GENE TECHNO SCIENCE

Unlimited drug discovery from the beginning

Mothers

Ticker symbol: 4584

Gene Techno Science Co., Ltd.

Financial results for the fiscal year ended March 2017

May 18, 2017

GENE TECHNO SCIENCE

Corporate overview and business highlights

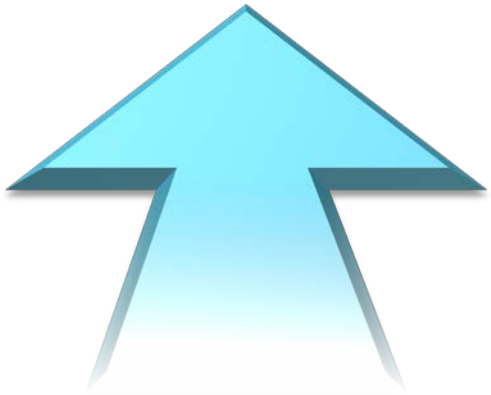
Corporate Overview

Chief Executive		Masaharu Tani, President
Founded		March 2001
Capital		4.194 billion yen (as of March 2017)
Locations	Head office	Kita 2-Nishi 9-1, Chuo-ku, Sapporo
	Tokyo office	2-10-8 Nihonbashi, Chuo-ku, Tokyo
	Laboratory	Kita 21-Nishi 11, Sapporo Inside the Center of Promotion for Platform for Research on Biofunctional Molecules, Hokkaido University Creative Research Institution

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-α9 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	Listed on the Tokyo Stock Exchange Mothers Index
	Obtained marketing approval for filgrastim biosimilar
Aug 2013	Formed capital and business alliance for biosimilars with ITOCHU CHEMICAL FRONTIER Corporation
Sep 2014	Signed joint development agreement for darbepoetin alfa biosimilar with Sanwa Kagaku Kenkyusho Co., Ltd. (started phase III in September 2016)
Mar 2016	Joined Noritsu Koki Group through common stock takeover bid and formed capital and business alliance
May 2016	Signed capital and business alliance agreement with Senju Pharmaceutical Co., Ltd. for biosimilars in the field of ophthalmology
	Signed basic agreement with Changchun Changsheng Life Sciences Ltd. to expand our biosimilar business in Chinese market
Oct 2016	Formed capital and business alliance with Japan Regenerative Medicine Co., Ltd. to develop business in regenerative medicine using cardiac stem cells
Dec 2016	Signed joint development agreement with Mochida Pharmaceutical Co., Ltd. for biosimilars in the field of oncology
	Formed capital and business alliance for life science business with JSR Corporateion
Feb 2017	Signed joint research agreement with Juntendo University for immune tolerance induction technology
Mar 2017	Formed capital and business alliance for developing new biosimilars with ITOCHU CHEMICAL FRONTIER Corporation

