



*Unlimited Drug Discovery from the Beginning*

Gene Techno Science Co., Ltd.

Financial results for the fiscal  
year ending March 2016

20<sup>th</sup> May, 2016

Stock Code: 4584

# Corporate overview and business highlights

# Corporate Overview

Representative	Masanari Kawaminami, President	
Establishment	March 2001	
Capital Stock	3,037,041 K JPY (as of April 13, 2015)	
Address	Headquarters	1, Kita-2, Nishi-9, Chuo-ku, Sapporo, Hokkaido, Japan
	Tokyo Office	2-10-8, Nihonbashi, Chuo-ku, Tokyo
	Laboratory	Center for Promotion of Platform for Research on Biofunctional Molecules Creative Research Institution, Hokkaido University North 21, West 11, Kita-ku, Sapporo, Hokkaido

Time	Event
Mar 2001	GTS founded to translate findings from research conducted at the Institute for Genetic Medicine at Hokkaido University into diagnostic reagents and drugs
Jun 2007	Out-licensed anti- $\alpha$ 9 integrin antibody to Kaken Pharmaceutical Co., Ltd.
Oct 2007	Signed joint development agreement for filgrastim (G-CSF) biosimilar with Fuji Pharma, Co., Ltd.
Nov 2012	Obtained marketing approval for filgrastim biosimilar
Nov 2012	GTS listed on the Tokyo Stock Exchange Mothers Index
May 2013	Filgrastim biosimilar listed in NHI price list and brought to market
Aug 2013	Formed capital and business alliance for biosimilars with Itochu Chemical Frontier Corporation
Jan 2014	Signed joint development agreement for darbepoetin alfa biosimilar with Sanwa Kagaku Kenkyusho Co., Ltd.
Aug 2015	Signed agreement with Mochida Pharmaceutical Co., Ltd. to develop biosimilars in the field of oncology
Nov 2015	Signed agreement with Senju Pharmaceutical Co., Ltd. to develop biosimilars in the field of ophthalmology
Mar. 2016	Signed agreement for a capital tie-up and business alliance with Noritsu Koki o.,Ltd.

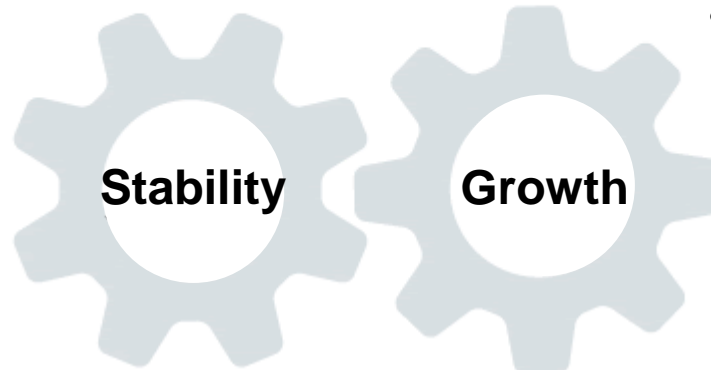
## Hybrid Business Model of Biosimilars and New Biologics

### Development in Biosimilars

- Development and provision of drug substances
- Alliances with pharmaceutical companies



Stable and profitable business at early stage



### Development in New Biologics

- R&D centered on therapeutic antibodies
- Laboratory located at Hokkaido University Creative Research Institution

