

# **Gene Techno Science Co., Ltd.**

## **Financial Results for the Fiscal Year Ended**

### **March 2018**

**May 16, 2018**





# Corporate overview and business highlights

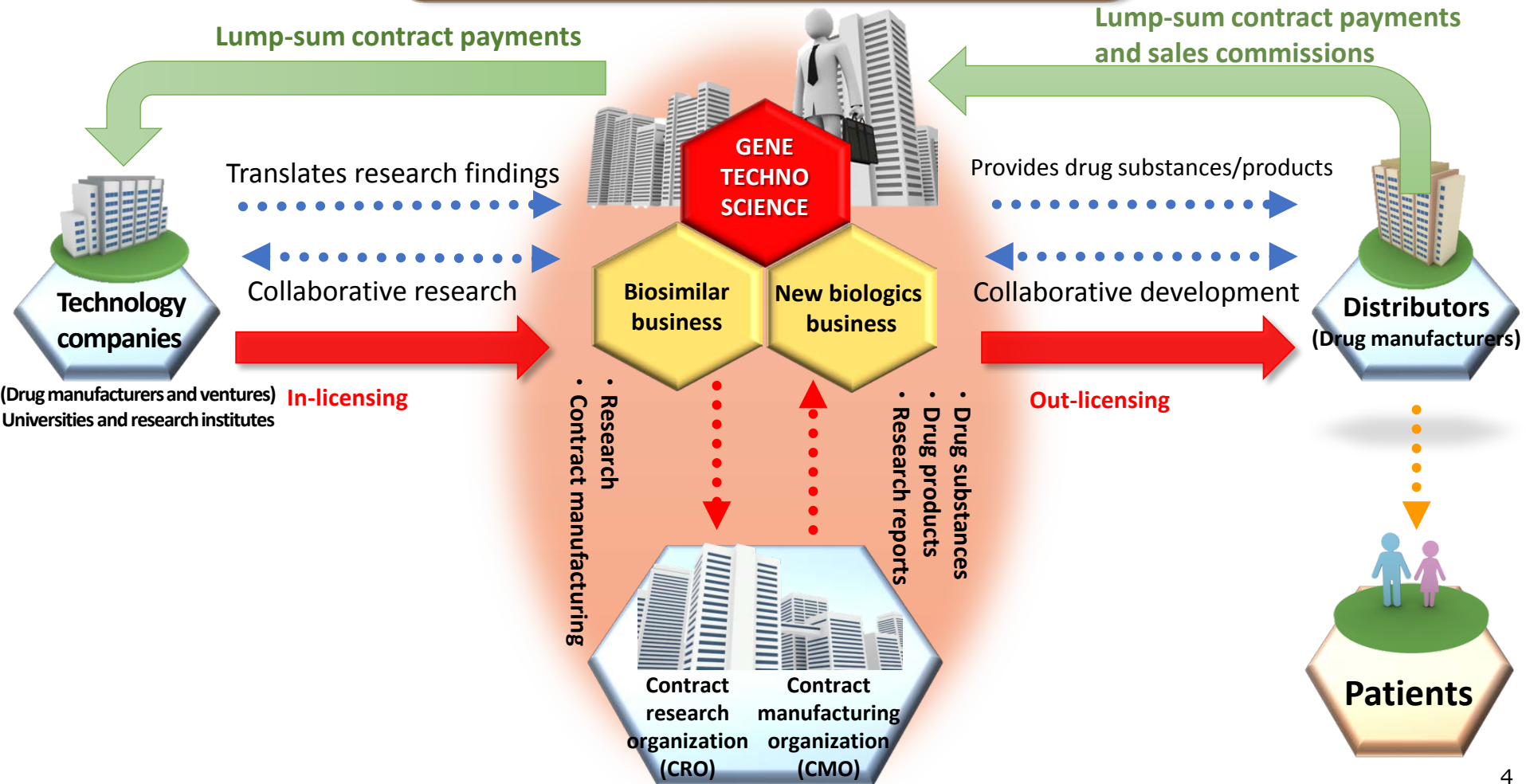
# Corporate overview

<b>Chief Executive</b>	Masaharu Tani, President
<b>Founded</b>	March 2001
<b>Listed on the stock exchange</b>	November 2012 (Tokyo Stock Exchange Mothers Section)
<b>Capital</b>	100 million yen (as of August 1, 2017)
<b>Locations</b>	<b>Head office</b> Kita 2-Nishi 9-1, Chuo-ku, Sapporo
	<b>Tokyo office</b> 2-10-8 Nihonbashi, Chuo-ku, Tokyo
	<b>Laboratory</b> Kita 21-Nishi 11, Kita-ku, Sapporo Inside the Center of Promotion for Platform for Research on Biofunctional Molecules, Hokkaido University Creative Research Institution