Business model

Hybrid business structure combining biosimilars and new biologics



Biosimilar

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

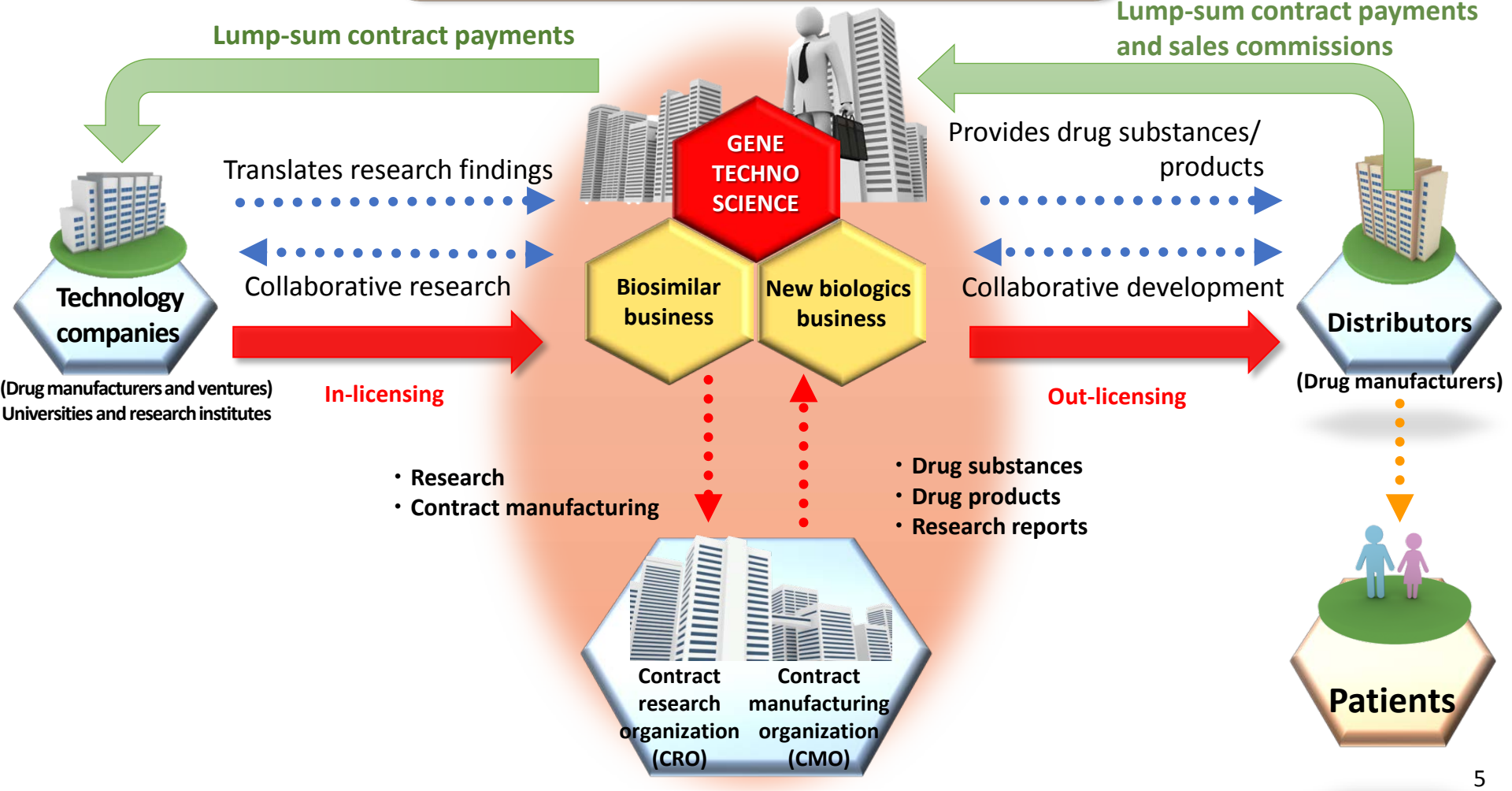
Biological Product

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

System for business development

Advantages of a fabless business model

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



Business highlights for fiscal year ended March 2017

◆ Financial results for fiscal year ended 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)
Results from fiscal year ended March 2016 (A)	1,160	△820	△785	△787	△151.45
Results from fiscal year ended March 2017 (B)	1,089	△1,184	△1,176	△1,224	△137.01
Change (B-A)	△71	△364	△391	△437	

Filgrastim biosimilar sales figures were as forecast.

Some R&D spending was front-loaded into expenses due to the early start of development processes that were scheduled for next fiscal year.

※The company split each share into two 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 2018

◆ Sales and profit forecasts

	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)
Results from fiscal year ended March 2017 (A)	1,089	△1,184	△1,176	△1,224	△137.01
Forecasts for fiscal year ending March 2018 (B)	1,166	△977	△992	△994	△103.96
Change (B-A)	77	207	184	230	

- ✓ We predict that sales of filgrastim will remain steady
- ✓ We expect to receive income from contracts for GTS-developed products with partner companies and achieve development milestones
- ✓ We are actively pursuing an increase in upside through alliance-making efforts

- ✓ Sales of filgrastim alone are predicted to fully cover fixed expenses
- ✓ We will appropriate any retained earnings exceeding fix expenses to R&D expenses, and predict that this will reduce losses while also accelerating R&D progress

◆ R&D expense forecasts

	R&D expenses (in millions of yen)
Results from fiscal year ended March 2017 (A)	1,433
Forecasts for fiscal year ending March 2018 (B)	1,197
Change (B-A)	△236

- ✓ We will pass peak R&D spending
- ✓ We will accelerate R&D efforts to ensure sound progress with product launches

Business Highlights (1)

Highlight 1

Joined Noritsu Koki Group

- ✓ Announced capital and business alliance with Noritsu Koki Bio Holdings L.L.C. (March 28, 2016)
- ✓ We aim to advance business development in biologics including biosimilars and regenerative medicine with Noritsu Koki Group.
- ✓ We raised a total of 3.1 billion yen through allocation of new shares to third parties.

Highlight 2

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

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

Highlight 3

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

- ✓ Announced the signing of a joint venture agreement for joint development and coordinated distribution of ophthalmology biosimilars on November 12, 2015. (May 12, 2016)
- ✓ We will continue to develop our biosimilar business through this partnership.

