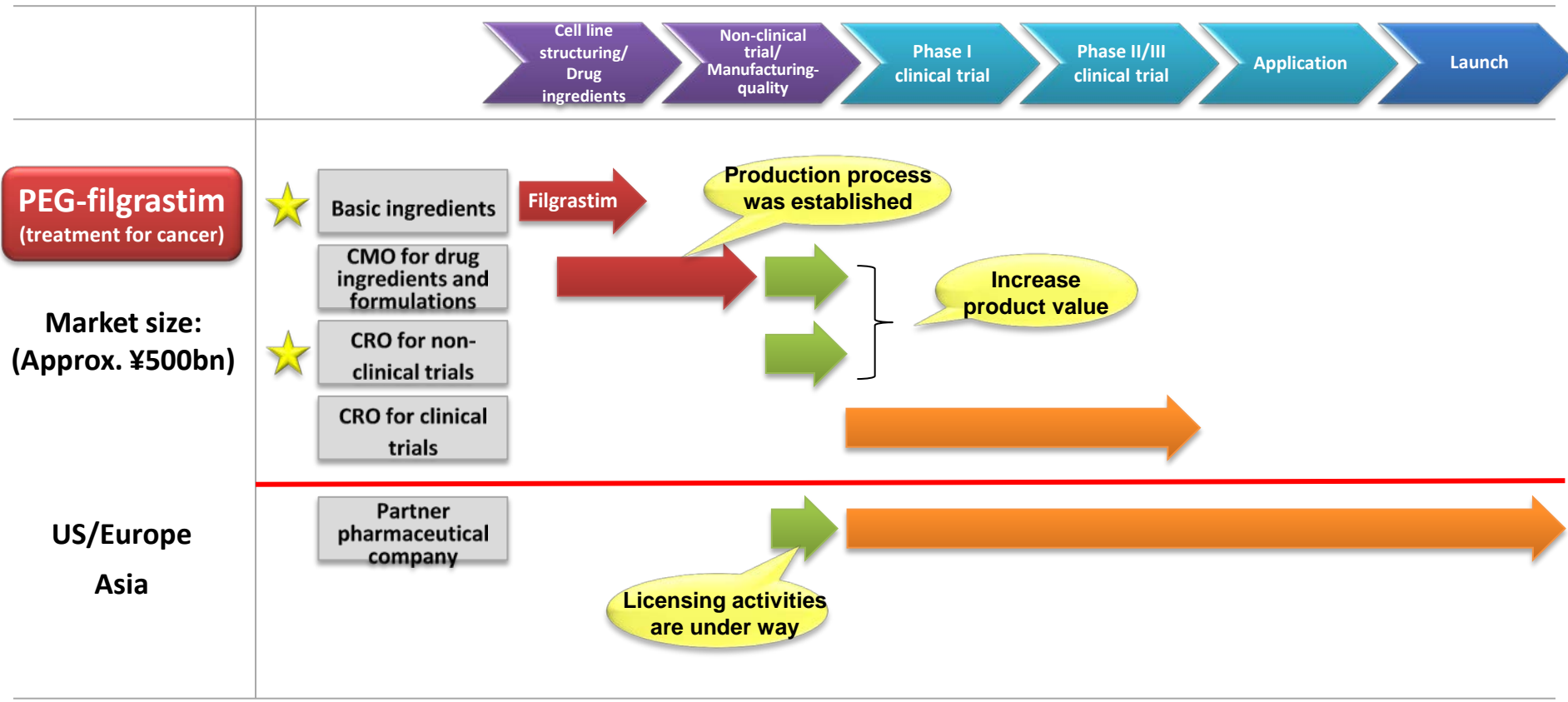
Starting in FY3/16, earnings from sales of the filgrastim biosimilar are expected to be more than fixed expenses.

- 1) This will allow us to continue R&D activities with no financial concerns.
- 2) Earnings in excess of fixed expenses will be used for R&D, **which will further increase the speed of R&D projects.**

Stable Source of Sales and Overseas Activities for Filgrastim BS/PEG-filgrastim BS