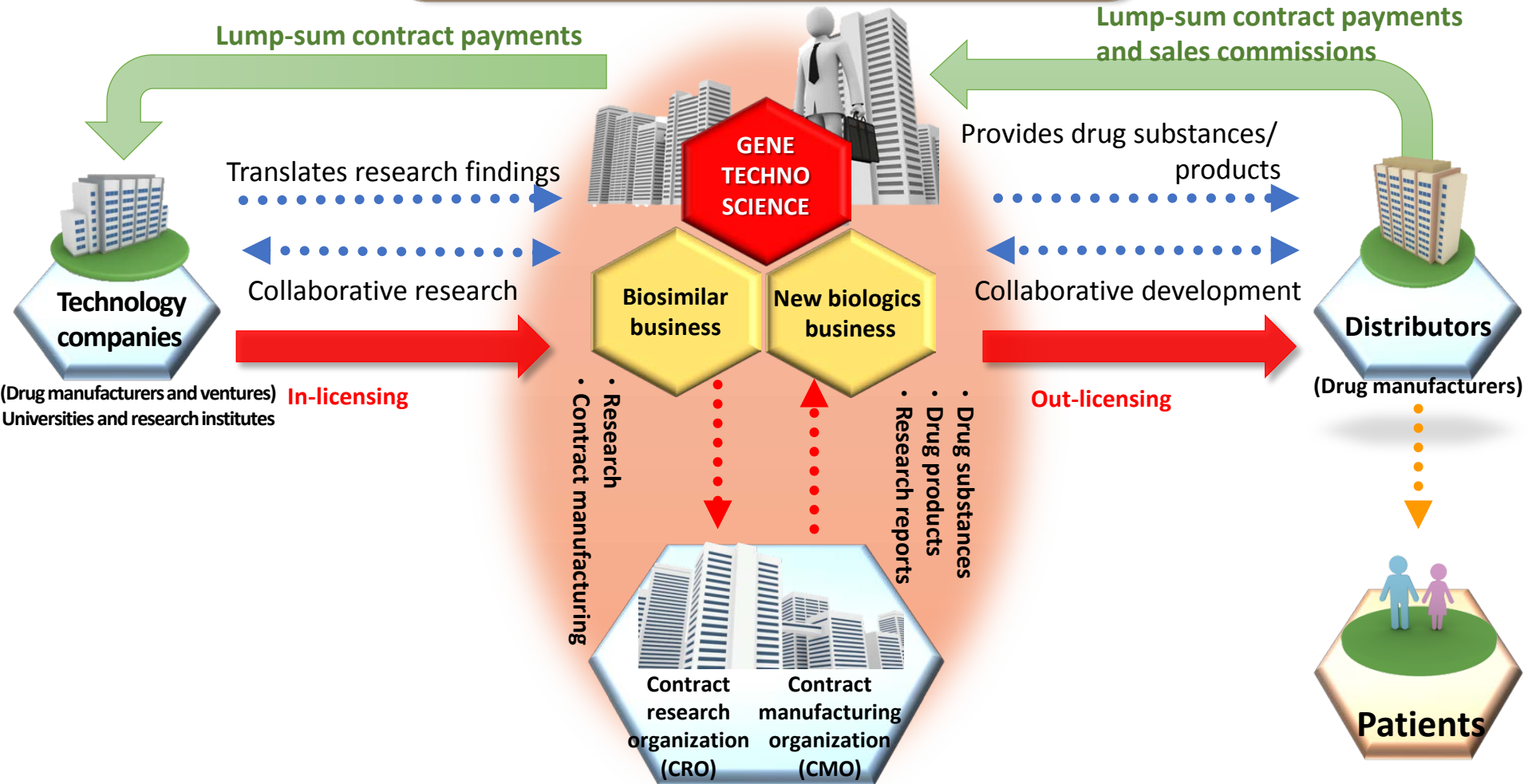


Targeting high growth

# R&D structure: Fabless model

## Advantages of a fabless business model

- 1) Flexibility: Can structure the optimal collaborative organization for each project
- 2) Speed: Can start projects quickly and change plans quickly
- 3) Investment risk: Avoids large capital investments in items such as manufacturing equipment



# Highlights of Operating Results

## ◆ FY 2016 Financial Results

	Net Sales (Million Yen)	Operating Income (Million Yen)	Ordinary Income (Million Yen)	Net Income (Million Yen)	Net Income per share (Yen)
Revised Forecast as of 12 <sup>th</sup> Nov. 2015 (A)	1,132	△1,045	△1,019	△1,021	△404.73
Results FY2016 (B)	1,160	△820	△785	△787	△302.91
Difference (B- A)	28	225	234	234	

The sales of Filgrastim Biosimilar was as expected.

Decrease in R&D expense through improvement in the development process without delay to minimize additional costs.

# Revised Forecast of Operational Results FY2017

## ◆ Forecast of Net Sales and Net Income

	Net Sales (Million Yen)	Operating Income (Million Yen)	Ordinary Income (Million Yen)	Net Income (Million Yen)	Net Income per share (Yen)
Result FY 2016 (A)	1,160	△820	△785	△787	△302.91
Forecast FY 2017 (B)	1,685	△493	△494	△497	△113.07
Difference (B- A)	525	327	291	290	

- ✓ Increase in sales of Filgrastim Biosimilar.
- ✓ Milestone and Upfront payments from partners.

- ✓ Increased sales can **support the fixed costs**.
- ✓ Surplus profits will be assigned for R&D expense **to accelerate the R&D and also to compress the loss**.

## ◆ Forecast of R&D expense

	R&D expense (Million Yen)
Result of FY 2016 (A)	1,075
Forecast FY (B)	1,283
Difference (B- A)	208

Accelerate the R&D to enable market launch of the pipelines.

## Highlight 1

### Business and Capital collaboration with Noritsu Koki Co.,Ltd.

- ✓ Agreement in Business and Capital collaboration in Biologics Business including start up of new Bio Business (28<sup>th</sup> March, 2016)
- ✓ **Third-party allotment (2 billion Yen) (13<sup>th</sup> April, 2016)**
- ✓ **On-going Takeover bid by 30<sup>th</sup> May, 2016.**

## Highlight 2

### Business collaboration with Mochida Pharmaceutical Co.,Ltd.

- ✓ Memorandum on business collaboration of Biosimilar in oncology field. (11<sup>th</sup> August, 2015)

## Highlight 3

### Business and Capital collaboration with Senju Pharmaceutical Co.,Ltd.

- ✓ Memorandum on Business and Capital collaboration of Biosimilar in ophthalmology area 12<sup>th</sup> November, and a **Joint Commercialization agreement on 12<sup>th</sup> May, 2016.**
- ✓ Acquisition of shares by Senju Pharmaceutical Co.,Ltd.