Highlight 4

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

- ✓ Announced the signing of a memorandum of understanding for considering opportunities for new business in the healthcare field while utilizing both parties' knowledge of the pharmaceutical industry. (June 29, 2016)

Business Highlights (2)

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.

- ✓ Announced the launch of a phase III clinical study in Japan for the 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)

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

Highlight 8

Formed capital and business alliance with JSR Corporation

- ✓ Announced a capital and business alliance with JSR Corporation (December 5, 2016)
- ✓ We hope to strengthen our businesses by coordinating our biologics business and JSR Corporation's life science business.
- ✓ Allocated 500 million yen in shares to JSR through allocation of new shares to third parties.

Business Highlights (3)

Highlight 9

Signed joint venture agreement for oncology biosimilars with Mochida Pharmaceutical Co., Ltd.

- ✓ Announced a joint venture agreement for joint development and coordinated distribution of oncology biosimilars on August 11, 2015. (December 5, 2016)
- ✓ We will continue to develop our biosimilar business through this partnership.

Highlight 10

Signed joint research agreement with Juntendo University for immune tolerance induction technology

- ✓ Announced a joint research agreement with Juntendo University. (February 27, 2017)
- ✓ We are working to develop clinical applications for new immunosuppressive therapies using immune tolerance techniques.
- ✓ These could be used to treat or cure many diseases or symptoms related to the immune system, including immune diseases, transplantation complications, allergic rhinitis, and food allergies.

Highlight 11

Formed capital and business alliance for jointly developing new biosimilars with ITOCHU CHEMICAL FRONTIER Corporation

- ✓ Announced a capital and business alliance with ITOCHU CHEMICAL FRONTIER Corporation. (March 9, 2017)
- ✓ We hope to expand our biosimilar business through joint development of a biosimilar we are currently developing.
  *This is a different biosimilar than that for which we formed a capital and business alliance on August 5, 2013.
- ✓ Allocated 300 million yen in shares to ITOCHU CHEMICAL FRONTIER Corporation through allocation of new shares to third parties.

Decrease in capital and capital reserve and appropriation of retained earnings

We plan to discuss this matter at the 17th General Meeting of Shareholders scheduled for June 28, 2017 to ensure flexibility and maneuverability in our capitalization strategy.

Shareholders' equity after implementation

(Units: millions of yen)

Item	As of March 31, 2017	After implementation
Shareholders' capital	3,472	3,472
Capital	4,194	100
Paid-in capital	4,097	3,372
Capital reserve	4,097	3,372
Retained earnings	△4,818	–
Retained earnings - Other	△4,818	–
Accumulated retained earnings	△4,818	–
Valuation, translation adjustments and others	3	3
Valuation difference on available-for-sale securities	3	3
Equity warrant	23	23
Total shareholders' equity	3,500	3,500

(Decrease)

→ 4.094 billion yen

→ 724 million yen

Total: 4.818 billion yen

Appropriated to losses

Date to be made effective: July 31, 2017

Note: For details, please refer to "Notice regarding Decrease in Capital and Capital Reserve and Appropriation of Retained Earnings" dated May 17, 2017.

GENE TECHNO SCIENCE

Biologics market

- New biologics and biosimilars -

GENE TECHNO SCIENCE

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

The number of biologics in the top 10 best 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)	Rixutan	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