Time		Event
2001	March	GTS founded to translate findings from research conducted at the Institute for Genetic Medicine at Hokkaido University into diagnostic reagents and drugs
2007	June	Out-licensed anti- $\alpha 9$ integrin antibody to Kaken Pharmaceutical Co., Ltd.
	October	Signed joint development agreement for filgrastim (G-CSF) biosimilar with Fuji Pharma, Co., Ltd.
2012	November	Listed on the Tokyo Stock Exchange Mothers Section and obtained marketing approval for filgrastim biosimilar
2013	May	Filgrastim biosimilar listed in NHI price list and brought to market
	August	Formed capital and business alliance for biosimilars with ITOCHU CHEMICAL FRONTIER Corporation
2014	January	Signed joint development agreement for darbepoetin alfa biosimilar with Sanwa Kagaku Kenkyusho Co., Ltd. (started phase III clinical trial in September 2016)
2016	April	Joined Noritsu Koki Group through common stock takeover bid and formed capital and business alliance
	May	Signed joint venture agreement with Senju Pharmaceutical Co., Ltd. for biosimilars in the field of ophthalmology (phase III clinical trial started in November 2017). Signed basic agreement with Changchun Changsheng Life Sciences Ltd. to expand our biosimilar business to the Chinese market
	October	Formed capital and business alliance with Japan Regenerative Medicine Co., Ltd. (JRM) to develop business in regenerative medicine using cardiac stem cells
	December	Signed collaboration agreement with Mochida Pharmaceutical Co., Ltd. for biosimilars in the field of oncology
2017	February	Signed joint research agreement with Juntendo University for immune tolerance induction technology
	March	Formed capital and business alliance for developing new biosimilars with ITOCHU CHEMICAL FRONTIER Corporation
	June	Co-funded a regenerative medicine firm, Minerva Medica Co., Ltd., with local businesses in Hokkaido. Minerva Medica and Sapporo Medical University signed a collaborative contract on research and development of treatment of diabetic nephropathy using a patient's own bone marrow mesenchymal stem cells
2018	April	Entered into a three-company capital and business alliance contract with NanoCarrier Co., Ltd. and Nortitsu Koki Co., Ltd. to start drug development with the purpose of creating new biotechnologies.

# System for business development

- Advantages of a fables 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 the fiscal year ended March 2018

## ◆ Financial results for the fiscal year ended March 2017

	Sales (in millions of yen)	Selling, general and administrative expenses		Operating profit (in millions of yen)	Ordinary profit (in millions of yen)	Net income for the year (in millions of yen)	Net income per share (in yen) *
		Total	R&D expenses included				
<b>Results from the fiscal year ended March 2018 (A)</b>	<b>1,059</b>	<b>1,550</b>	<b>(1,107)</b>	<b>△913</b>	<b>△903</b>	<b>△904</b>	<b>△94.54</b>
Results from the fiscal year ended March 2017 (B)	1,089	1,876	(1,433)	△1,184	△1,176	△1,224	△137.01
Change (A-B)	△30	△326	△326	271	273	320	
(Reference) Forecasts for the fiscal year ended March 2018	1,166		1,197	△977	△992	△994	

### Key points

#### 1. Steady earnings

Filgrastim biosimilar sales figures were as forecasted.

#### 2. Steady progress of development

R&D spending was mainly on the biosimilar operations.  
(Development is going smoothly)

#### 3. Profitable excluding R&D expenses

No major changes to fixed costs other than R&D expenses.  
(Profits from the filgrastim business can cover them)

\* The company split each share into two shares on October 1, 2016. Net income per share for the quarter is calculated based on the assumption that the split was conducted at the beginning of the fiscal year ended March 2017.