## Highlight 4

### Business collaboration with Changchun Changsheng Life Sciences LTD.

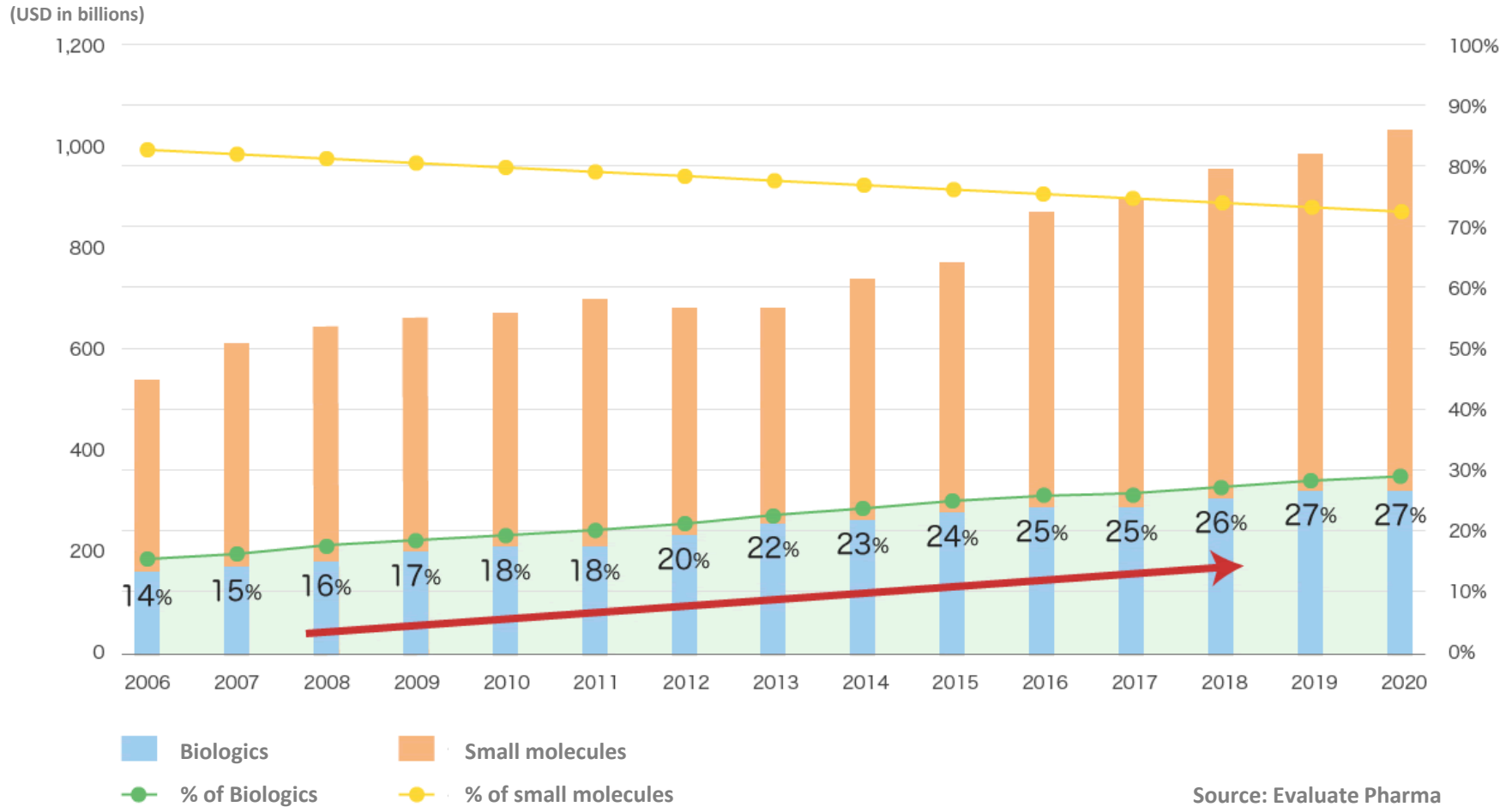
- ✓ **Memorandum for Joint Commercialization of Biosimilars in China on 12<sup>th</sup> May, 2016.**



# **Biologics market**

- **New biologics and biosimilars** -

## Global gross sales of pharmaceuticals and share of biologics Actual in 2006-2014 / Forecast in 2015-2020



**Biologics market is steadily expanding**

# Global Sales Ranking of Major Pharmaceuticals (2014)



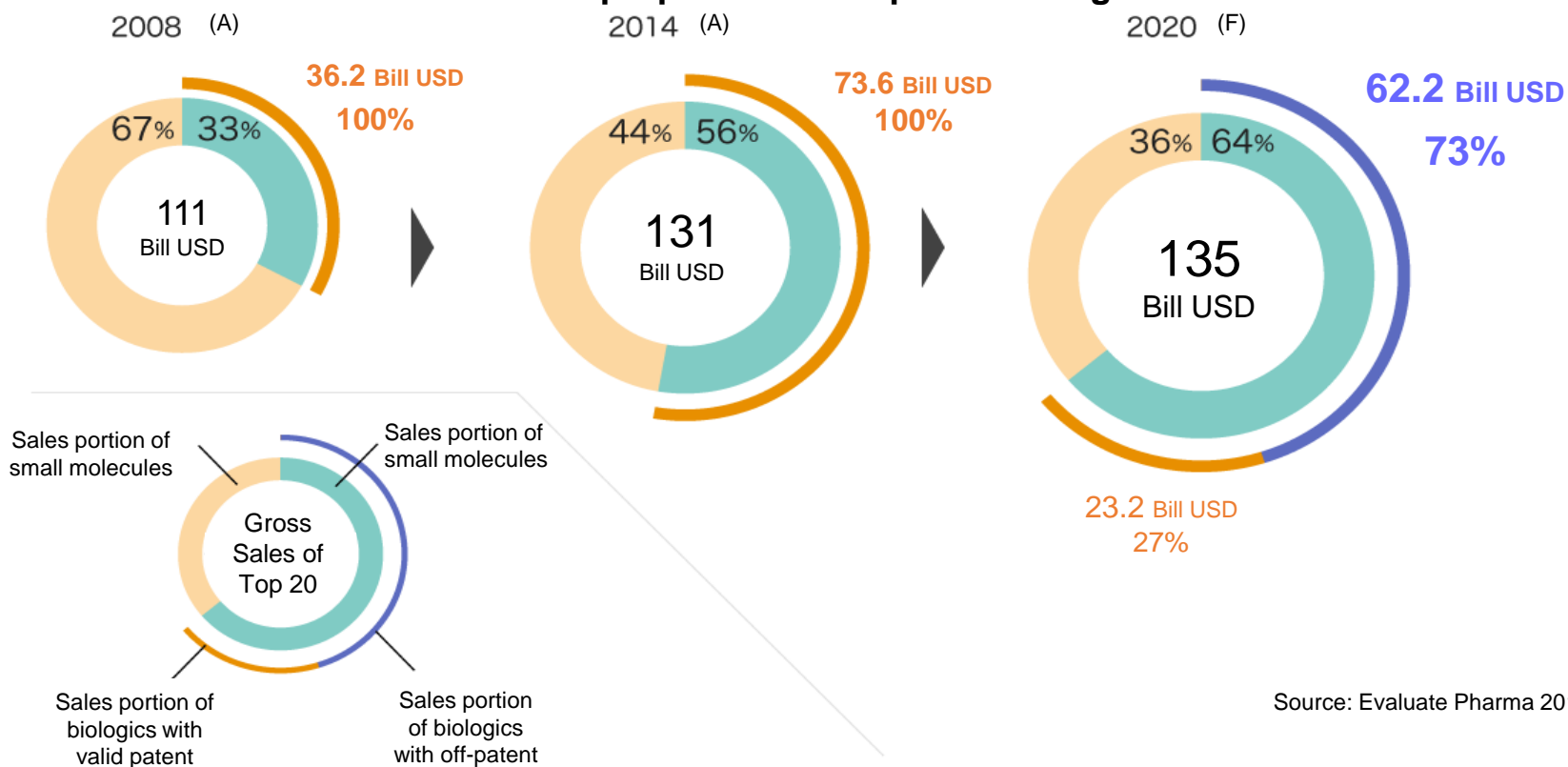
Ranking	Product name	Generic name	Indication	Manufacturer	Sales (USD in millions)
1	Humira	Adalimumab	Rheumatoid/psoriasis	Abbvie/Eisai	12,890
2	Sovaldi	Sofosbuvir	Hepatitis C	Gilead Sciences	10,283
3	Enbrel	Etanercept	Rheumatoid/psoriasis	Amgen/Pfizer/Takeda	8,915
4	Remicade	Infliximab	Rheumatoid/Crohn's disease	J&J/Merck/ Mitsubishi Tanabe	8,807
5	Lantus	Insulin	Diabetes mellitus	Sanofi	8,428
6	Rituxan	Rituximab	Anti-cancer drug (lymphoma)	Biogen/Roche/Chugai	7,547
7	Seretide	Salmeterol	Anti-asthmatic drug	Glaxo Smith Kline	7,058
8	Avastin	Bevacizumab	Anti-cancer drug/colon , breast	Genentech/Roche/Chugai	7,018
9	Herceptin	Trastuzumab	Anti-cancer drug/breast cancer	Genentech/Roche/Chugai	6,863
10	Januvia	Sitagliptin	Diabetes Mellitus	Merck/Daewoo	6,358
11	Crestor	Rosuvastatin	Hyperlipidemia	Shionogi/Astra Zeneca	5,987
12	Lyrica	Pregabalin	Nerve pain	Pfizer	5,209
13	Revlimid	Lenalidomide	Field of cancer	Celgene	4,980
14	Gleevec	Imatinib	Field of cancer	Novartis	4,746
15	Abilify	Aripiprazole	Depression	Otsuka Pharmaceutical	4,638
16	Neulasta	PEG filgrastim	Field of cancer	Amgen/Kyowa Hakko Kirin	4,599
17	Nexium	Esomeprazole	Gastritis, peptic ulcer	Astra Zeneca	4,325
18	Lucentis	Ranibizumab	Age-related macular degeneration	Novartis/Roche	4,301
19	Spiriva	Tiotropium	Obstructive pulmonary disease	Pfizer/Boehringer	4,300
20	Prevenar 13	Pneumonia vaccine	Pneumonia vaccine	Pfizer	4,297

