



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

## **Financial Results for 1Q/FY2018** **(Fiscal Year Ending March 2019)**

**August 6, 2018**

# Our Strategic Direction



**GTS  
3.0**

**Biotech Engineering Company,  
striving for value creation**

– Aiming at providing comprehensive healthcare solutions for patients as well as families and caregivers –



**Explore new business opportunities by providing a healthcare solution for the therapeutic areas where a current solution is insufficient**

## **Our Focus**

- ❖ Pediatric disease (including juvenile one)
- ❖ Rare disease
- ❖ Intractable disease
- ❖ Asia-endemic disease

## Financial Highlight

- Sales of Filgrastim BS was in line with the forecast
- Milestone revenue was recorded as development stage of biosimilars pipeline had advanced
- Special payment was made in relation to the retirement of GTS Chairman

## Business Highlight

- Business alliance contract was signed by three companies: NanoCarrier Co., Ltd., Nortitsu Koki Co., Ltd. and GTS (the Company)
- New Management Team has started
- Decision was made on starting a negotiation to terminate collaboration agreement with Changsheng Bio, our partner for commercializing Adalimumab biosimilars in China
- Collaborative Research Agreement with chromocenter Inc. was executed

# Financial Results for 1Q/FY2018

	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				
Results for 1Q/FY2018 (A)	273	251	(141)	△55	△62	△108	△5.69
Results for 1Q/FY2017 (B)	171	213	(104)	△118	△114	△115	△6.02
Change (A-B)	102	38	(37)	63	52	7	
(Reference) Forecasts for FY2018	1,060		1,300	△1,180	△1,180	△1,182	

## Key points

### 1. Steady earnings

- Filgrastim biosimilar sales figures were as forecasted.
- Milestone revenue in biosimilars portfolio was recorded.

### 2. Steady progress of development

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

### 3. SG&A expenses on schedule

Special payment in relation to the retirement of GTS chairman (45 million yen: extraordinary loss)

\*The company split each share into two shares on July 1, 2018. Net income per share for the quarter is calculated based on the assumption that the split was conducted at the beginning of FY2018.