# Financial forecasts for the fiscal year ending March 2019

## ◆ Financial forecasts for the fiscal year ending March 2019

	Sales (in millions of yen)	Operating profit (in millions of yen)	Ordinary profit (in millions of yen)	Net income for the year (in millions of yen)	Net income per share for the year (in yen)
<b>Forecasts for the fiscal year ending March 2019 (A)</b>	<b>1,060</b>	<b>△1,180</b>	<b>△1,180</b>	<b>△1,182</b>	<b>△123.54</b>
<b>Results from the fiscal year ended March 2018 (B)</b>	<b>1,059</b>	<b>△913</b>	<b>△903</b>	<b>△904</b>	<b>△94.54</b>
<b>Change (A-B)</b>	<b>1</b>	<b>267</b>	<b>277</b>	<b>278</b>	

### Key points

1. Sales: Affected by the price revision of filgrastim, but sales volume increased and the total sales amount is **about the same as the previous year**
2. Profit: Increased R&D spending due to the **GBS-007 development promotion**
3. R&D costs: The budget for the current year is **1,300 million yen** (1,107 million yen for the previous year); mainly spent on biosimilar research and development

# Business highlights for FY2017 (1)

## Biosimilar business

September 2017

- GBS-005 (adalimumab)
- Business collaboration with Changchun Changsheng Life Sciences Ltd.
- **Completion of technology transfer to Changchun Changsheng**
- Preparation for commercialization in China

November 2017

- GBS-007 (ophthalmology)
- Co-development together with Senju Pharmaceutical Co., Ltd.
- **Phase III of a clinical trial has started**
- Exploring overseas businesses



Business foundation

## New biologics business

September 2017

- GND-004 (ophthalmology, cancer)
- New antibody candidate originated from the Company
- Expected effectiveness in blocking the formation of neovascular vessels based on a new mechanism
- **A patent has been applied for; starting out-licensing activities**



Growth driver

## New businesses

June 2017

- Bone marrow mesenchymal stem cells (diabetic nephropathy)
- **Minerva Medica Co., Ltd. was established by some companies including us**
- **Minerva Medica Co., Ltd. and Sapporo Medical University signed a collaborative research contract**

September 2017

- Immunologic tolerance induction technology (autoimmune diseases)
- In a collaborative research agreement with Juntendo University
- **Signed an outsourcing contract with Medinet Co., Ltd., a cell processing specialist, for building a platform for cells to be used in cell treatment**
- Aiming for the next step, i.e. the clinical trial



Second phase growth driver

# Business highlights for FY2017 (2)

**April 2018: A business alliance contract signed by three companies: NanoCarrier Co., Ltd., Noritsu Koki Co., Ltd. and GTS (the Company)**