❖ Red letters represent biologics.

# Biologics Market Expansion

## Top 20 sales and share of biologics in global market

- Sales and its proportion of off-patent biologics -



Source: Evaluate Pharma 2015

### No. of Biologics / Small Molecules of Top 20 Items

	2008 (A)	2014 (A)	2020 (F)
<b>Biologics</b>	<b>7</b>	<b>10</b>	<b>12</b>
<b>Off-patent biologics</b>	<b>0</b>	<b>0</b>	<b>8</b>
<b>Small molecules</b>	<b>13</b>	<b>10</b>	<b>8</b>

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

# Biosimilar Market Expansion: US Market is now Open

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



**Guidelines for biosimilars published in April 2015**  
**Zarxio® produced by Sandoz obtained manufacturing and marketing approval in 2015.**



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

## EU: Guidelines in place

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

- 1. Somatropin
- 2. Erythropoetin
- 3. Filgrastim
- 4. Insurin
- 5. Infliximab
- 6. Follitropin



Ministry of Health, Labour and Welfare

## Japan: Guidelines in place

Biosimilars of filgrastim and infliximab have been marketed since 2013.

- 1. Filgrastim
- 2. Infliximab
- 3. Somatropin
- 4. Erythropoetin
- 5. Insurin



## US: Market opened

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

- Filgrastim
- Approval: March, 2015
- Market Launch: Sep., 2015

**Approval may be obtained in many countries other than the US, EU, and Japan if the drug is approved in one of the three areas**  
(\*Some countries require approval in two or more countries among US, EU, or Japan)

**Q: Why is the medical expense increasing with increased use of generics?**

**A: Expensive biologics are used more frequently, offsetting the effect of switching to generics.**

**Lower Medical expense = “Biosimilars”**

## Contribution to individuals

- I. Lower individual charge by lower medical cost.
- II. More patients can use the drugs.



## Contribution to the society

- III. Large decrease in the medical expenditure.

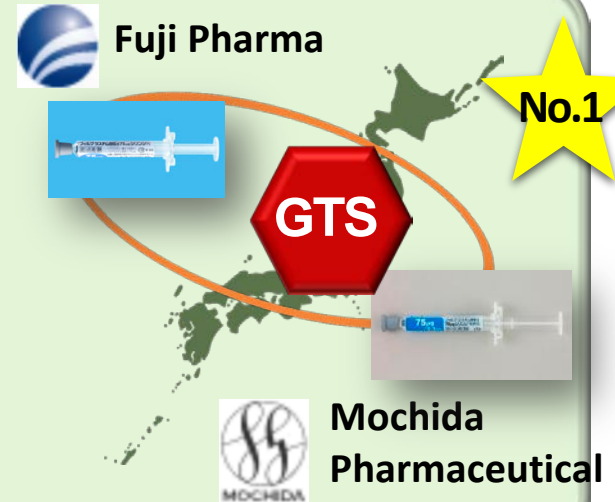
# Biosimilar Business

## ◆ Launch of Filgrastim Biosimilar

**1st biosimilar launched in accordance with the Japanese biosimilar guideline.**

Nov. 2012 Obtained approval for manufacturing and marketing by Japanese authority.

May 2013 Launched by Fuji Pharma Co., Ltd and Mochida Pharmaceutical Co., Ltd



◆ GTS: Development of Drug Substance



◆ Fuji + Mochida: Clinical studies and marketing.