Progress with Development of PEG-filgrastim Biosimilar



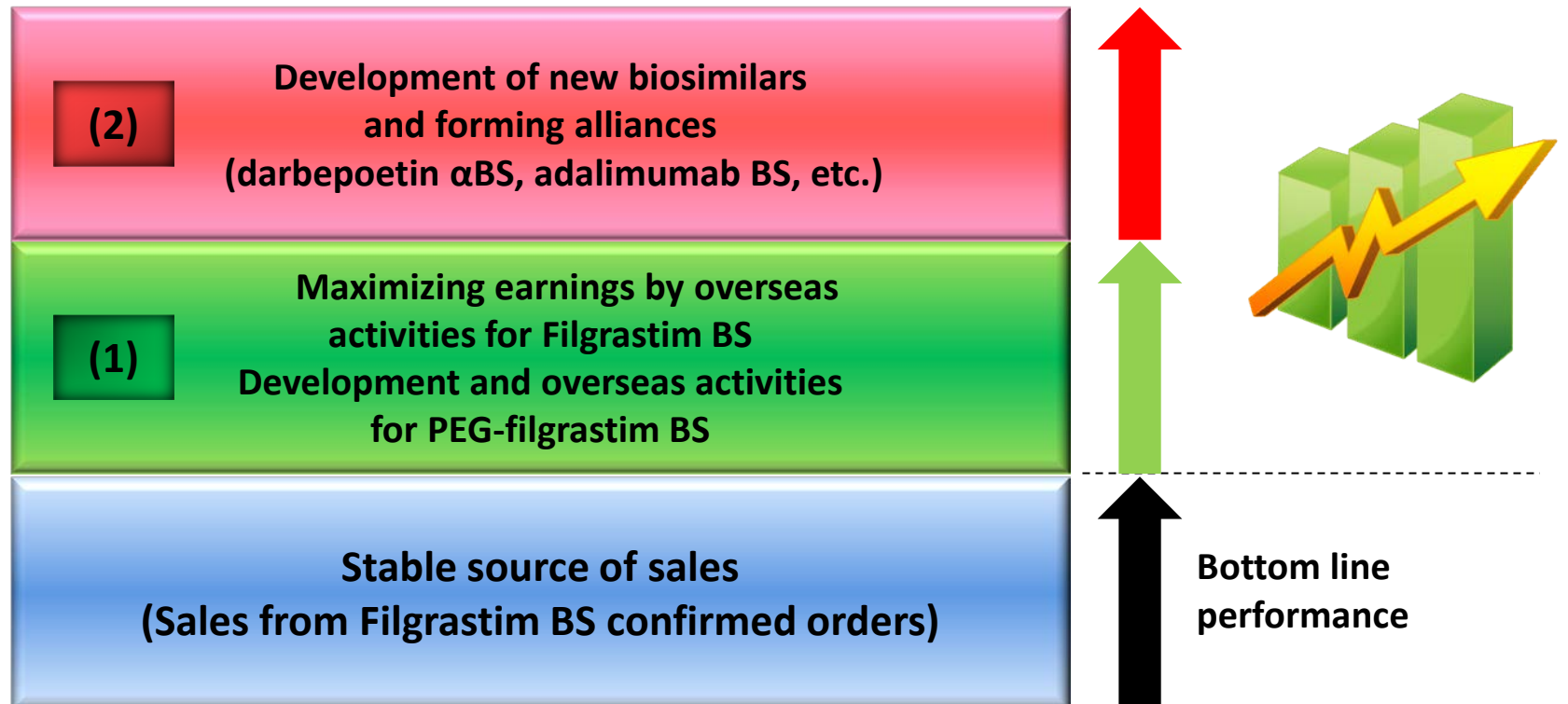
★ Secure

→ Activities up to end of FY3/15

→ Progress in FY3/16

→ Planned progress in fiscal FY3/17 onward

New Biosimilar Pipeline



Steady Progress with Development of New Biosimilar Pipeline

darbepoetin alfa

(Treatment for renal anemia)

- ✓ Preparations are under way to start clinical trials
- ✓ Steady progress with joint development activities with Sanwa Kagaku Kenkyusho

adalimumab

(Treatment for rheumatoid arthritis)

- ✓ Non-clinical trials are under way
- ✓ Currently working on forming alliances with pharmaceutical companies in Japan and other countries

Potential sales for the four major pipeline items are **¥50 billion in Japan** and **¥860 billion worldwide**

<u>Biosimilar Market*</u>	
Japan	World (excluding Japan)
¥5.2 billion	¥40 billion
¥8.0 billion	¥208 billion
¥22.4 billion	¥92 billion
¥14.4 billion	¥520 billion
<hr/>	
Total: ¥50 billion	¥860 billion

Filgrastim
(Treatment for neutropenia caused by cancer chemotherapy)
Original drug: ¥13 billion in Japan, ¥100 billion worldwide