Source: Evaluate Pharma 2016

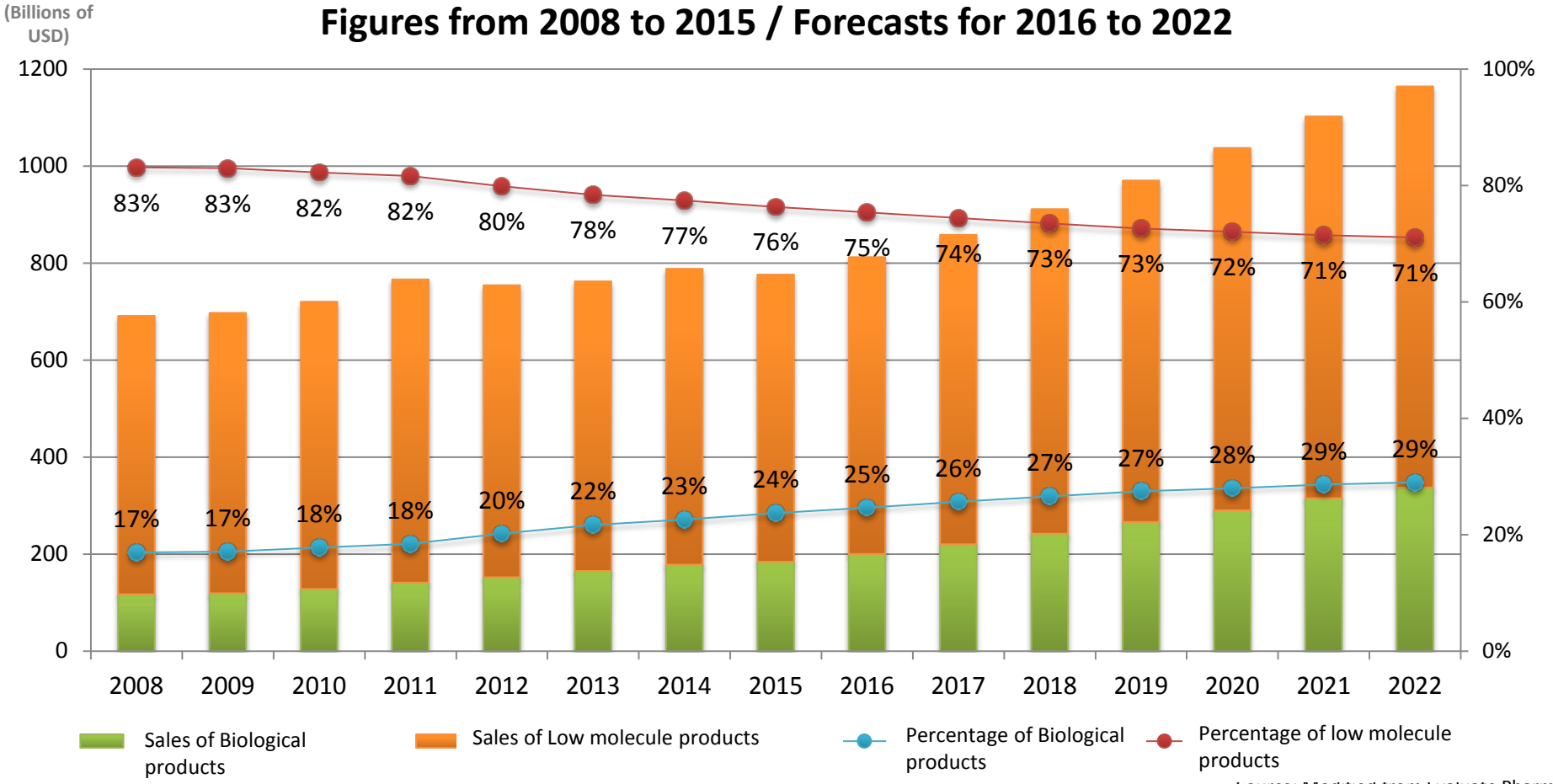
・Numbers in parentheses are the 2014 rankings.

GENE TECHNO SCIENCE

Expansion of the biologics market

Total global drug sales and share of biologics

Figures from 2008 to 2015 / Forecasts for 2016 to 2022



Source: Modified from Evaluate Pharma

In the year 2022, the global market share of biologics in terms of sales...
is predicted to increase to 29% and 337 billion dollars.
= The biologics market is expanding!

GENE TECHNO SCIENCE

Biosimilar market: Products brought to market

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

EU

Since the approval of somatropin (human growth hormone preparation) in 2006, six biosimilars have been brought to market.

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

New marketing approvals obtained
January 2016: Etanercept biosimilar
(Samsung Bioepis)

Japan

Ministry of Health, Labour and Welfare

Since the publication of guidelines in 2013, biosimilars of filgrastim and infliximab have been approved and marketed.

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

United States

The biosimilar market has gradually been opening since around 2015.

1. Filgrastim

New marketing approvals obtained
April 2016: Infliximab biosimilar (Pfizer/Celltrion)
August 2016: Etanercept biosimilar (Sandoz)
September 2016: Adalimumab biosimilar (Amgen)