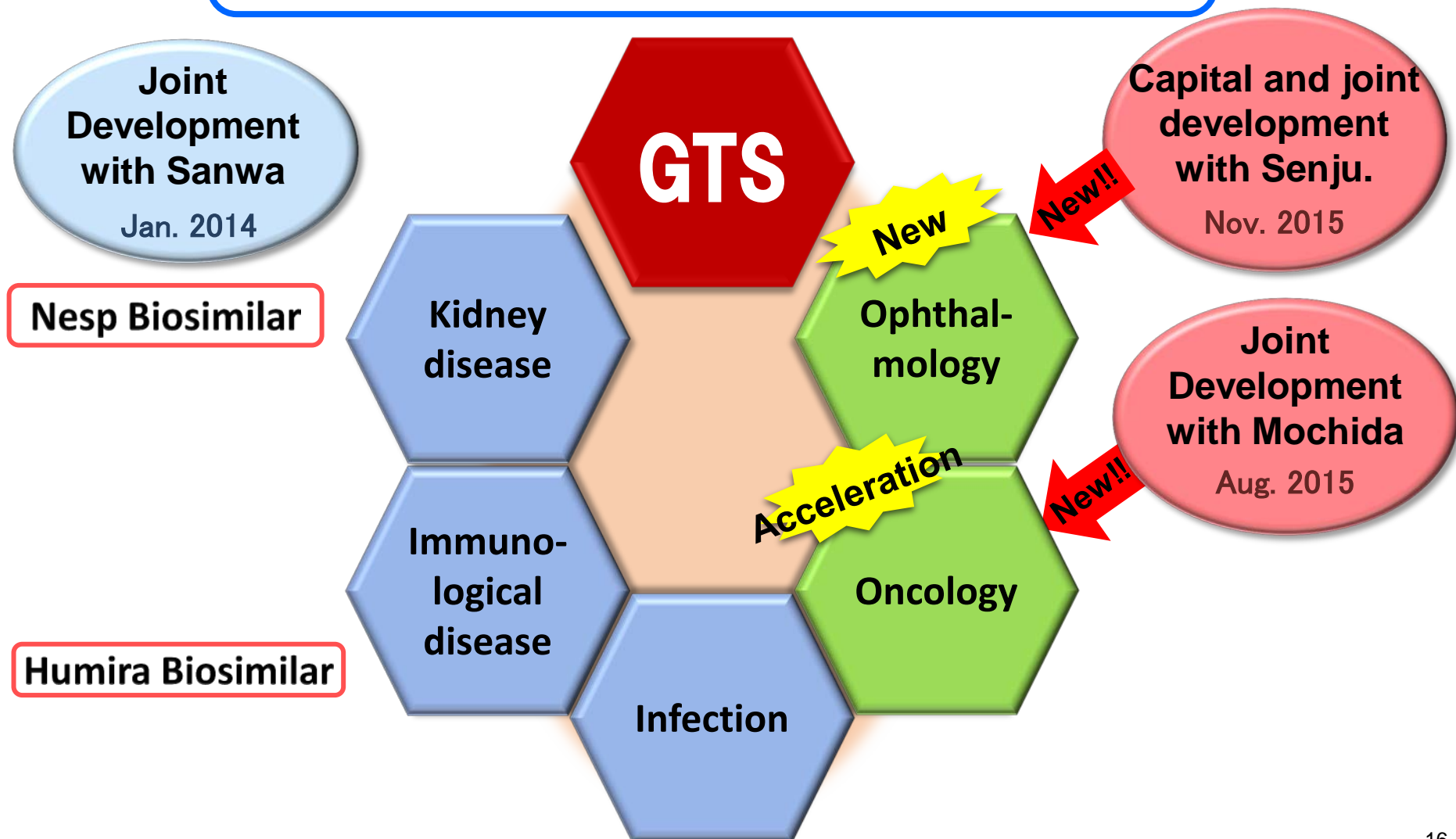
**Filgrastim BS inj. ○○μg Syringe「F」/「Mochida」**

**Sales in FY 2016 is expected to grow steadily.**



# Strengthening Biosimilar Portfolio

- 1) Ophthalmology area added!!
- 2) Acceleration of development in Oncology area!!



# Becoming an affiliate of Noritsu Koki Co., Ltd.

④

**Start up of  
new Bio-tech  
Business**

**Towards the 2<sup>nd</sup> stage of Biologics!!**

## 【Details of Capital tie-up】

**1<sup>st</sup> Step: Third-party allotment Funding: About 2 billion Yen  
Subscriber Launchpad12 Limited**

**2<sup>nd</sup> Step: Takeover bid to be the subsidiary  
Buyer Launchpad12 Limited**

## 【Details of Alliance】

- (1) Mutual cooperation in biologics business.
- (2) Capital tie-up with subsidiaries of NK Relations.
- (3) Mutual cooperation of investment in biotech companies.
- (4) Mutual cooperation in search and commercialization for bio technology including new biologics, regenerative medicine, diagnostic reagent, gene diagnostics, health functional foods, healthcare service.
- (5) Utilization of analytical capability of medical database and big-data that the subsidiary of NK Relations owns in order to support commercialization of biologics.
- (6) Utilization of the business network and workforce of NK Relations and GTS each other to commercialize the above (1) - (5) in and outside Japan.

※ Launchpad12 Limited is a company established by NK Relations Co., Ltd., a wholly owned subsidiary of Noritsu Koki Co.,Ltd.