PEG-filgrastim
(Treatment for neutropenia caused by cancer chemotherapy)
Original drug: ¥20 billion in Japan**, ¥520 billion worldwide

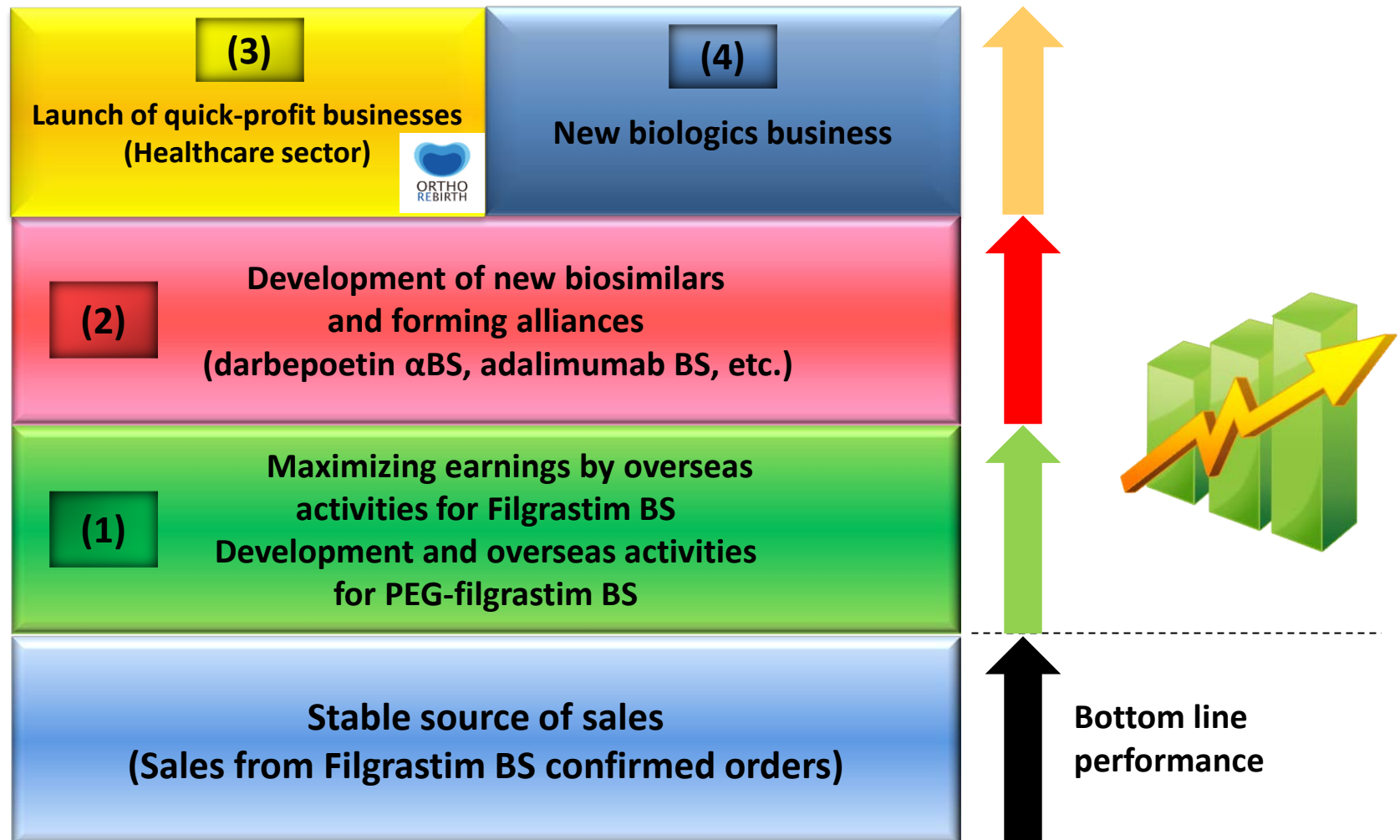
darbepoetin alfa
(Treatment for renal anemia)
Original drug: ¥56 billion in Japan, ¥230 billion worldwide

adalimumab
(Treatment for rheumatoid arthritis)
Original drug: ¥36 billion in Japan, ¥1,300 billion worldwide