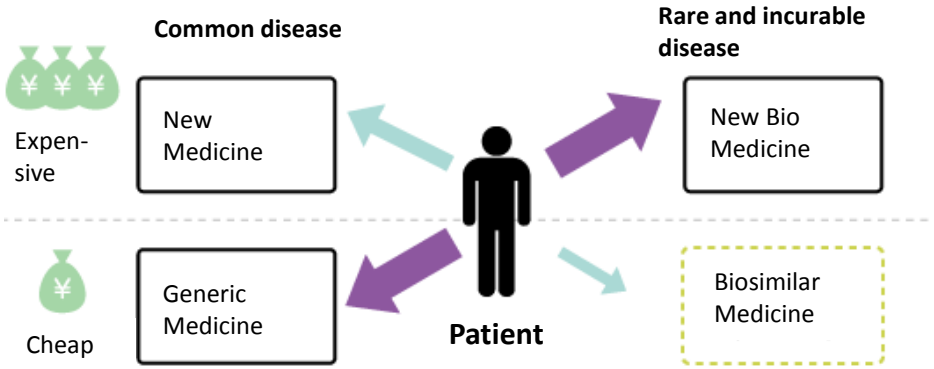
GENE TECHNO SCIENCE

The societal need for biosimilars

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.

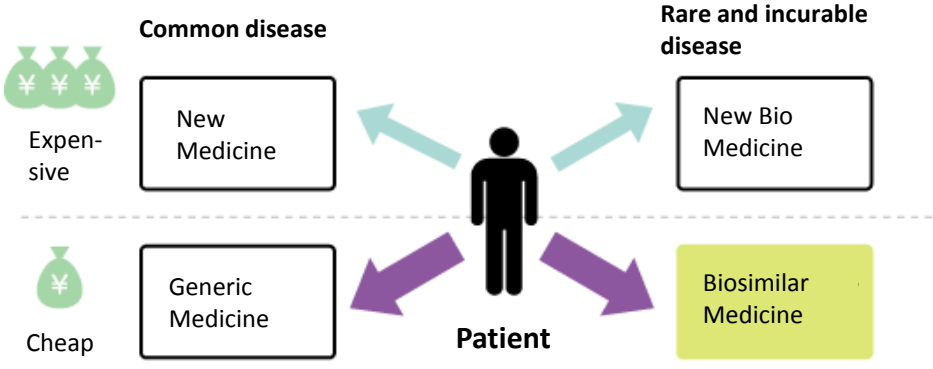
Current situation



△

- **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.**

Ideal situation



Bioslimilar is widely used

○

- **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!

GENE TECHNO SCIENCE

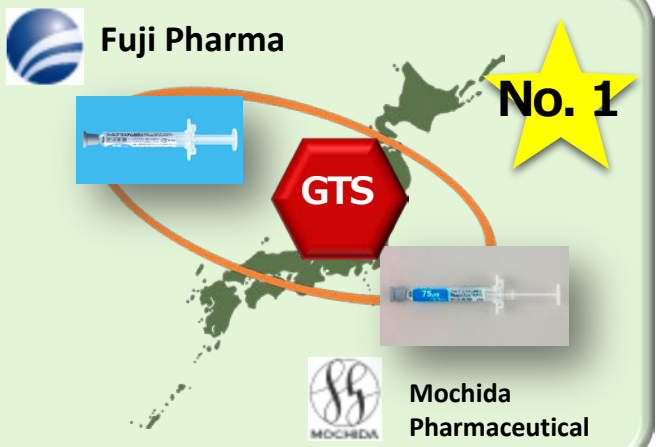
Biosimilar business

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"

We are also seeing steady growth in sales for fiscal year ending March 2018!

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!

3) Accelerated development of our biosimilar business in the field of oncology!