# Details of third-party allotment and takeover bid

## 1<sup>st</sup> Step: Third-party allotment

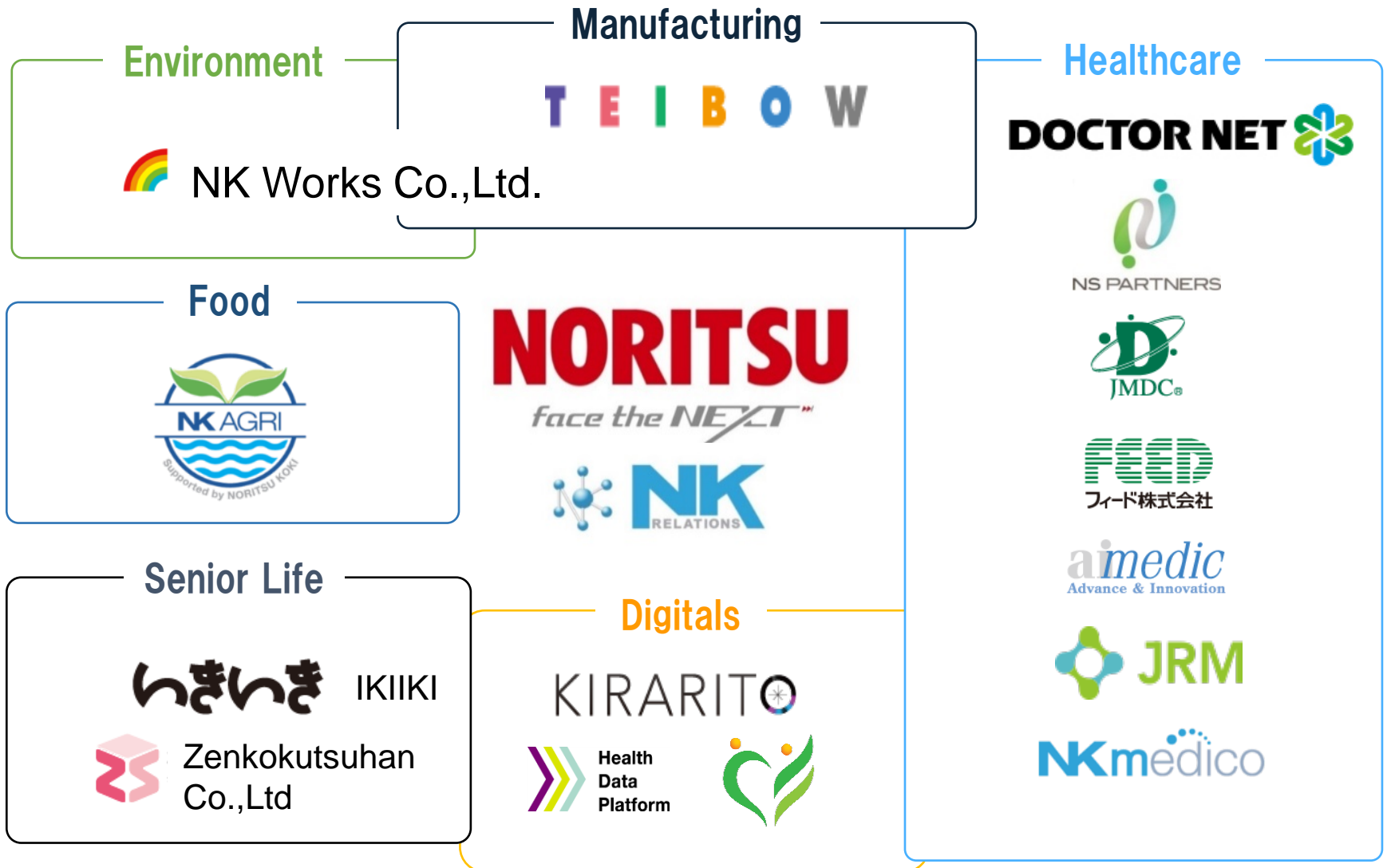
<b>Subscriber</b>	<b>Launchpad12 Limited</b>
<b>Issued Shares</b>	<b>816,327</b>
<b>Issue Price</b>	<b>JPY2,450 / stock</b>
<b>Payment Due Date</b>	<b>13<sup>th</sup> April, 2016</b>
<b>Funding Amount</b>	<b>JPY2,000,001,150-</b>

## 2<sup>nd</sup> Step: Takeover bid

<b>Buyer</b>	<b>Launchpad12 Limited</b>
<b>No. of Acquisition</b>	<b>Not limited✕</b>
<b>Purchase Price</b>	<b>JPY3,000 / stock</b>
<b>Period of Takeover Bid</b>	<b>15<sup>th</sup> April 2016 to 30<sup>th</sup> May 2016</b>
<b>* The number of acquisition is not limited; however, the listing will be maintained.</b>	

# Start up of New Bio Business

## Stable profit through business changeover



“2<sup>nd</sup> Stage of Noritsu”: Focusing on main 3 fields for funding and development.

