



*Unlimited Drug Discovery from the Beginning*

**Mothers**

Ticker symbol: 4584

# Gene Techno Science Co., Ltd.

Financial results for the second quarter of the fiscal  
year ending March 2017

November 15, 2016

# Corporate overview and business highlights

# Corporate overview

<b>Chief Executive</b>		<b>Masanari Kawaminami, President</b>
<b>Founded</b>		<b>March 2001</b>
<b>Capital</b>		<b>3,793,294,000 yen (as of October 4, 2016)</b>
<b>Locations</b>	<b>Head office</b>	<b>Kita 2-Nishi 9-1, Chuo-ku, Sapporo</b>
	<b>Tokyo office</b>	<b>2-10-8 Nihonbashi, Chuo-ku, Tokyo</b>
	<b>Laboratory</b>	<b>Kita 21-Nishi 11, Sapporo Inside the Center of Promotion for Platform for Research on Biofunctional Molecules, Hokkaido University Creative Research Institution</b>

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

## Hybrid business structure combining biosimilars and new biologics

### Development on Biosimilars

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

### Development on New Biologics

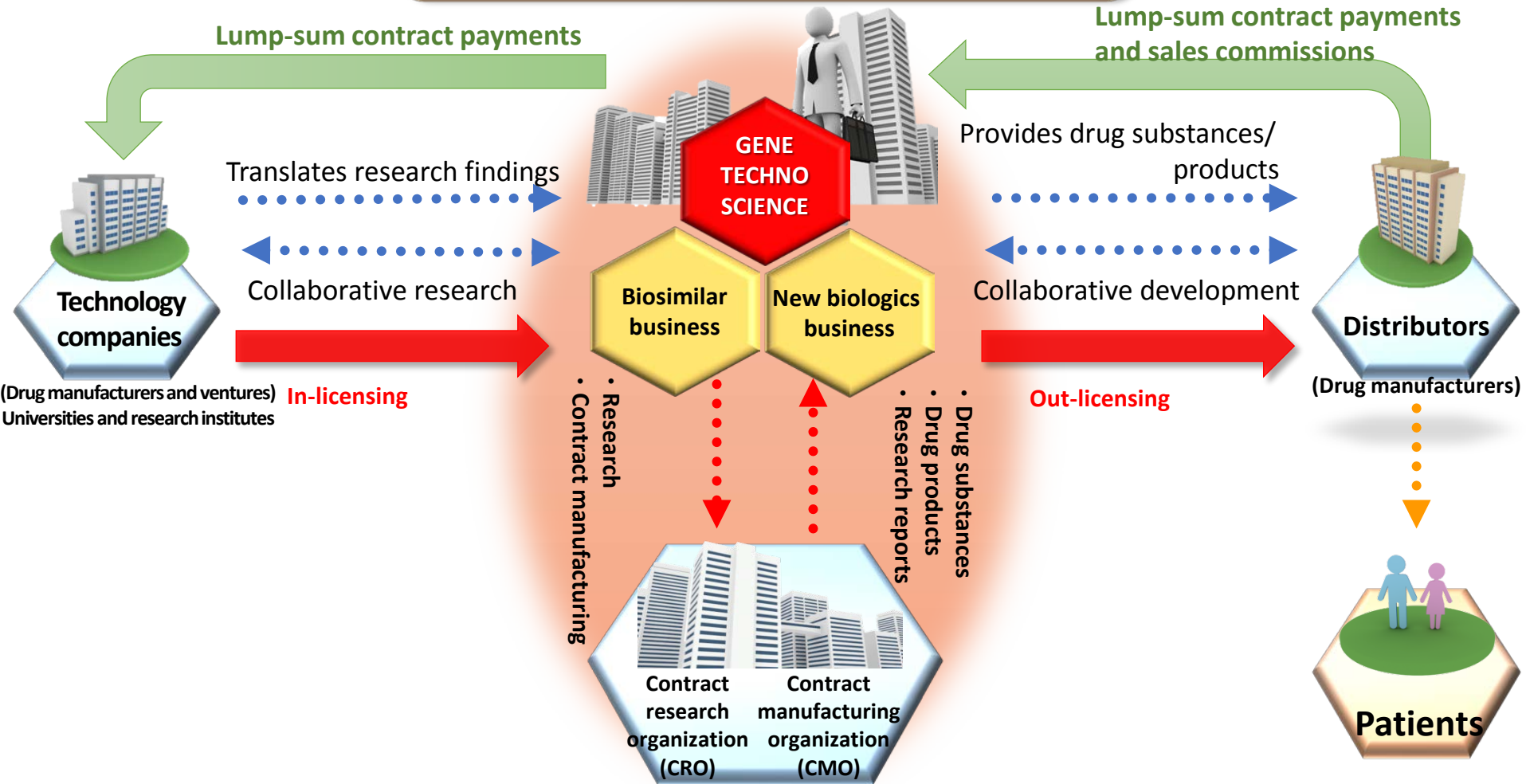
- R&D centered on therapeutic antibodies
- Laboratory located at Hokkaido University Creative Research Institution



# 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



## ◆ Financial results from the second quarter of 2016 (April–September)

	Sales (in millions of yen)	Operating profit (in millions of yen)	Ordinary profit (in millions of yen)	Net profit for the quarters (in millions of yen)	Per share net profit for the quarter (in yen)*
Financial results from April–September 2015 (A)	791	△116	△99	△100	△20.61
Financial results from April–September 2016 (B)	490	△731	△757	△803	△92.85
Change (B-A)	△301	△615	△657	△703	—

\* Following a decision made at the GTS board of directors meeting held on September 13, 2016, the company split each share into 2 shares on October 1, 2016. Per-share net profit is calculated based on the assumption that the split was conducted at the beginning of the fiscal year ended March 2016.