# A business alliance of NanoCarrier Co., Ltd., Nortitsu Koki Co., Ltd. and GTS (the Company)

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

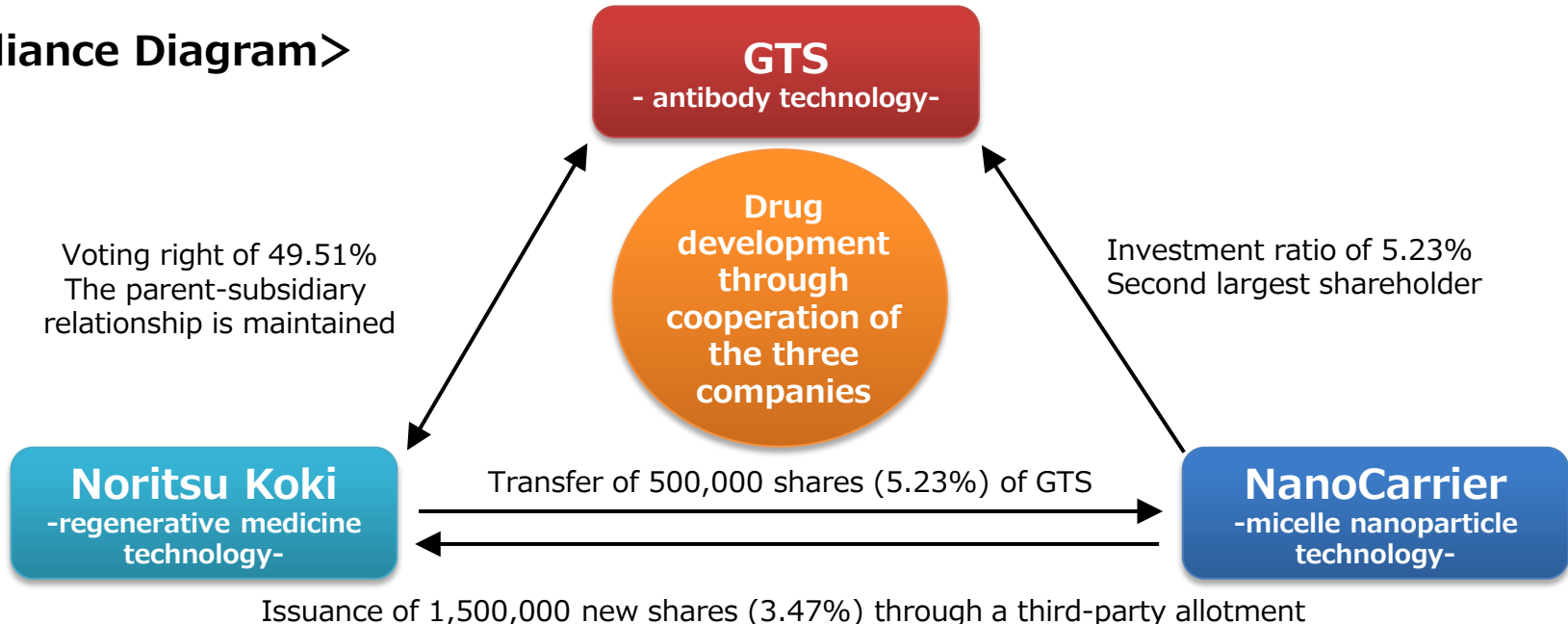
## Goals

- 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

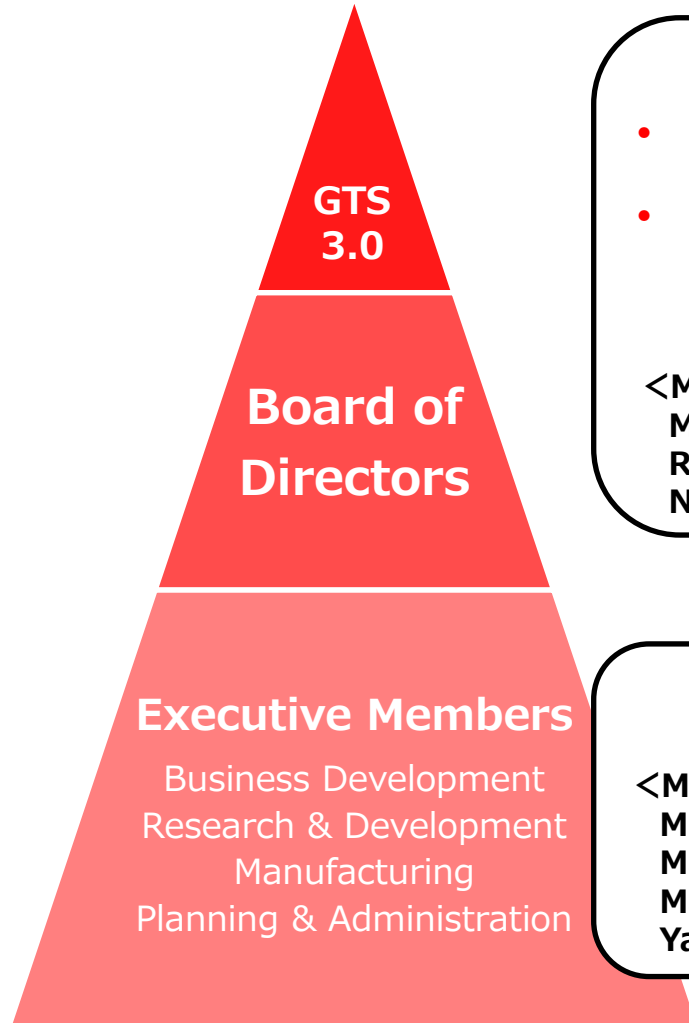
## <Combining the strengths of each company>

- 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>



# New Management Team



**- New Management Team -**

- Quick and appropriate decision making by directors with biotech knowledge and experience
- Improvement of governance by directors from GTS and NK as well as one outside directors



**<Member>**

<b>Masaharu Tani</b>	President & CEO
<b>Ryo Noguchi</b>	CEO of Japan Regenerative Medicine Co., Ltd.
<b>Norikazu Eiki</b>	Former chairman of Bayer Yakuhin, Ltd. Outside Director

**- Experts from each functions supporting new Management Team -**

**<Member>**

<b>Munechika Sakabe</b>	CBO
<b>Masayuki Kawakami</b>	CTO
<b>Masakuni Ueno</b>	Head of Administration
<b>Yasuo Sakae</b>	Head of Corporate Planning/IR



**Decision on collaboration agreement with Changsheng Bio, our partner for commercializing Adalimumab biosimilars in China**

## **Backdrop**

- July 15, 2018  
Regulators (State Food and Drug Administration) revealed that Changsheng Biotechnology had forged data during the production of 110,000 rabies vaccines and sold more than 250,000 “substandard” diphtheria, tetanus and pertussis (DTP) vaccines to medical centres last year and had ordered it to halt production of a rabies vaccine due to substandard production
- July 27<sup>th</sup>, 2018
  - We (GTS) decided to start negotiation with Changsheng Biotechnology to terminate collaboration agreement for commercializing Adalimumab biosimilars in Chinese market
  - We found Changsheng Biotechnology’s corporate culture as problematic from a series of scandals and judged they are not our appropriate partner because they committed unethical act which we cannot understand at all from a viewpoint of pharmaceutical companies who should consider patients’ safety as a first priority.

## **Next step**

- Start negotiation with Changsheng Biotechnology immediately
- Search for a new partner for Adalimumab biosimilars and other biosimilars in China because it has a strategic value for us as a market for biosimilars.