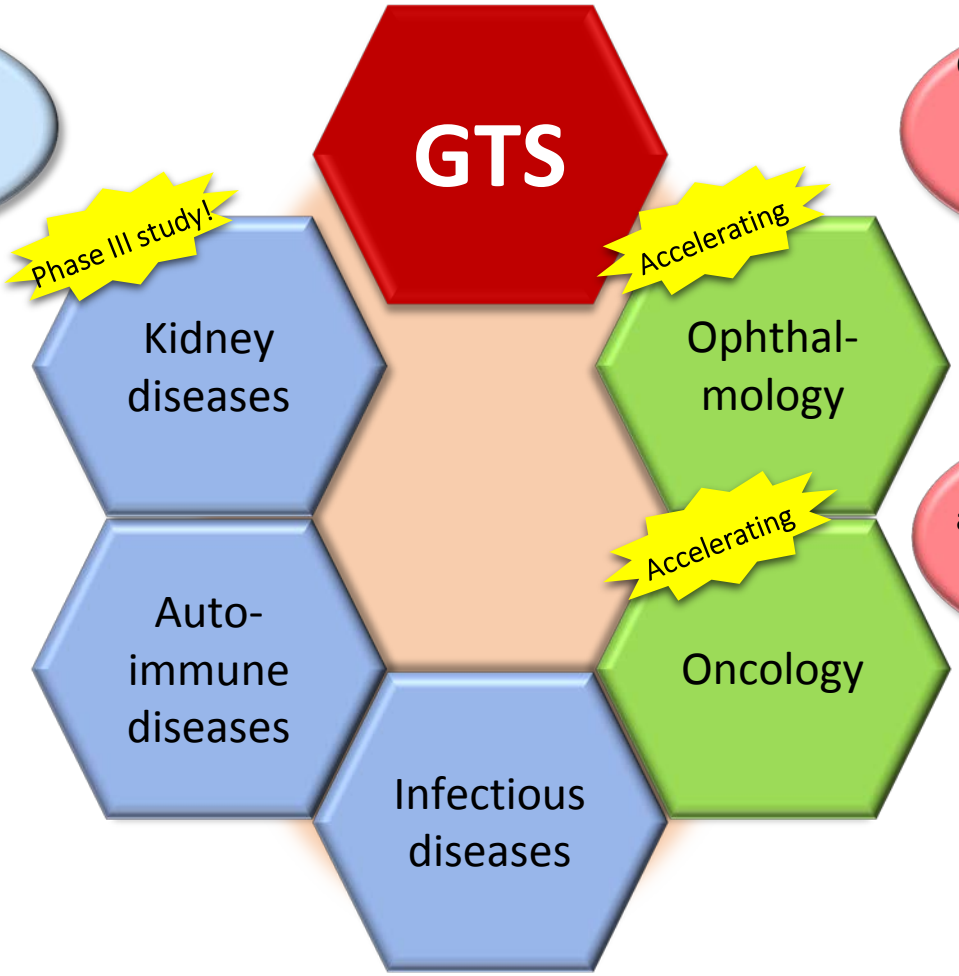
Business alliance with Sanwa Kagaku Kenkyusho
January 2014–

Nesp biosimilar

- September 2016: Started phase III

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
November 2015–

- May 12, 2016: Signed joint venture agreement

Joint development alliance with Mochida Pharmaceutical
August 2015–

- December 5, 2016: Signed joint venture agreement

GENE TECHNO SCIENCE

Progress in our Biosimilar Pipeline

Development code	R&D	Phase I	Phase III	BLA/ Launch	Rough estimate of the scale of the biosimilar market* Japan	Global (excluding Japan)
GBS-001 (cancer) Filgrastim					¥8 billion	¥40 billion
GBS-010 (cancer) PEG-filgrastim					¥8 billion**	¥208 billion
GBS-011 (kidney disease) Darbepoetin alfa					¥22 billion	¥92 billion
GBS-005 (autoimmune disease) Adalimumab					¥14 billion	¥520 billion
GBS-007 (eye diseases)					¥25 billion***	¥307 billion***
GBS-008 (infectious diseases) Palivizumab					¥15 billion	¥59 billion
GBS-004 (cancer) Bevacizumab					¥38 billion	¥250 billion
				Total	¥130 billion	¥1,476 billion

* 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%)

** Because brand name sales started in 2014, 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.

GENE TECHNO SCIENCE

New biologics business

- Projects in regenerative medicine (cell therapy) -

Capital and Business Alliance with Japan Regenerative Medicine Co., Ltd. (JRM)

Reasons

- **Stepping into the field of regenerative medicine!**
- **Starting a new pipeline using cardiac stem cells that JRM is developing.**

Establishing treatments using cardiac stem cells!

- **JRM-001 is a cell therapy product that JRM has been developing since the technology was transferred from Dr. Hidemasa Oh of Okayama University Hospital.**
- **It is a cell suspension of cardiac stem cells produced by isolating and culturing autologous heart tissue collected during heart surgery.**
- **Transplantation of JRM-001 into the coronary artery of the heart using a catheter about 1 to 1.5 months after surgery could potentially regenerate heart tissue and improve heart function.**

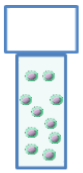
The first application will be for treatment of congenital heart disease in children!