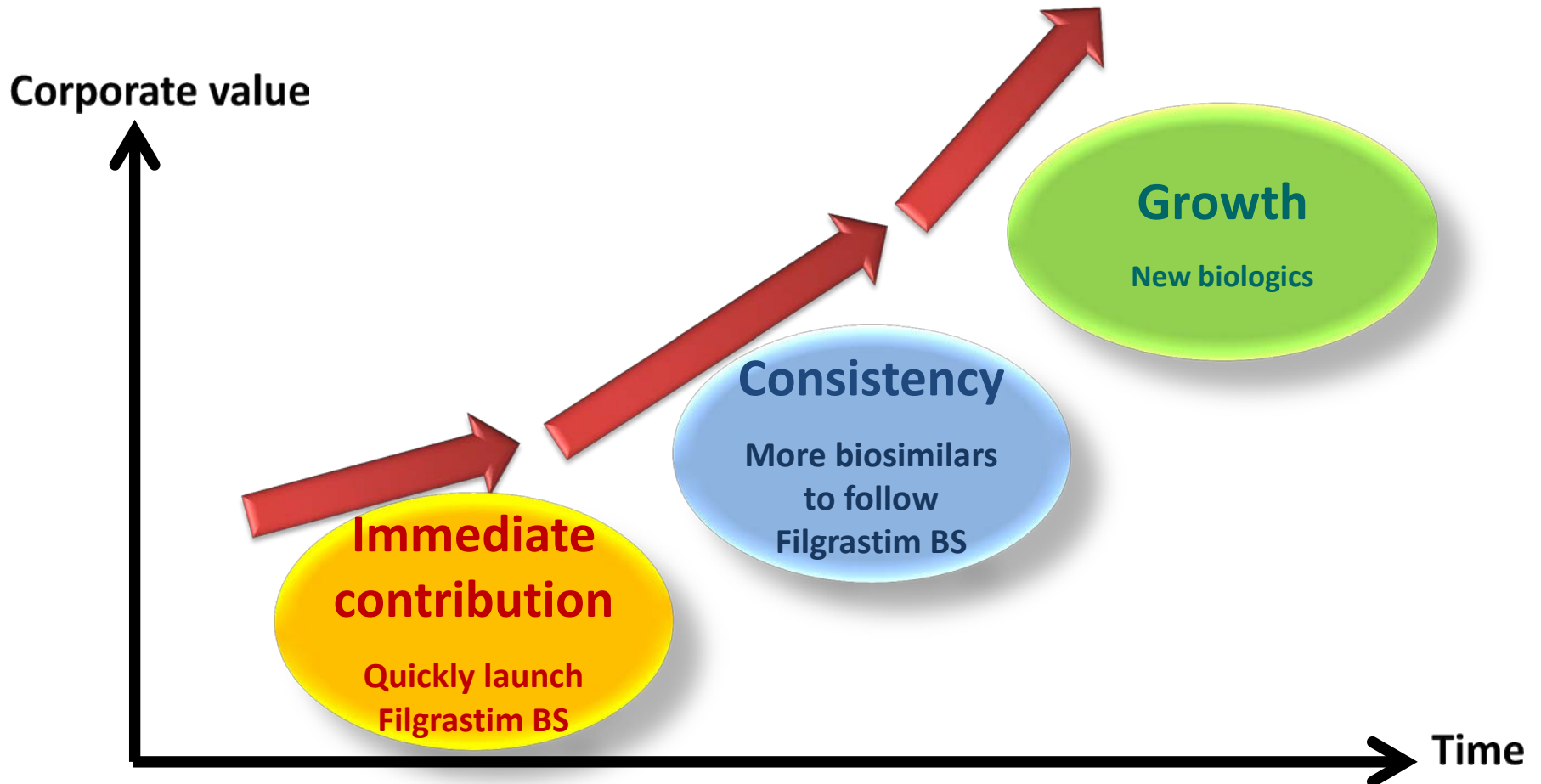
* Assume the biosimilar market is about 40% of sales of original patented drugs
(Biosimilar penetration rate 60% x Price of 70% of original drug = 42%)

** Since original drug sales started in 2014, estimate uses as reference peak sales in the new drug price calculation materials (Central Social Insurance Medical Council, November 26, 2014)

Consistent Progress with Quick-profit Businesses and the New Biologics Business



Be a Bio-venture Firm with Profitability and Growth Potential!



Become an innovative bio-venture firm with profitability and the growth potential!

Gene Techno Science is constantly aiming for higher goals!

 **Disclaimer**

This presentation was prepared for the purpose of providing information about the current operations of Gene Techno Science Co.,Ltd.

Information in this presentation is based on the current economic and social situation as well as assumptions that Gene Techno Science Co.,Ltd. believes are reasonable. This information may be revised without prior notice due to a change in the operating environment or for other reasons.

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Boundless Capability of Drug Discovery from the Ground