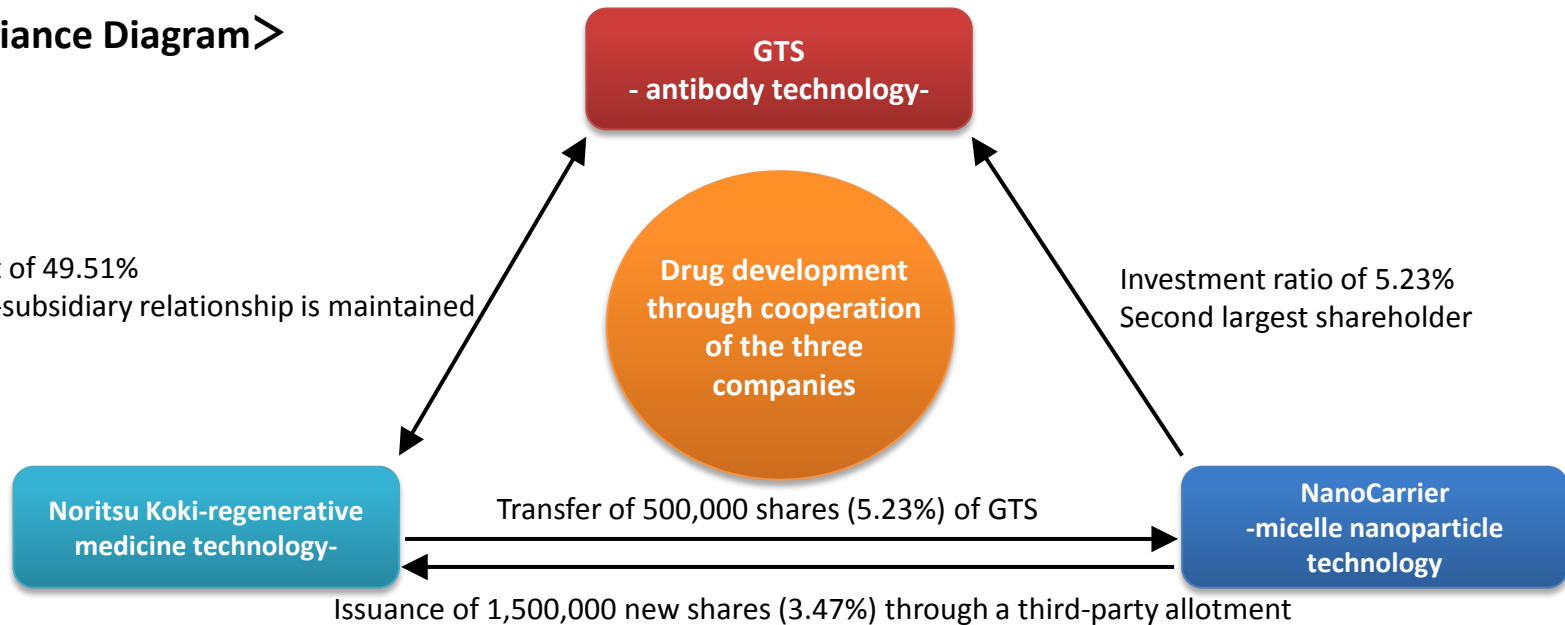
## Goals

- To create innovative technologies and medicines by combining the strengths of each company
- A capital alliance by NanoCarrier owning shares of GTS and Noritsu owning shares of NanoCarrier

### <Combining the strengths of each company>

- NanoCarrier utilizes its own micelle nanoparticle technology in developing innovative pharmaceuticals, mainly anticancer medicines encapsulated with low molecule, nucleic acid or peptide.
- Noritsu Koki is promoting a regenerative medicine business with their drug development division, and we are providing support to it by utilizing our antibody technology gained through the biosimilar operation.

### <Alliance Diagram>





# Election of new directors

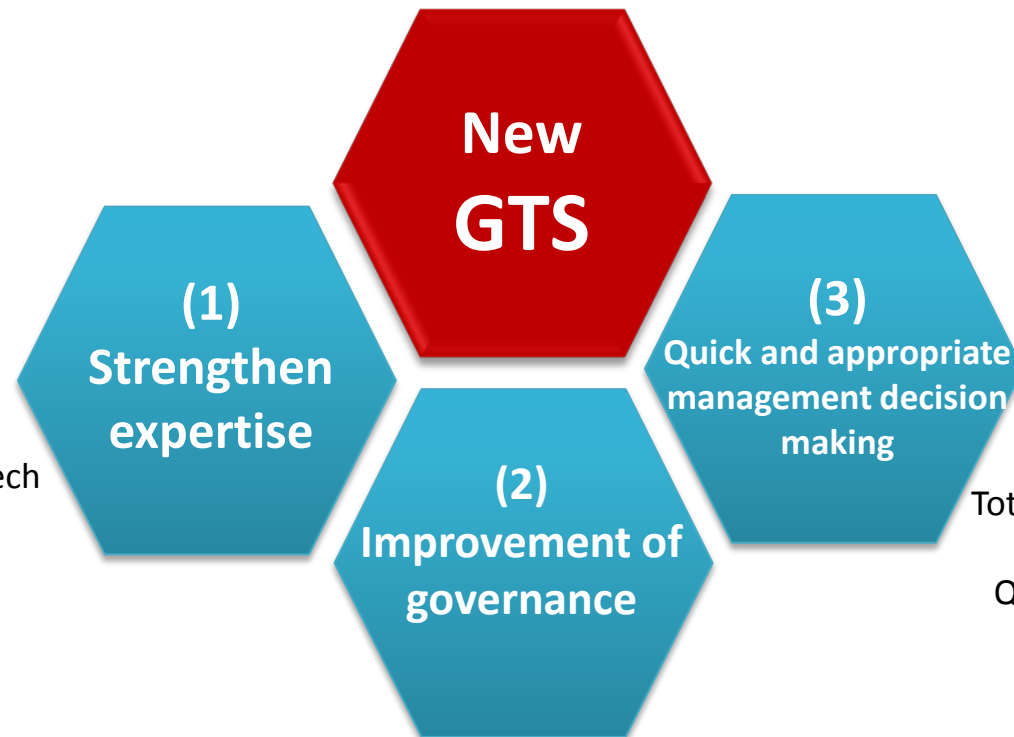
**Transition to a new management team upon an approval at a shareholders' meeting on June 28, 2018**

– Three director candidates –

Masaharu Tani (the current President of the Company)