Hospital → JRM → Hospital

1. Operational repair to treat single ventricle disease

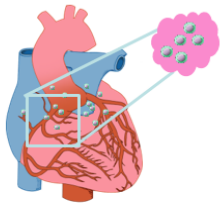
CPC center

3. Receive material

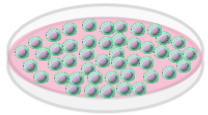


5. Dispatch JRM-001

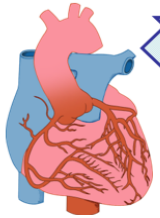
Expected improvement in heart activity



2. Obtain autologous tissue from heart during operation



4. Culturing the separated heart stem cell



6. Transplant into the heart

Source: Prepared from JRM materials

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

GENE TECHNO SCIENCE

Joint Research with Juntendo University

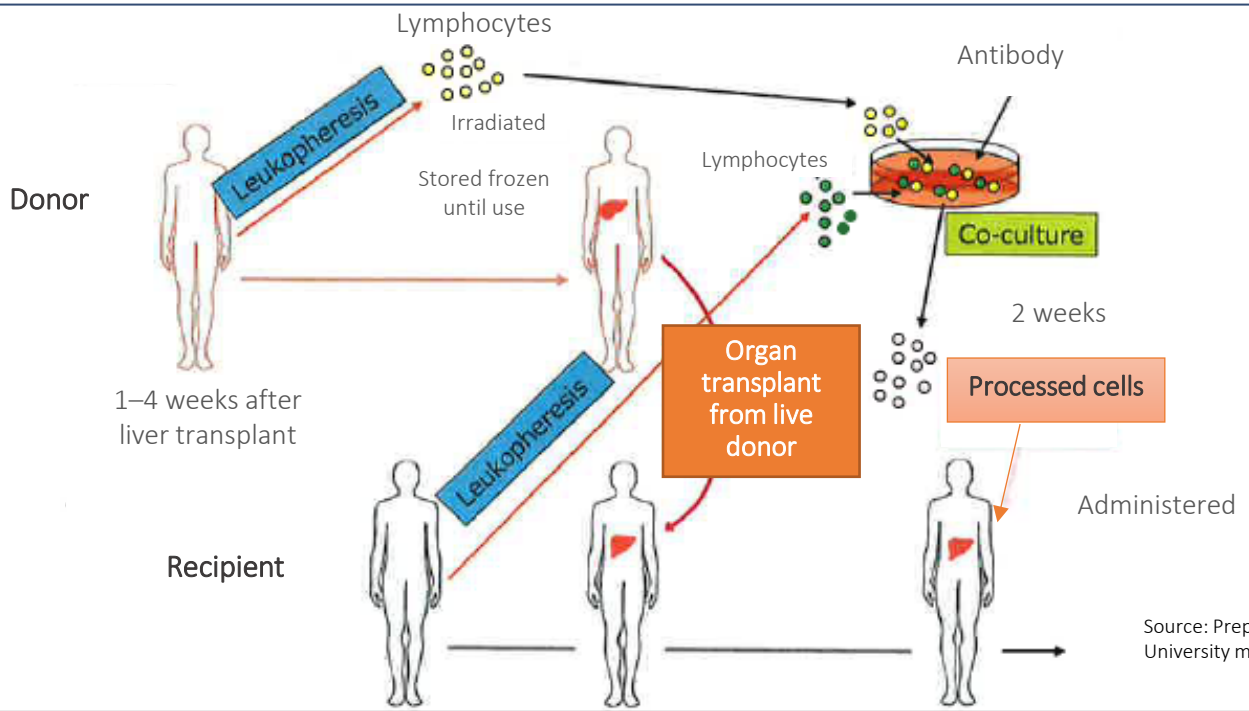
Reasons

- **Stepping into the field of regenerative medicine!**
- **We are expanding our immune tolerance induction technology to applications such as preventing transplant rejection and treating allergies.**

To establish the world's first technology for induction of immune tolerance!

- **We are conducting joint-research on therapies involving control of immune function.**
- **Using organ transplantation as an example, white blood cells collected from the body are processed with donor immune cells in a culture machine to induce immune tolerance. Transplantation of these processed cells into the organ recipient (i.e., cell therapy) could potentially suppress rejection of the transplanted organ.**

Example



Source: Prepared from Juntendo University materials

We foresee applications in the treatment of autoimmune disorders, organ transplants, and allergies (allergic rhinitis).

GENE TECHNO SCIENCE

Medium-term vision

Starting up a new biologics business focused on regenerative medicine

In addition to our existing businesses, we are starting up a new biologics business focused on regenerative medicine!

Research and develop treatments for refractory diseases and rare diseases using **cutting-edge technology**.

↓

- Ensure high growth potential and distribute development risk -

JRM

Develop cell and gene therapy products that use cardiac stem cells

- These have the potential for treating and curing **serious heart diseases (e.g., diseases that require organ transplantation)** in Japan, where organ transplantation is rare and subject to many restrictions.

Boost growth!