Focusing on profitable area

## Data analysis of medical data

- Prescription database
- Database of diagnostic imaging
- Database of medicines

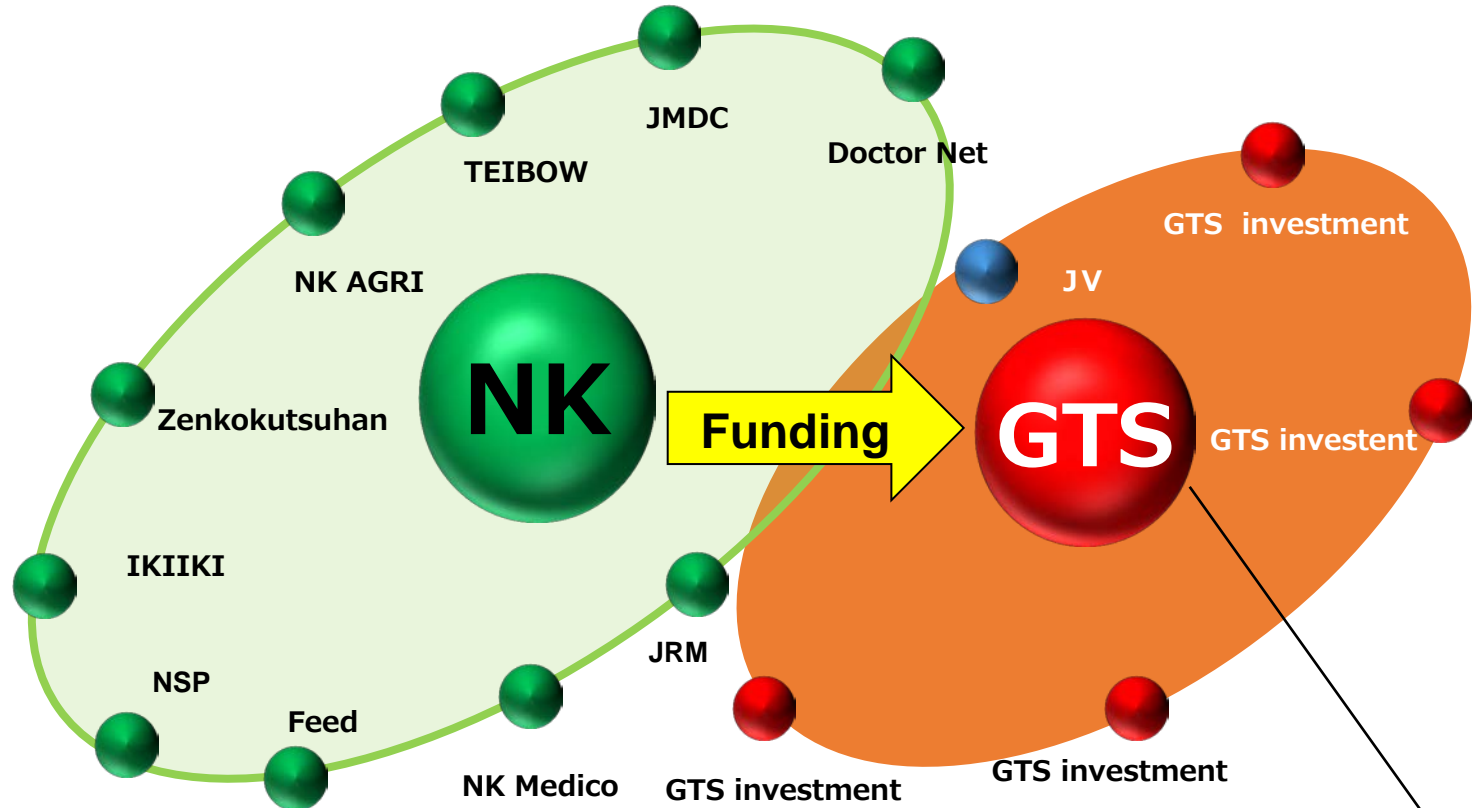
## Biologics

- Biologics
- Regenerative medicine
- Diagnostics

## Digitals

- Machine Learning (AI)
- Fintech
- Cloud Sourcing

**【Goal】 To be the Core of Noritsu group driving the bio business area!**



Not only the current pipelines but also initiating M&A of potential biologics partners.





1st Japanese group specializing  
in various Bio business.

**GTS**

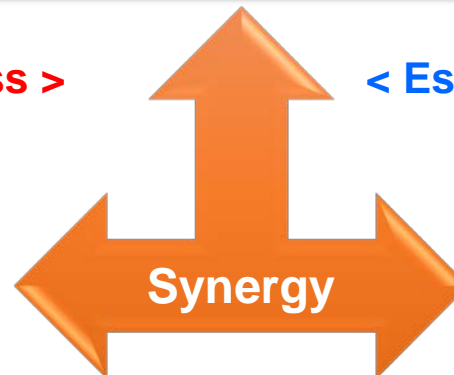
**NK**

## < Establishment of stable business >

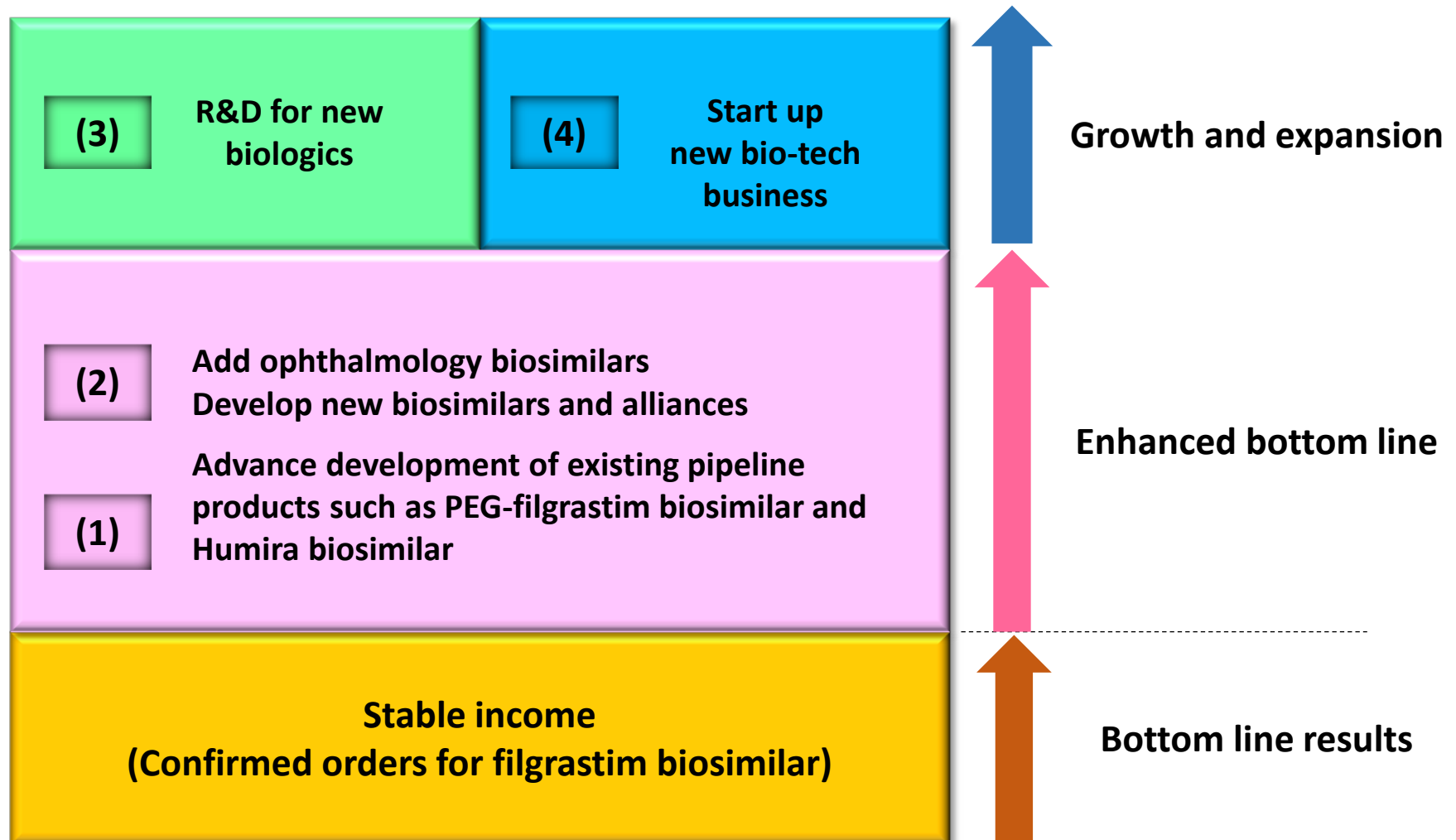
- ✓ Fundraising from NK for GTS's R&D cost
- ✓ Entry of new bio business field, including regenerative medicine
- ✓ Networking & human resource