**New** Ryo Noguchi (the current CEO of Japan Regenerative Medicine Co., Ltd.)

**New** Norikazu Eiki (the former chairman of Bayer Yakuhin, Ltd.) **\*outside director**

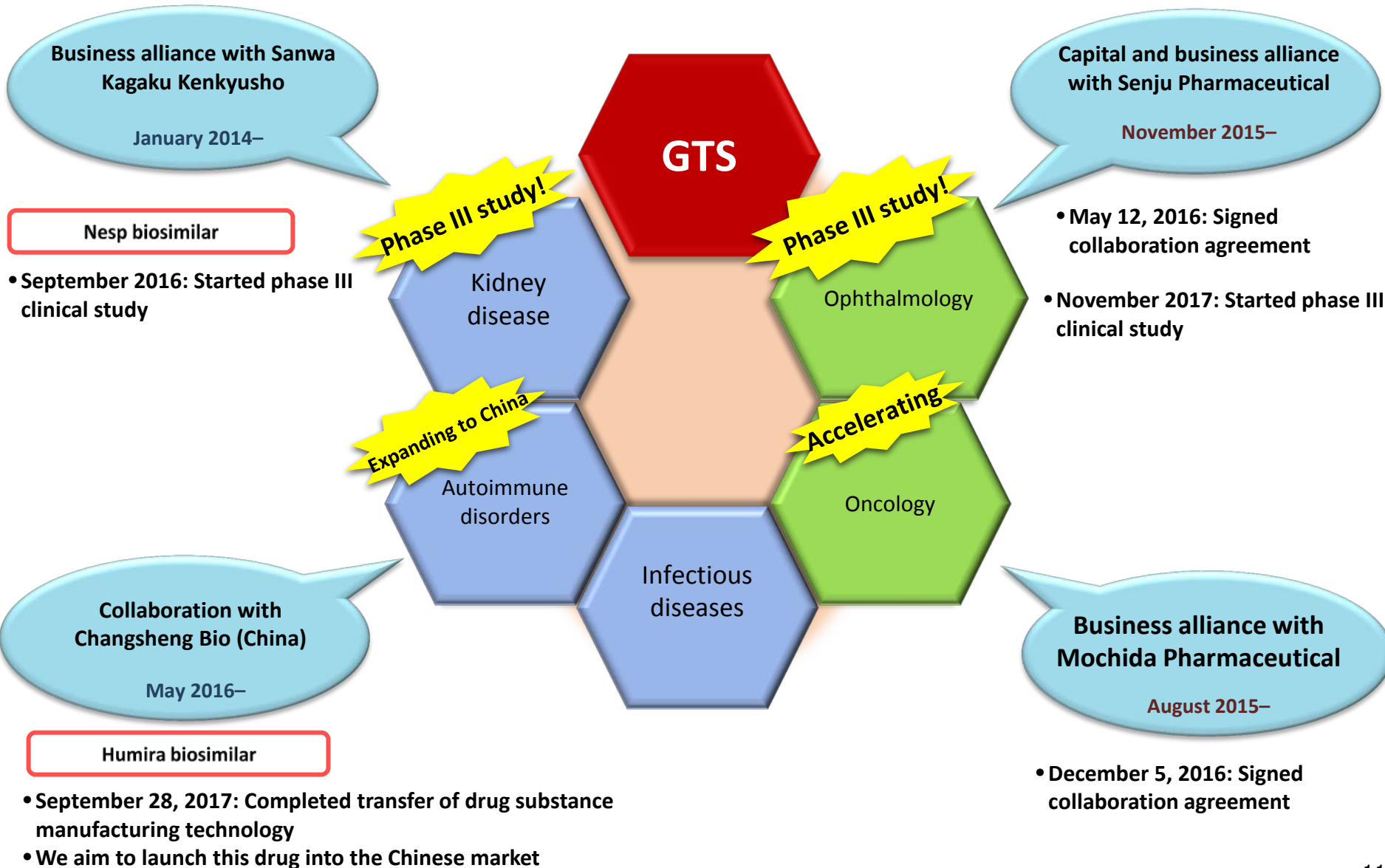


One from GTS, one from the Noritsu Koki Group, and one director from outside  
Improve management transparency and strengthen governance










# Business progress

# Advances in our biosimilar business






## (1) Biosimilars Business



Development code	Target disease	R&D	Clinical trial		Application submitted/reviewed Approved/ marketed	Affiliates
			Phase I	Phase III		
<b>GBS-001</b> Filgrastim	Cancer					Fuji Pharma Co., Ltd. Mochida Pharmaceutical Co., Ltd.
<b>GBS-004</b> Bevacizumab	Cancer					
<b>GBS-005</b> Adalimumab	Immunological diseases					Changchun Changsheng Life Sciences Limited (China)
<b>GBS-007</b>	Ophthalmic diseases					Senju Pharmaceutical Co., Ltd.
<b>GBS-008</b> Palivizumab	Infectious diseases					
<b>GBS-010</b> Pegfilgrastim	Cancer					
<b>GBS-011</b> Darbeoetin alfa	Kidney disease					Sanwa Kagaku Kenkyusho Co., Ltd.