- Future revenue source
- Distribute development risk

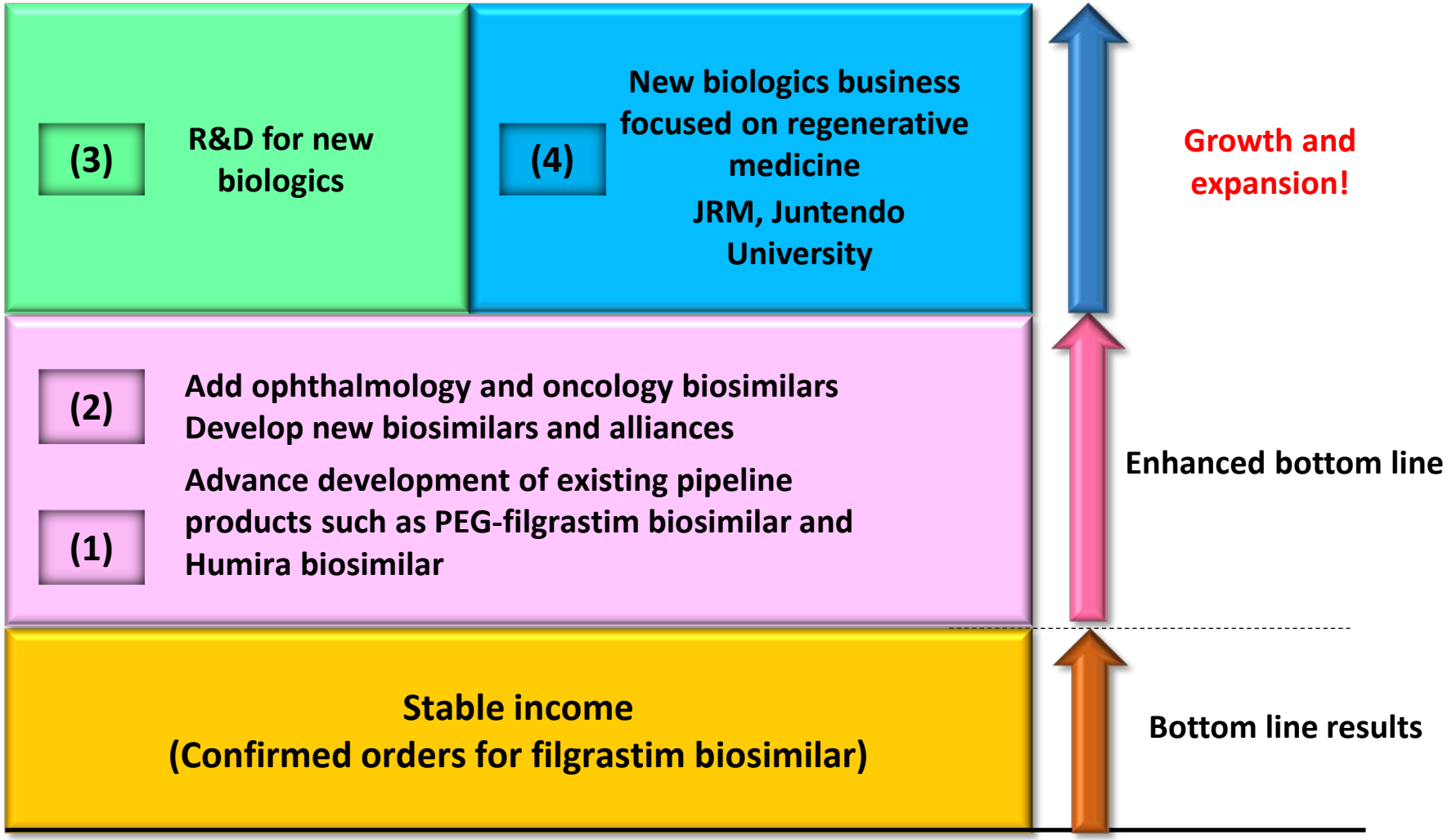
Juntendo University

Develop new immunosuppressive therapies that use immune tolerance technology

- These have the potential for treating or curing **common diseases and symptoms** such as allergic rhinitis and food allergies.
- Controlling immune function and suppressing transplant rejection could help ensure effective treatment of diseases that require organ transplantation.

Medium-term income vision

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



GENE TECHNO SCIENCE

We are becoming a profitable and growing bio-venture!

Keep an eye on our progress!

GENE TECHNO SCIENCE

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 provided was prepared on the basis of currently 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.

Contact information:
Management Division
TEL. 011-876-9571

GENE TECHNO SCIENCE

Unlimited drug discovery from the beginning