## ◆ Financial forecasts for fiscal year ending March 2017

	Sales (in millions of yen)	Operating profit (in millions of yen)	Ordinary profit (in millions of yen)	Net profit for the quarters (in millions of yen)	Per share net profit for the quarters (in yen)*
Initial forecasts for fiscal year ending March 2017 (A)	1,685	△493	△494	△497	△56.22
Revised forecasts for fiscal year ending March 2017 (B) (Revised August 5, 2016)	1,685	△493	△494	△542	△61.35
Results from fiscal year ended March 2016 (for reference)	1,160	△820	△785	△787	△151.45
Change (B-A)	0	0	0	△45	—

Posted ¥45 million loss on valuation of investment securities

\* Following a decision made at the GTS board of directors meeting held on September 13, 2016, the company split each share into 2 shares on October 1, 2016. Per-share net profit is calculated based on the assumption that the split was conducted at the beginning of the fiscal year ended March 2016.

## Highlight 1

### Joined Noritsu Koki Group

- ✓ Signed capital and business alliance contract with Launchpad12, a limited liability company (currently Noritsu Koki Bio Holdings L.L.C.) (March 28, 2016)
- ✓ We aim to advance business development in biosimilars and regenerative medicine with Noritsu Koki Group
- ✓ Maintained 58% ownership by allocation of new shares to a third party and a takeover bid (takeover bid outcome announced May 31, 2016). We raised a total of 3.1 billion yen.

## Highlight 2

### Signed agreement with Changchun Changsheng Life Sciences Ltd. (Changsheng Bio) to expand our biosimilar business to the Chinese market

- ✓ We signed an agreement to develop our biosimilar business in China (May 12, 2016)
- ✓ We will transfer drug substance manufacturing techniques for biosimilars for which we have been developing drug substances, and Changsheng Bio will exclusively manufacture and distribute drug substances in China

## Highlight 3

### Signed agreement (joint development agreement) for ophthalmology biosimilars with Senju Pharmaceutical Co., Ltd.

- ✓ This agreement for joint development and coordinated distribution of ophthalmology biosimilars signed on November 12, 2015 will accelerate biosimilar business development for both companies (May 12, 2016)



## Highlight 4

**Signed memorandum of understanding with DyDo Drinco, Inc. to consider opportunities for new business in the healthcare field**

- ✓ Signed memorandum of understanding to consider opportunities for new business in the healthcare field while utilizing both parties' knowledge of the pharmaceutical industry (June 29, 2016)

## Highlight 5

**Joined Japan Biosimilar Association**

- ✓ Joined to further accelerate our biosimilar business by collaborating in efforts to promote adoption of biosimilars (August 30, 2016)

## Highlight 6

**Started a phase III clinical study in Japan for darbepoetin alfa biosimilar (GBS-011), which we are jointly developing with Sanwa Kagaku Kenkyusho Co., Ltd.**

- ✓ Started a phase III clinical study in Japan for a jointly developed darbepoetin alfa biosimilar for treating renal anemia (September 16, 2016)

## Highlight 7

**Formed capital and business alliance with Japan Regenerative Medicine Co., Ltd. (JRM)**

- ✓ Noritsu Koki Group signed a capital and business alliance contract with JRM (October 13, 2016)
- ✓ We hope to develop a regenerative medicine business using cardiac stem cells JRM is developing

# Biologics market

- New biologics and biosimilars -

# Top 10 Best-Selling Drugs in the World (2015)

The number of biologics in the top 10 sellers continues to grow!

2014: 7/10 ⇒ 2015 8/10!

Drugs in red are biologics

Ranking	Brand name	Generic name	Indication	Manufacturer	Sales (millions of USD)
1	Humira	Adalimumab	Rheumatism/Psoriasis	AbbVie/Eisai	14,359
2	Sovaldi	Sofosbuvir	Hepatitis C	Gilead Sciences	13,864
3	Enbrel	Etanercept	Rheumatism/Psoriasis	Amgen/Pfizer/Takeda	9,037
4	Remicade	Infliximab	Rheumatism/Crohn's disease	J&J/Merck/Tanabe Mitsubishi	8,151
5 (6)	Rituxan	Rituximab	Cancer/Lymphoma	Biogen/Roche/Chugai	7,393
6 (5)	Lantas	Insulin glargine	Diabetes	Sanofi	7,089
7 (8)	Avastin	Bevacizumab	Cancer/Colon and breast cancer	Genentech/Roche/Chugai	6,945
8 (9)	Herceptin	Trastuzumab	Cancer/Breast cancer	Genentech/Roche/Chugai	6,794
9 (10)	Januvia	Sitagliptin	Diabetes	Merck	6,333
10 (20)	Prevenar 13	Pneumonia vaccine	Pneumonia vaccine	Pfizer	6,328