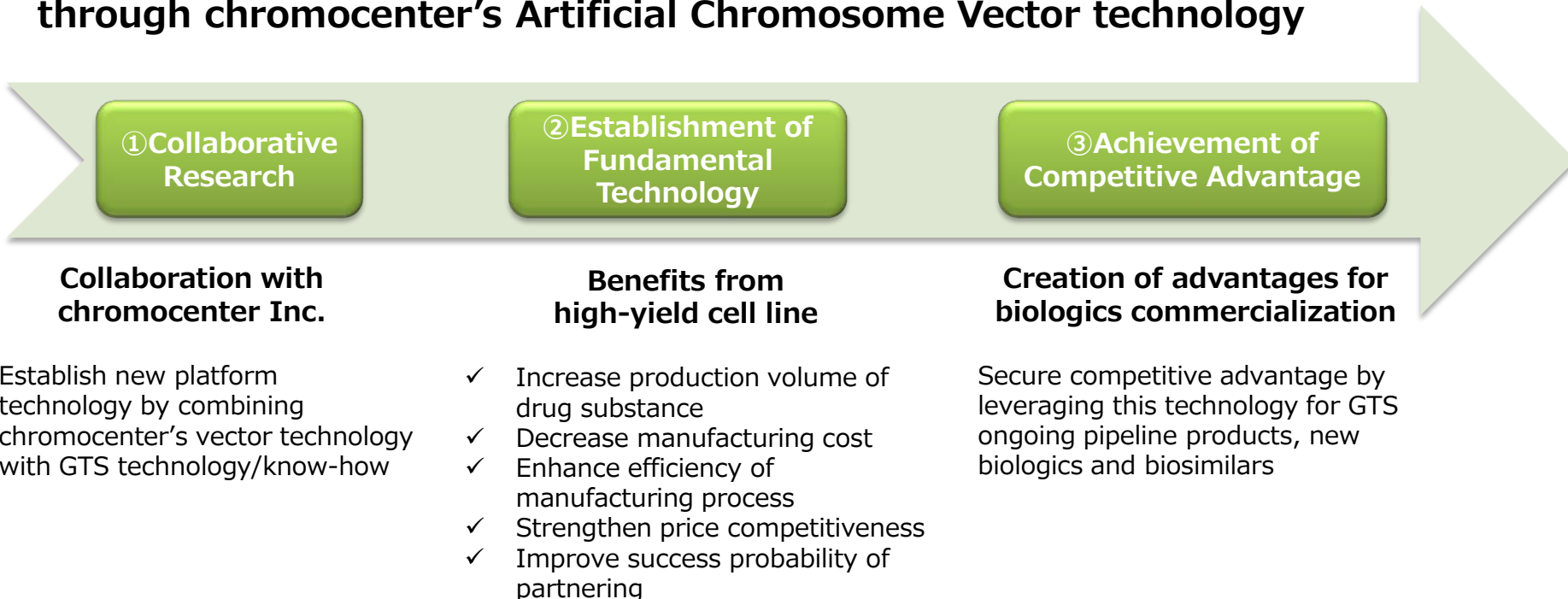
# Collaborative Research Agreement with chromocenter Inc.

**chromocenter Inc.** (<http://chromocenter.com/eng/>)

A biotechnology specialist who has leading-edge technologies such as Artificial Chromosome Vector, Chromosome Analysis, etc.

## Purpose of this collaboration

Develop high-yield protein producing cell lines for biosimilars by optimizing gene construct encoding amino acid sequence of recombinant protein through chromocenter's Artificial Chromosome Vector technology





# Progress in each pipeline



## (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	[Progress bar]				Fuji Pharma Co., Ltd. Mochida Pharmaceutical Co., Ltd.
<b>GBS-004</b> Bevacizumab	Cancer	[Progress bar]				
<b>GBS-005</b> Adalimumab	Immunological diseases	[Progress bar]				Terminating an agreement with Changchun Changsheng Life Sciences Limited (China) and searching new partners
<b>GBS-007</b>	Ophthalmic diseases	[Progress bar]				Senju Pharmaceutical Co., Ltd.
<b>GBS-008</b> Palivizumab	Infectious diseases	[Progress bar]				
<b>GBS-010</b> Pegfilgrastim	Cancer	[Progress bar]				
<b>GBS-011</b> Darbepoetin alfa	Kidney disease	[Progress bar]				Sanwa Kagaku Kenkyusho Co., Ltd.

\*Milestone revenue was recorded during 1Q FY2018 as development stage of pipeline products had advanced.

# 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							Searching partners
<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.



# Cautionary Statement

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This information material is provided for understanding Gene Techno Science (“GTS”), not for soliciting investment in GTS shares.

Information provided in this material may contain so-called “forward-looking statements.” These statements are based on current expectations, forecasts and assumptions that are subject to risks and uncertainties, which could cause actual outcomes and results to differ materially from these statements. Risks and uncertainties include success rate of R&D projects, new regulations and rules, relations with partners in the future, etc.

This material includes information on pharmaceutical products and regenerative medicine (or related products), etc., which is being developed or launched. However, this is not intended to promote our products or provide medical advices.



GENE TECHNO SCIENCE

# Gene Techno Science



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