## < Establishment of new core business >

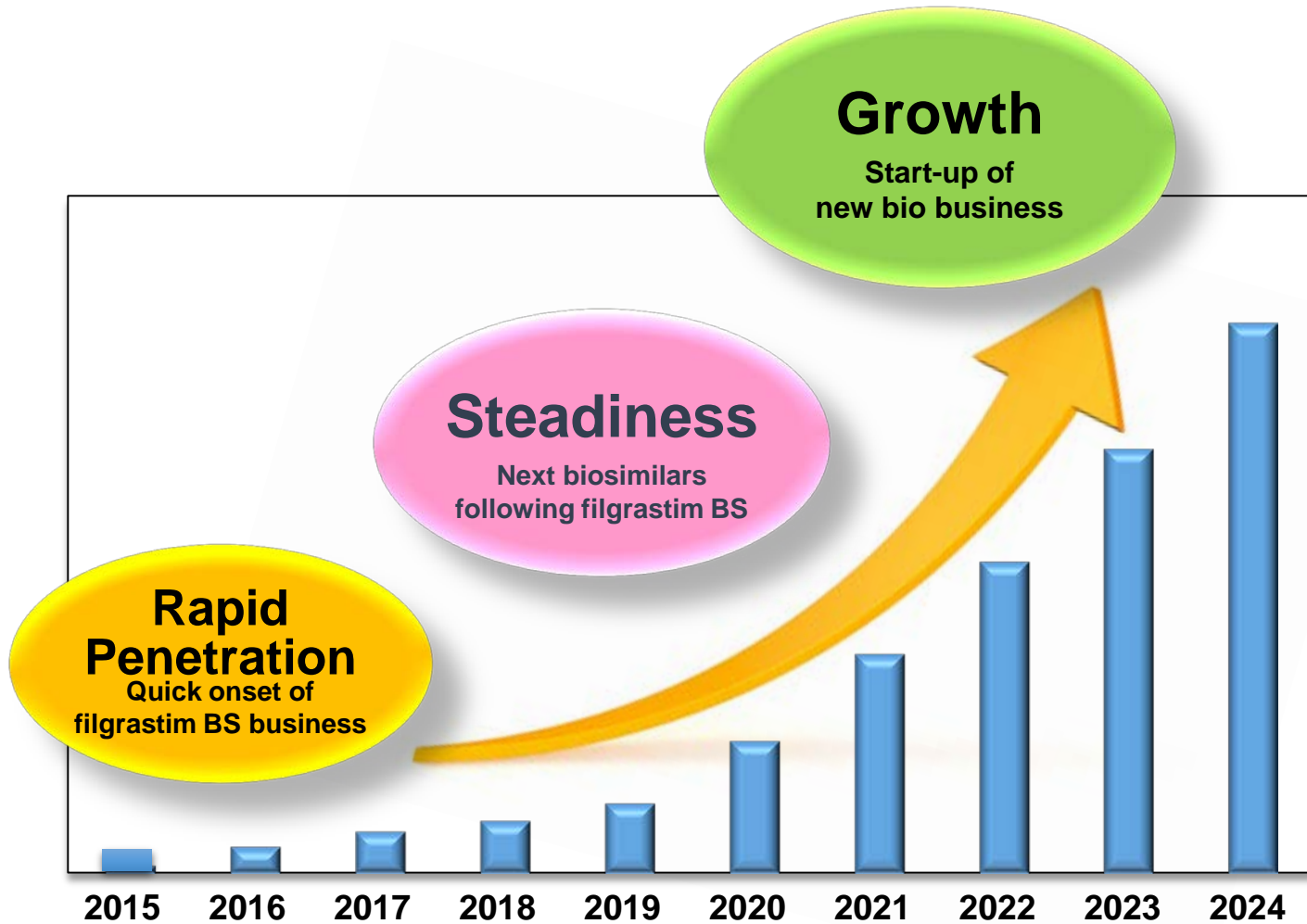
- ✓ Enhancement of promising and stable new business area
- ✓ Collaboration with GTS having deep know-how and experience
- ✓ Investment on expectation for long-term expansion & growth



**We are expanding into new biologics and healthcare using biosimilars as a stepping stone!**



# GTS with Profitability and Growth in the near Future



**Please look forward to us & keep in touch!!**

## Notes

This report was prepared as a reference for investors to help them understand the current financial situation of Gene Techno Science Co., Ltd (GTS).

The information within was prepared on the basis of generally recognized economic and social conditions and assumptions deemed logical by GTS at the time of writing, but may be changed without notice for reasons such as changes in the management environment.

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