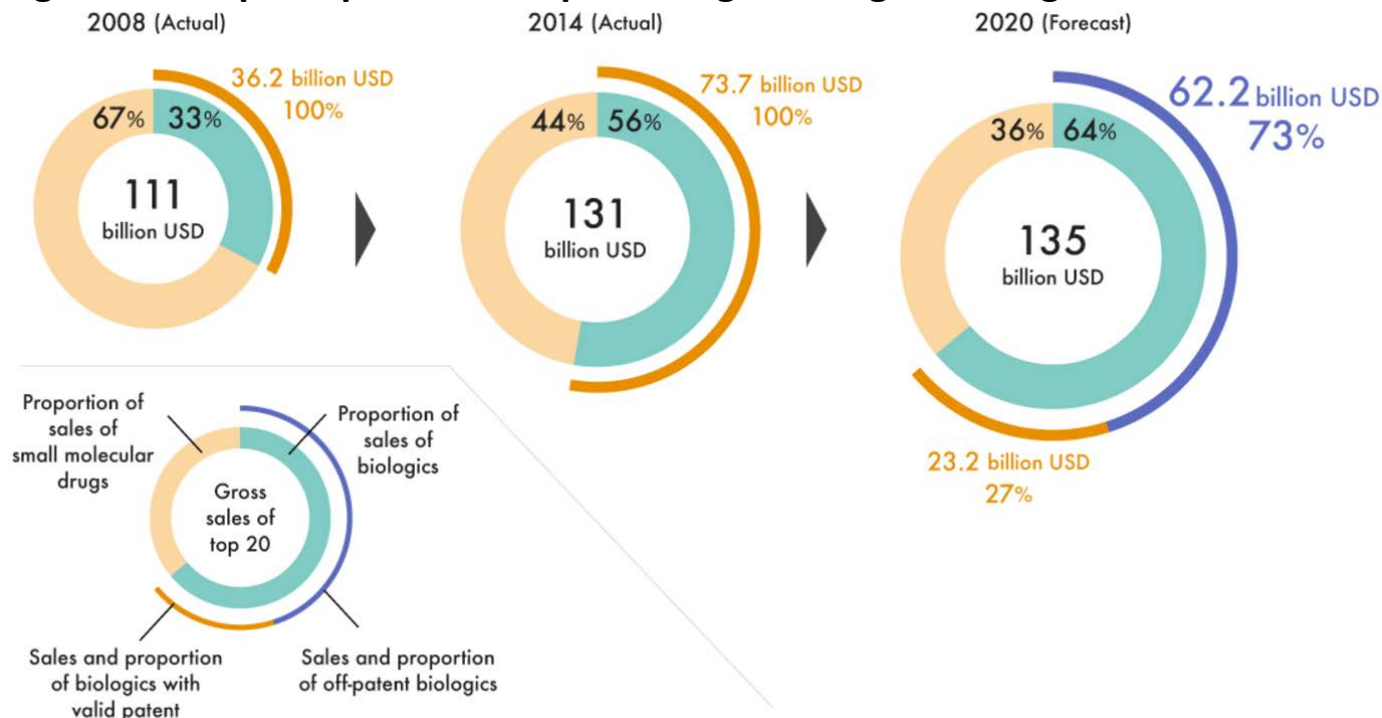
\* ( ) means the ranking of 2014.

Source: Evaluate Pharma 2016

# Expansion of the biologics market

## Sales of top 20 drugs in the global market and share of biologics

- Sales of biologics with expired patents and percentage among all biologics -



## Breakdown of biologics/low molecular weight drugs in the top 20 best-selling drugs (number of drugs)

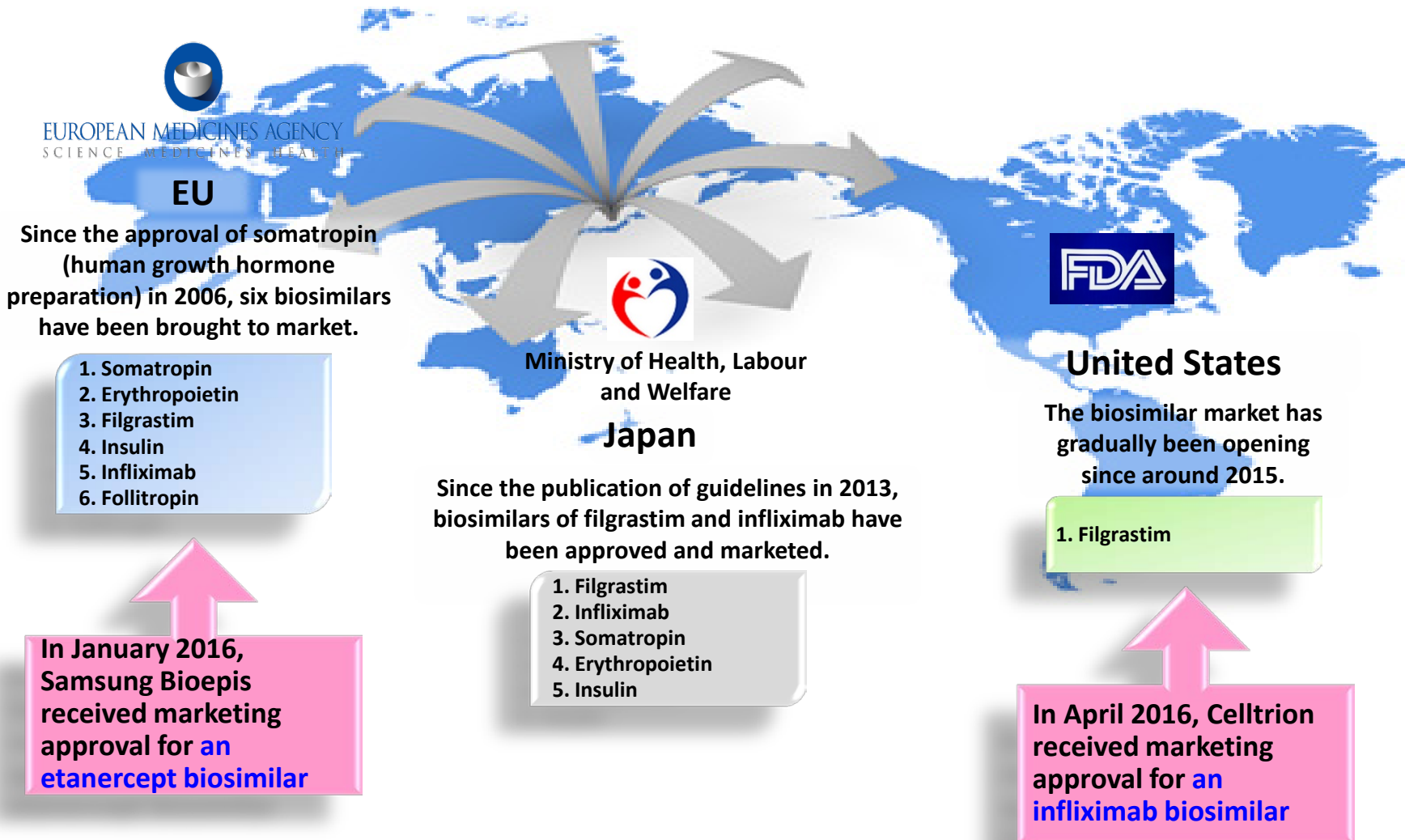
	2008 (actual)	2014 (actual)	2020 (forecast)
Biologics	7	10	12
Number of biologics with expired patents	0	0	8
Low molecular weight drugs	13	10	8

Source: Modified from Evaluate Pharma materials

**Between 2015 and 2020, patents for many biologics will expire in quick succession and the potential biosimilar market will expand rapidly**

# Biosimilar market: Products brought to market

Biosimilar development is steadily progressing in every country and region of the world.