# Progress in each pipeline

## (2) New biologics business

Development code	Target disease	Basic research	R&D	Clinical trial			Application submitted/ reviewed Approved/m arketed	Affiliates
				Phase I	Phase II	Phase III		
<b>GND-001</b> Anti-human $\alpha$ 9 integrin antibody	Immunological diseases, cancer							Kaken Pharmaceutical Co., Ltd.
<b>GND-004</b>	Ophthalmic diseases, cancer							In derivation
<b>GND-007</b>	Immunological diseases							

## (3) New biotech business (regenerative medicine)

Product	Target area	Basic research	Clinical trial	Approval on condition/te rm *	Sold at a market (Review effectiveness and further safety after sale)	Approved	Sales continue	Collaborating company/institution
<b>Cardiac stem cells</b>	Improvement of heart functions							Japan Regenerative Medicine Co., Ltd.
<b>Immunologic tolerance induction</b>	Auto immune diseases Organ transplants, allergies							Juntendo University
<b>Bone marrow mesenchymal stem cells</b>	diabetic nephropathy							Sapporo Medical University Minerva Medica Co., Ltd.

\* An approval system that encourages faster commercial viability of regenerative drug products.

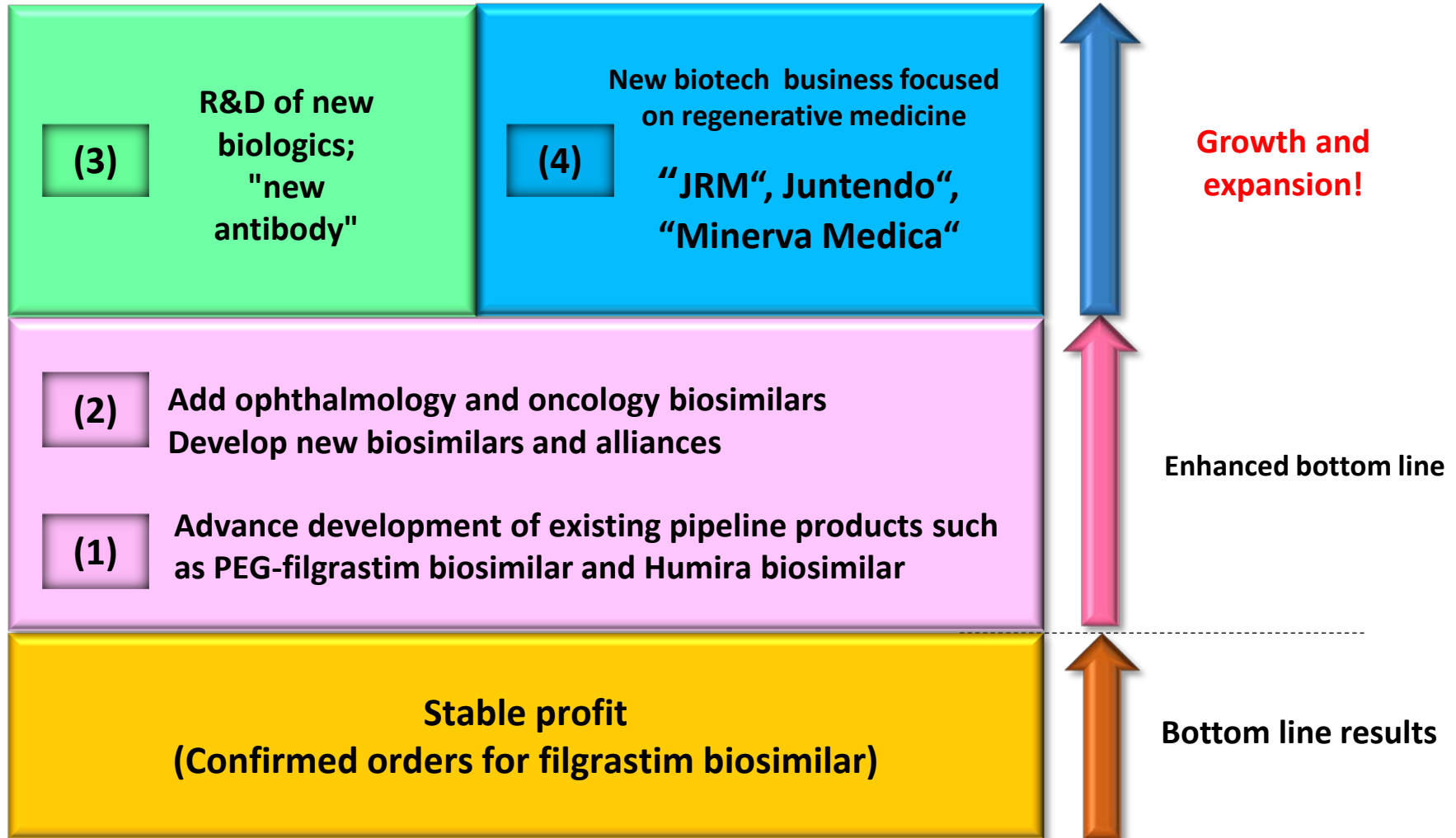
The process in which a patient receives an explanation about the risks, and with the agreement of the patient, the medicine is used. After the launch, safety measures will be taken.