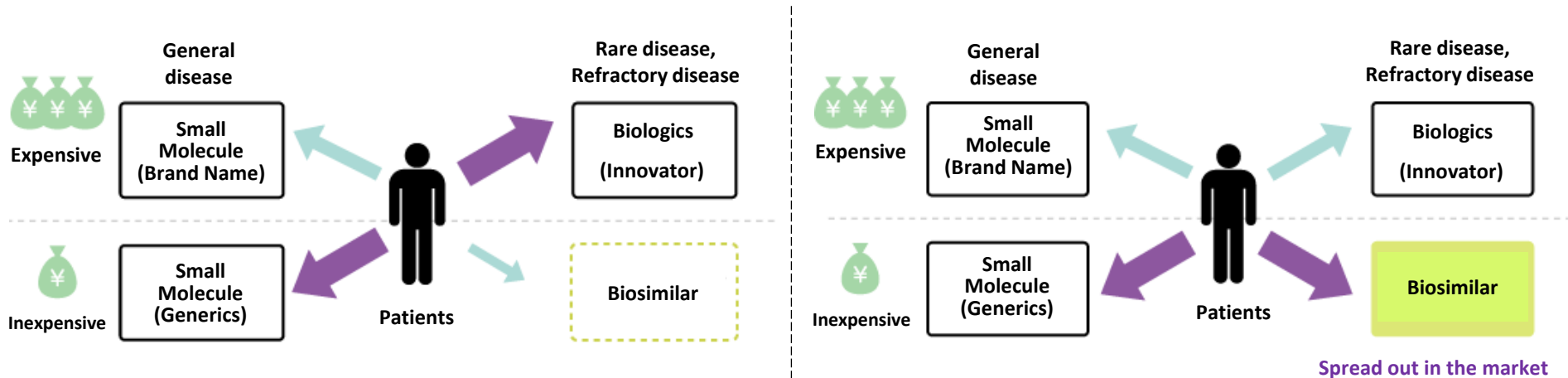


# The societal need for biosimilars (1)

Question: Why are medical costs not decreasing despite steady adoption of generics?

Reason: The use of expensive biologics is canceling out the effect of switching to generics.

## Current situation Ideal situation



- Use of biologics produces high medical costs.
- Even as generics are adopted, the use of expensive biologics also increases, and society as a whole does not see a large reduction in medical costs.



- Lower medical costs!
- Lower medical costs mean that more patients can receive advanced care.
- Reduces the strain of healthcare financing on the Japanese government

**Biosimilars** hold the key to reducing medical costs!

**Biosimilars** hold the key to reducing medical costs!

Administrative  
trends



A nonpartisan caucus of Diet members called the **Caucus for the Promotion of Biosimilars (BS Promotion Caucus)** was formed in March 2015



The industry-focused **Japan Biosimilar Association** was founded in April 2016. They facilitate exchange of information and discussion between industry, government, and universities to develop and promote biosimilars

We are also  
a member

**The government** is also pushing  
for adoption of generics!

# Biosimilar business



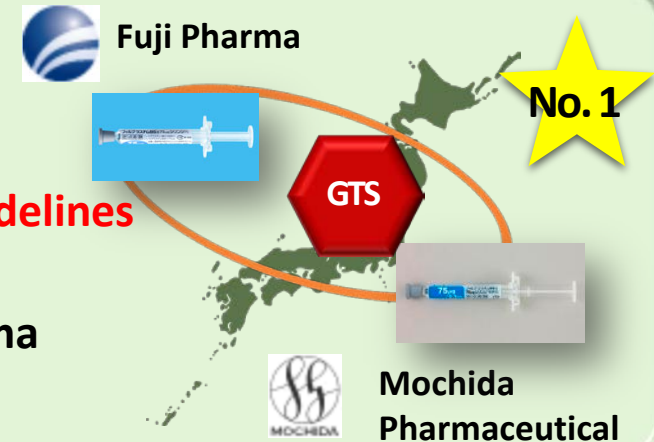
# Successes in developing our biosimilar business

## ◆ Filgrastim biosimilar brought to market in Japan

**First Japanese biosimilar following the biosimilar guidelines**

Nov 2012 Obtained marketing approval

May 2013 Started sales in Japan through Fuji Pharma and Mochida Pharmaceutical



◆ Gene Techno Science  
Drug substance development



◆ Fuji Pharma/Mochida  
Pharmaceutical  
Clinical development and sales

Filgrastim biosimilar injection ○○ μg syringe “F”/“Mochida”

Sales for fiscal year ending March 2017 are also looking good

# Advances in our biosimilar business

- 1) Accelerated development of our biosimilar business in the field of ophthalmology!
- 2) Started phase III study of darbepoetin alfa (Nesp) biosimilar!