# Medium-term vision

# Medium-term profit vision

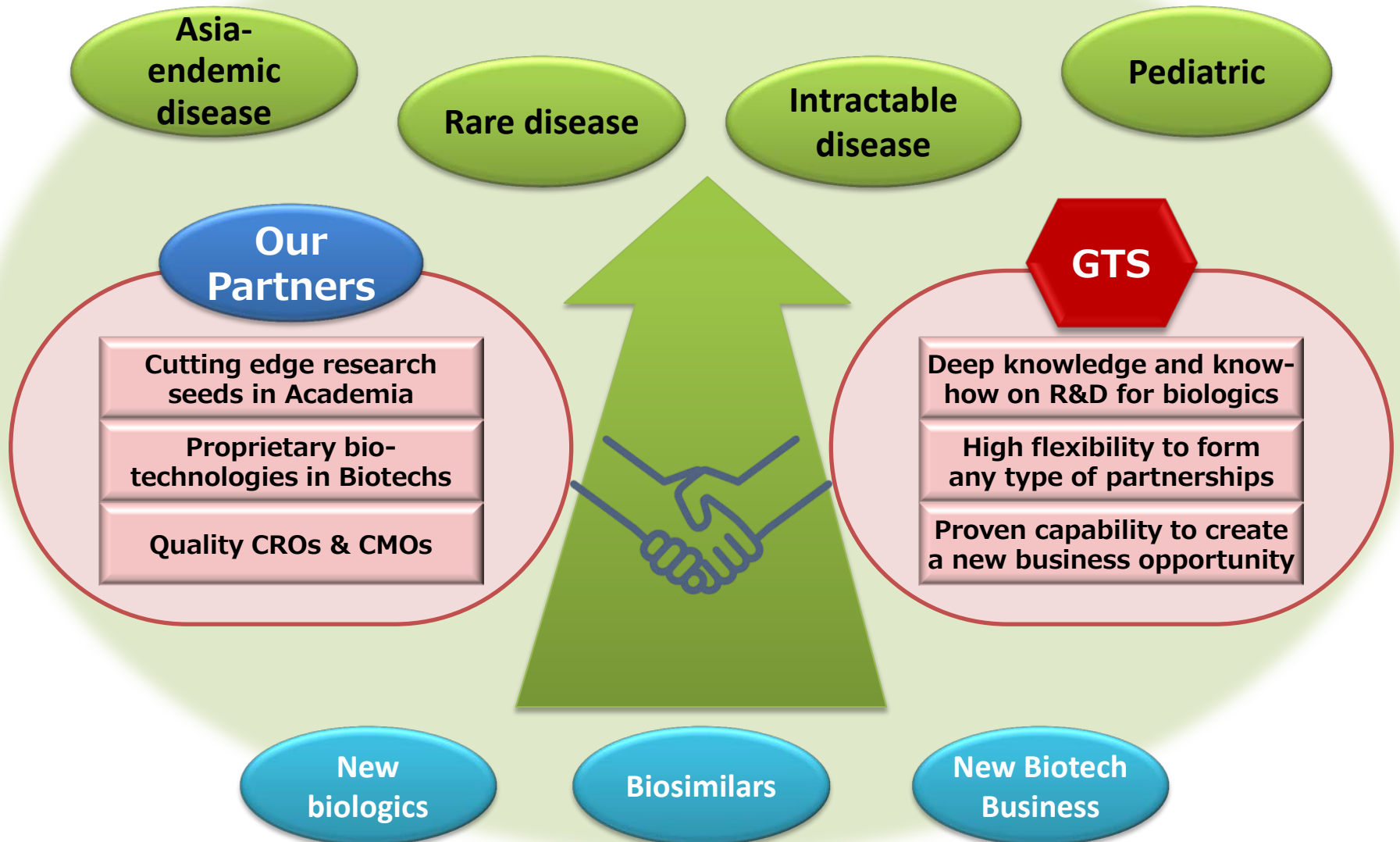
We are expanding into new biologics and regenerative medicine using biosimilars as a stepping stone!