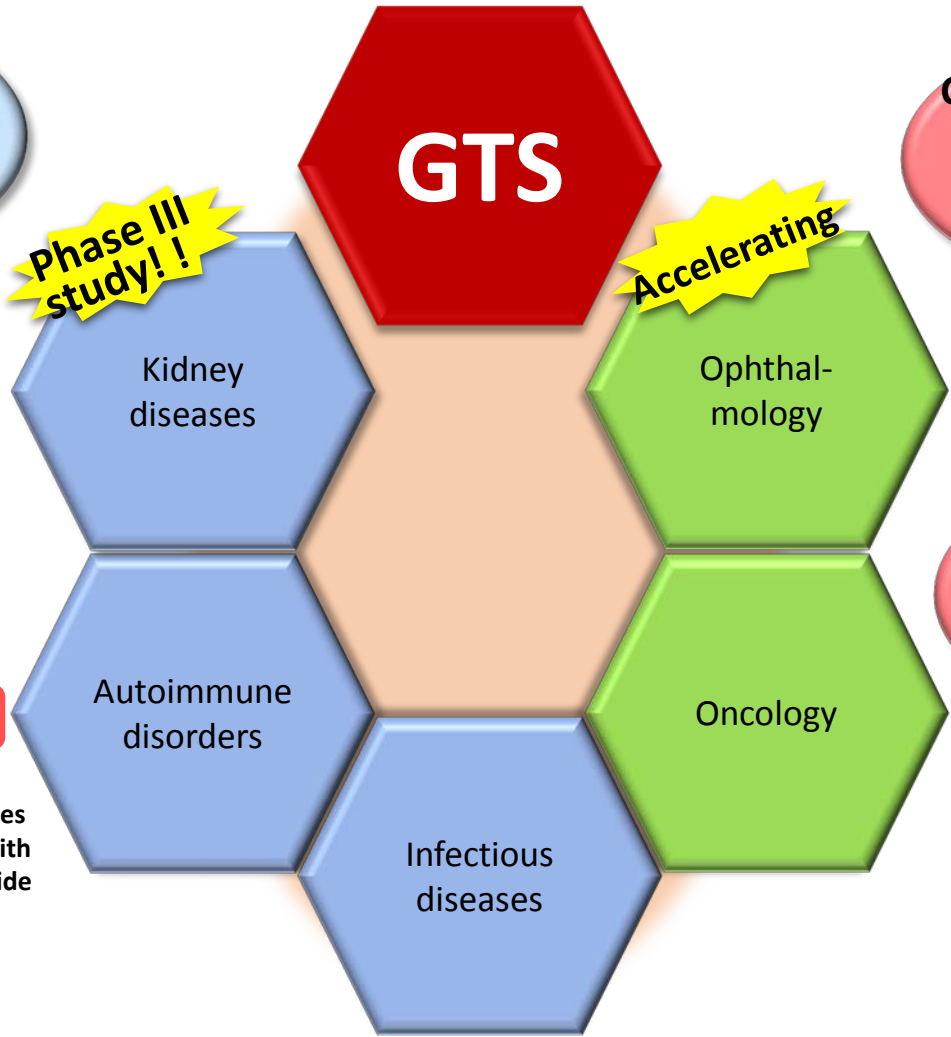
**Business alliance with Sanwa Kagaku Kenkyusho**  
January 2014–

**Nesp biosimilar**

- Preparing to start clinical studies

**Humira biosimilar**

- Completed nonclinical studies
- Preparing to start clinical studies
- Actively expanding alliances with pharmaceutical companies inside and outside Japan





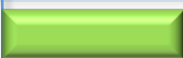




**Capital and business alliance with Senju Pharmaceutical**  
May 2016–

- Signed joint business agreement on May 12, 2016

**Capital and business alliance with Mochida Pharmaceutical**  
August 2015–

# Progress in our biosimilar pipeline

Development code	R&D	Phase I clinical study	Phase III clinical study	Application submitted/reviewed Approved/marketed	Rough estimate of the scale of the biosimilar market*	
					Japan	Global (excluding Japan)
<b>GBS-001</b> (cancer) G-CSF					¥8 billion	¥40 billion
<b>GBS-010</b> (cancer) PEG-G-CSF					¥8 billion**	¥208 billion
<b>GBS-011</b> (kidney disease) Darbepoetin alfa					¥22 billion	¥92 billion
<b>GBS-005</b> (autoimmune disorders) Adalimumab					¥14 billion	¥520 billion
<b>GBS-007</b> (eye diseases)					¥25 billion***	¥307 billion***
<b>GBS-008</b> (infectious diseases) Palivizumab					¥15 billion	¥59 billion
<b>GBS-004</b> (cancer) Bevacizumab					¥38 billion	¥250 billion
<b>Total</b>					<b>¥130 billion</b>	<b>¥1476 billion</b>