# Our Mission

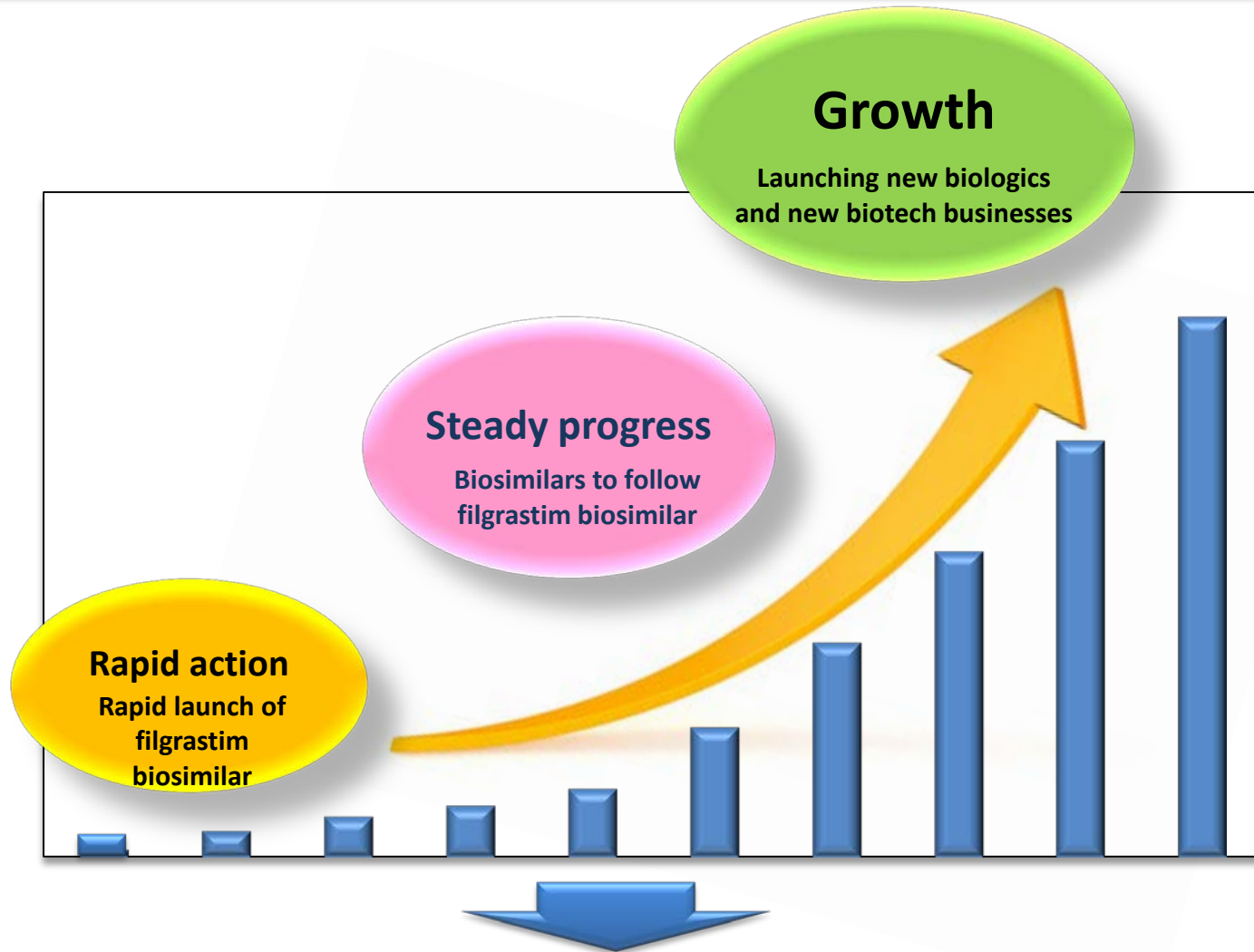
We are Biotech Engineering Company,  
striving for value creation !!

“ To design a new biotech business combining multi-new biotechnologies and to create a brand-new biologics and/or services for unmet medical needs ”





# We are becoming a profitable and growing bio-venture!



**Don't miss our future progress!**



GENE TECHNO SCIENCE

**Thank you for coming today.**



GENE TECHNO SCIENCE

**Unlimited drug discovery from the beginning**