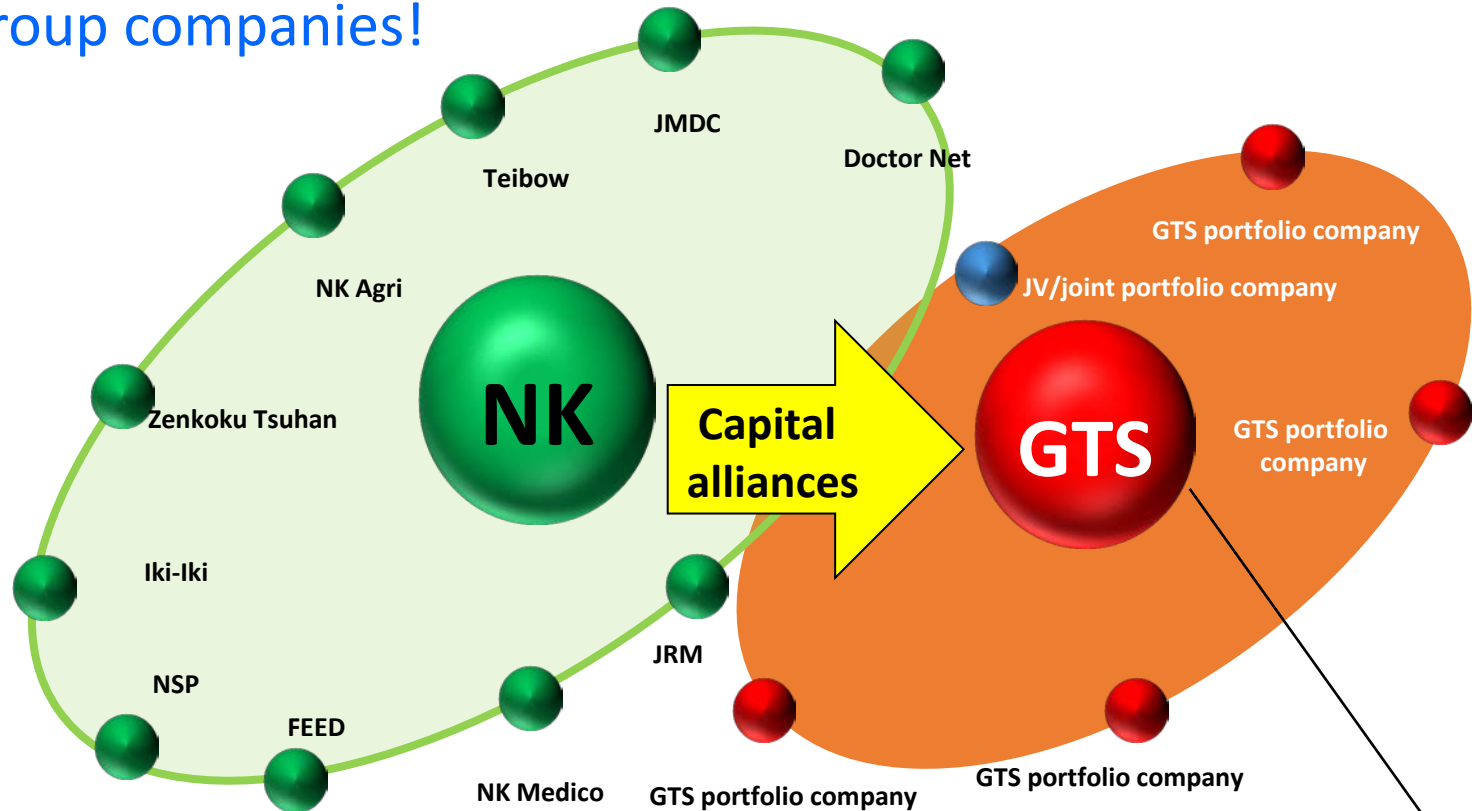
- \* It is estimated that the biosimilar market will be about 40% of the brand name drug market in terms of sales (Biosimilar penetration rate of 60% × Cost is 70% that of brand name drugs = 42%)
- \*\* Brand name sales started in 2014, so the drug price calculation is for a new drug. Peak sales were used as reference values (Central Social Insurance Medical Council, November 26, 2014).
- \*\*\* To avoid disclosing the name of the drug, the scale of the ophthalmology biologics market was used as a reference value.



# Alliance with Noritsu Koki Group

# Capital and business alliance with Noritsu Koki

Our goal is to be the **center of biotech company group formation** for the whole industry, not just for Noritsu Koki Group companies!



Formed a group of bio companies to actively promote M&A between promising bio-related companies in addition to progressing our development pipeline

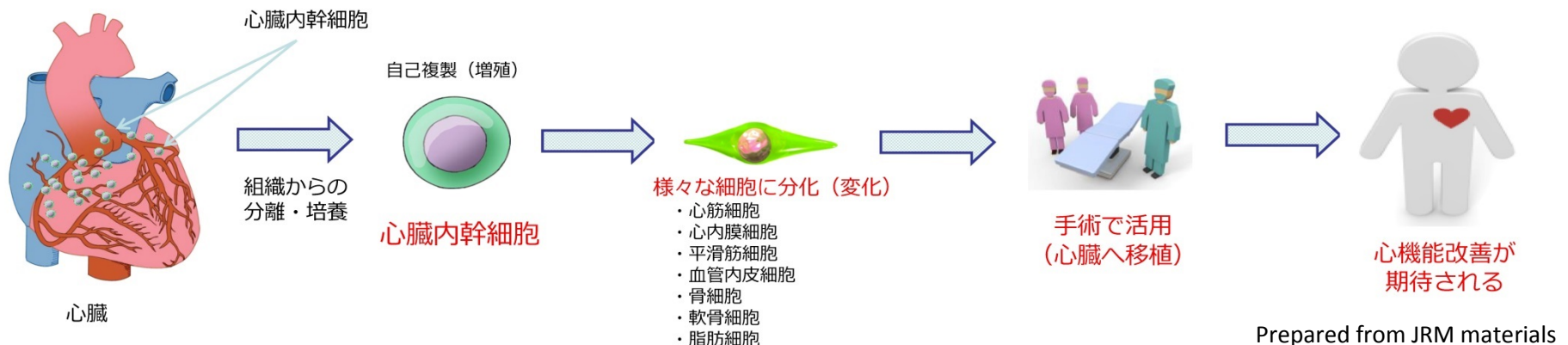
## Reason 1

- To plunge into the field of regenerative medicine!
- To expand the pipeline

Develop cell and gene therapy products using cardiac stem cells  
JRM is developing

## What are cardiac stem cells?

Cells taken from the heart that are transformed into various cells and used for applications such as heart surgery



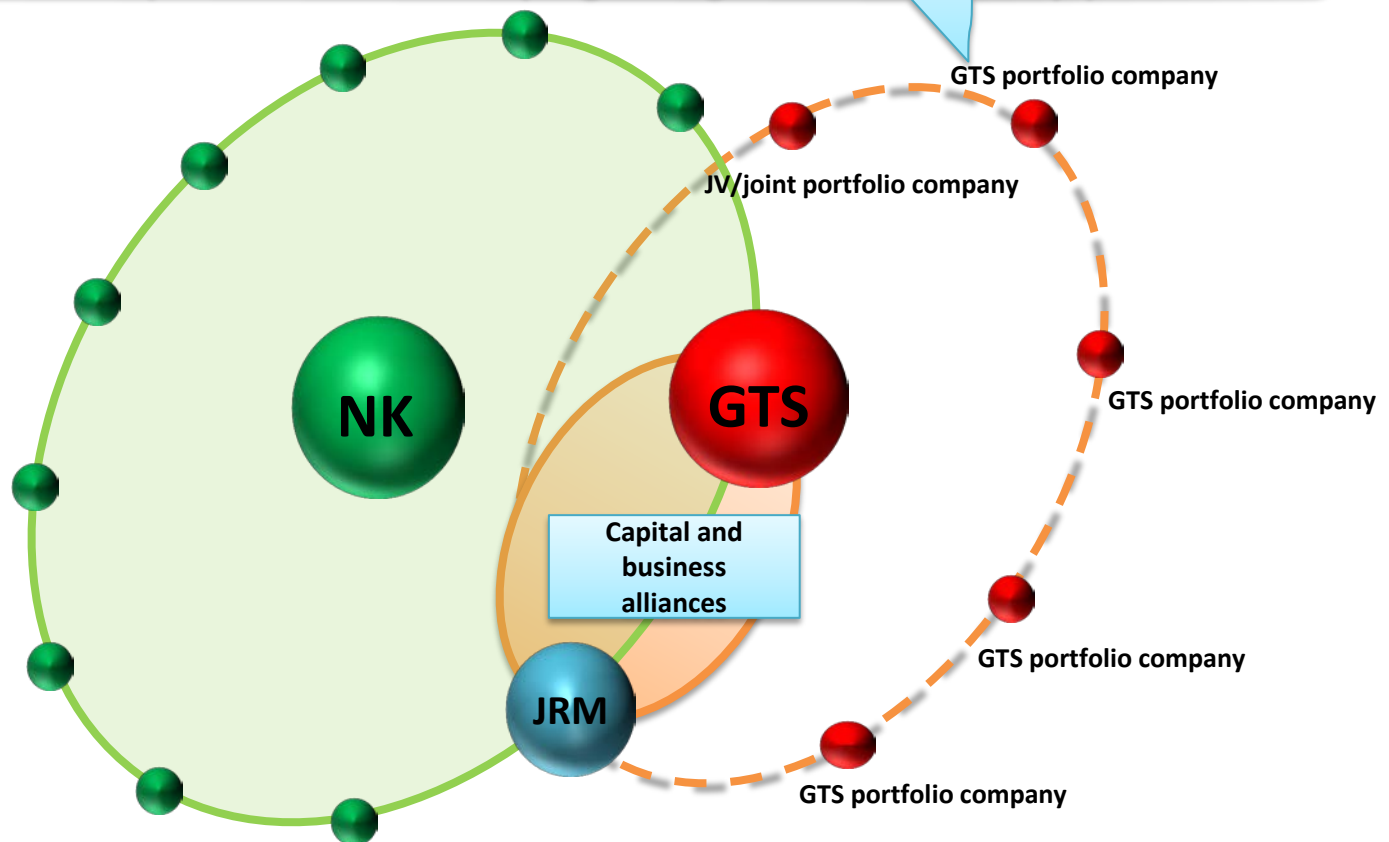
Cardiac stem cells hold hidden potential for new treatments for serious heart disease in Japan, where heart transplants are still difficult to get.

## Reason 2

- To implement a biotech business strategy within Noritsu Koki Group

To expand the biotech business centered on GTS and maximize the corporate value of Noritsu Koki Group as a whole

Formed a group of bio companies to actively promote M&A between promising bio-related companies in addition to progressing the development pipeline



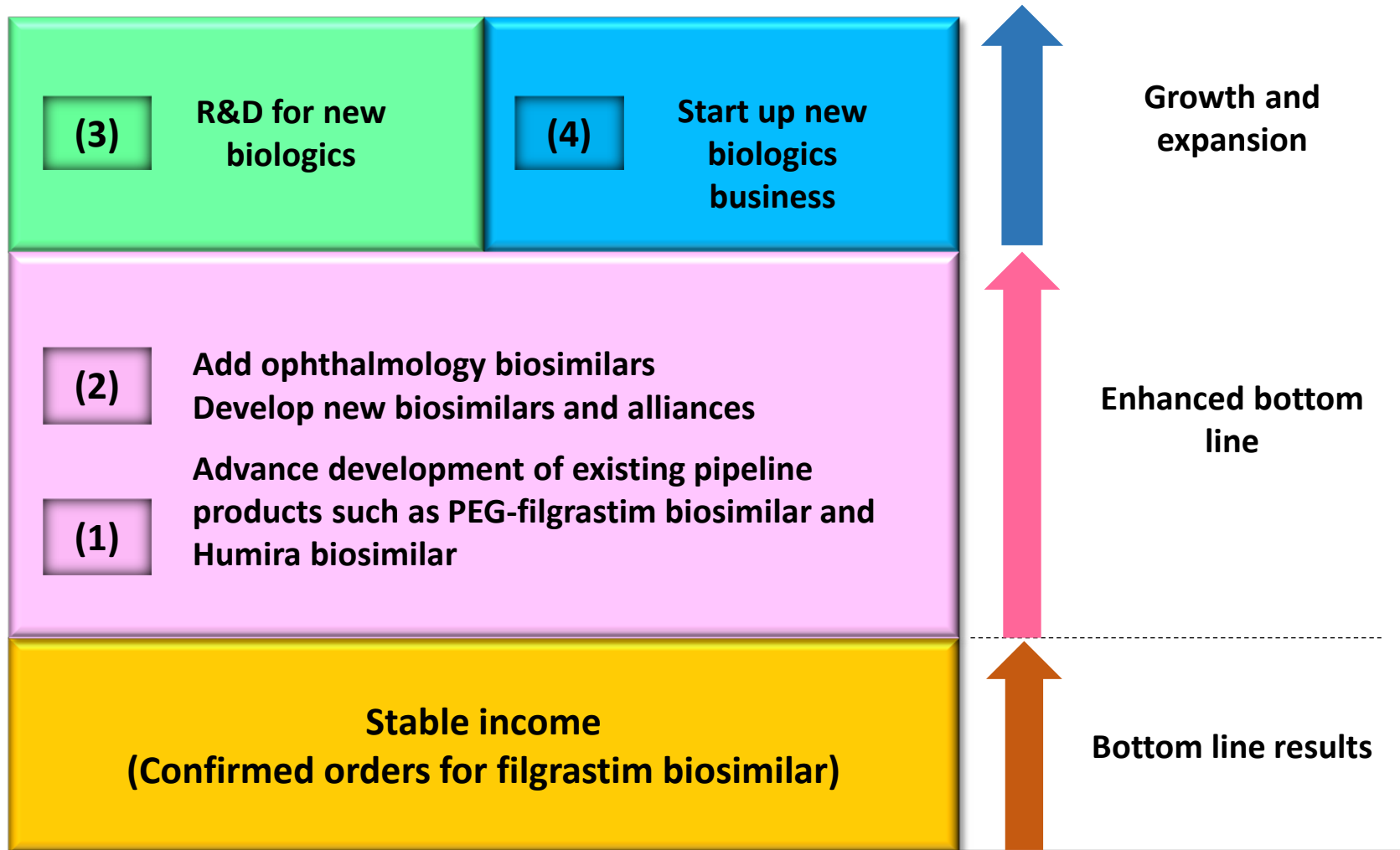


# Medium-term vision

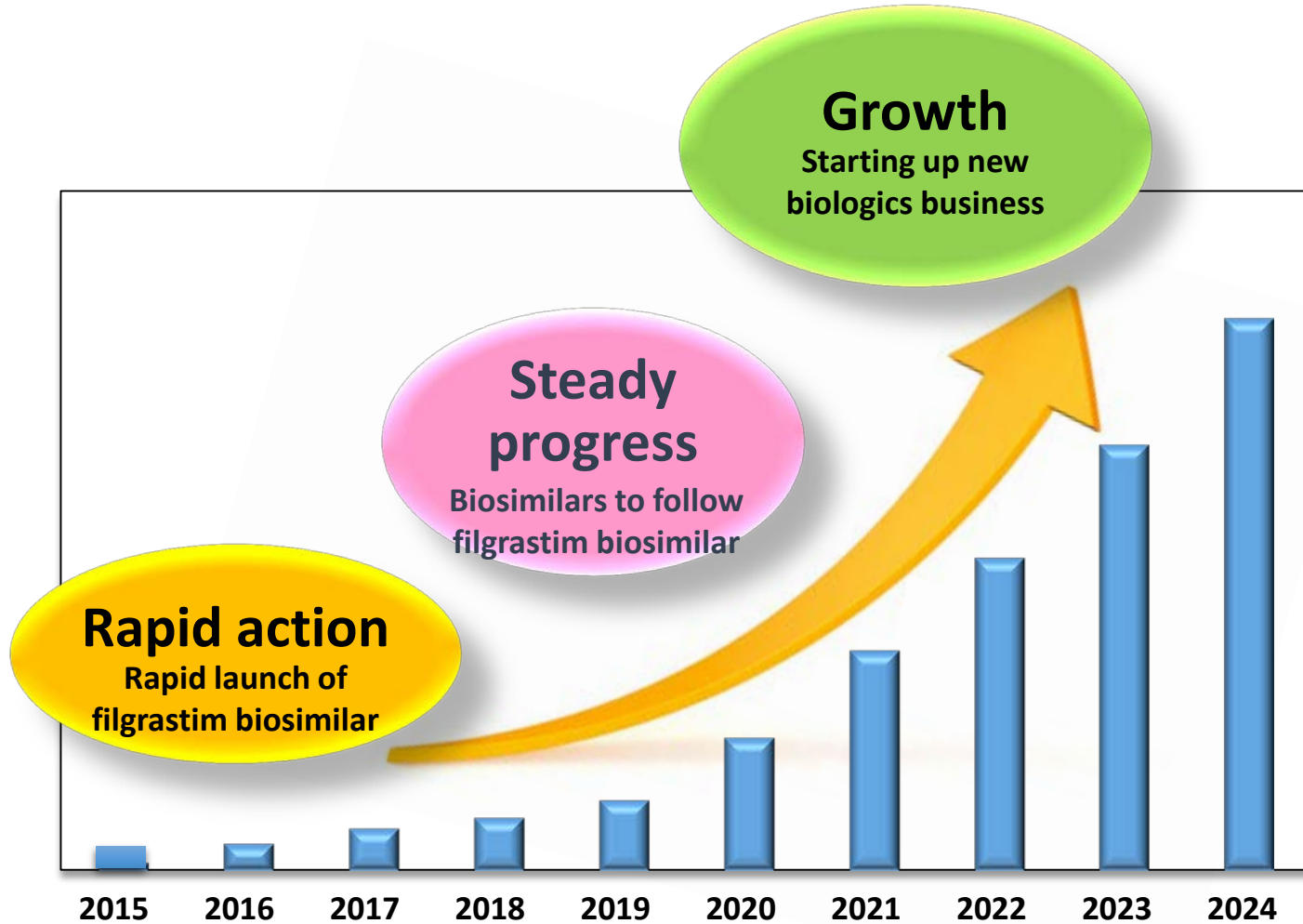


# Medium-term income vision

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



# We're becoming a profitable and growing bio-venture!



**Keep an eye on our progress!**

## 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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**Unlimited drug discovery from the beginning**