



# Gene Techno Science Co., Ltd.

## Financial Results for 2Q/FY2019 (Fiscal Year Ending March 2020)

November 5, 2019

# 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 ratio of R&D projects, new regulations, and rules, relations with partners in the future, etc.



# Overview of Financial Highlight in 2Q/FY2019

## Financial Highlight

### Financial Highlight in 2Q/FY2019

- ✓ Financial results was in line with the forecast
- ✓ Expenses for R&D was controlled almost as planned

# Financial Results for 2Q/FY2019

## ◆ Financial Result for 2Q/FY2019 (April to September 2019)

(M JPY)

	Sales	Selling, general and administrative expenses		Operating profit	Ordinary profit	Comprehensive income attributable to owners of the parent	Net income per share (in yen)
		Total	R&D expenses included				
Results for 2Q/FY2019 (A)	313	840	(484)	-611	-613	-6,550	-236.95
(Reference) Forecasts for FY2019	1,050		1,200	-1,220	-1,260	-7,260	

### Key points

- Sales of filgrastim biosimilars is expected to achieve the sales target in FY2019
- Milestone revenue in biosimilars portfolio was recorded.

- R&D spending was mainly on the biosimilar operations.

Impairment loss of 5,938M JPY was recorded for 2Q/FY2019 in relation to the one-time depreciation of goodwill

# Financial Results for 2Q/FY2019 (Non-consolidated)

## ◆ Financial Result for 2Q/FY2019 (April to September 2019) (M JPY)

	Sales	Selling, general and administrative expenses		Operating profit	Ordinary profit	Net income for the year
		Total	R&D expenses included			
<b>Gene Techno Science</b>						
Results for 2Q/FY2019 (A)	250	785	(462)	△601	△603	△6,539
Results for 2Q/FY2018 (B)	288	502	(285)	△291	△301	△347
Change (A – B)	△37	282	(177)	△309	△302	△6,192
<b>Advanced Cell Technology</b>						
Results for 2Q/FY2019	63	55	(21)	△9	△10	△10

Loss on valuation of stocks of subsidiaries and affiliates (impairment loss) of 5,938M JPY was recorded for 2Q/FY2019 in non-consolidated base in relation to the one-time depreciation of goodwill in consolidated base.



# Overview of Business Highlight in 2Q/FY2019

# Business Highlight for 2Q/FY2019

## New Biologics

- Continuing activities for license-out of Anti-RAMP2 antibodies

## Biosimilars

- Received the manufacturing and marketing approval for the biosimilar of darbepoetin alpha in Japan

## New Biotech (Cell Therapy)

- Sign a joint research and development agreement with ORTHOREBIRTH
- Academia-industry Collaboration with Showa University for a Development of Treatments in Cell Therapy Field
- Joint Research Agreement with Showa for a Development of Treatments for Bone-related Diseases
- Joint Research Agreement with Gifu Pharmaceutical University for a Development of Treatments for an Ophthalmologic
- Signed a Contract for Sale of SHED with Summit Pharmaceuticals International Corporation (SPI).
- Investment in Heartseed Inc., Regenerative Medicine Venture Company

## Others

- Conversion of Advanced Cell Technology and Engineering into Wholly-Owned Subsidiary of GTS
- Changes in Financing Arrangement
- Establishment of Remcare Ltd.
- Appointment of Scientific Advisor



# Collaborative research and business with Academia

Collaborative research and business by utilizing SHED with Showa Univ. and Gifu Pharmaceutical Univ (GPU).

GTS  
×  
ACTE  
Cell Therapy PJ

## Target Diseases in GTS

### Academia-industry Collaboration with Showa University

Comprehensive collaborative research and business activities  
other than bone-related diseases

**Bone-related  
diseases**

Agreement  
in Sep 2019

**Other diseases**

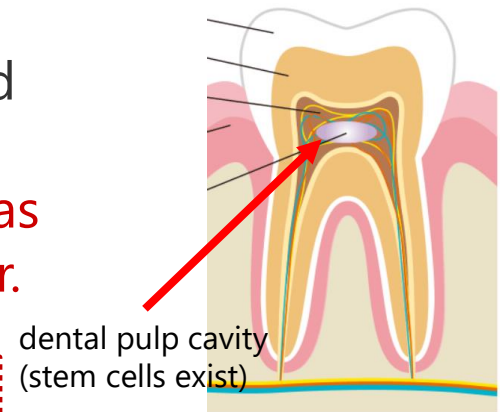
**Ophthalmologic  
diseases / GPU**

Agreement  
in Sep 2019

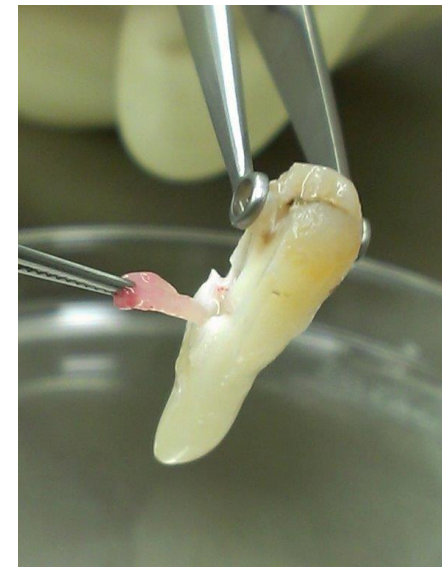
Seeking out a new opportunity with  
academia for other diseases

# What is SHED?

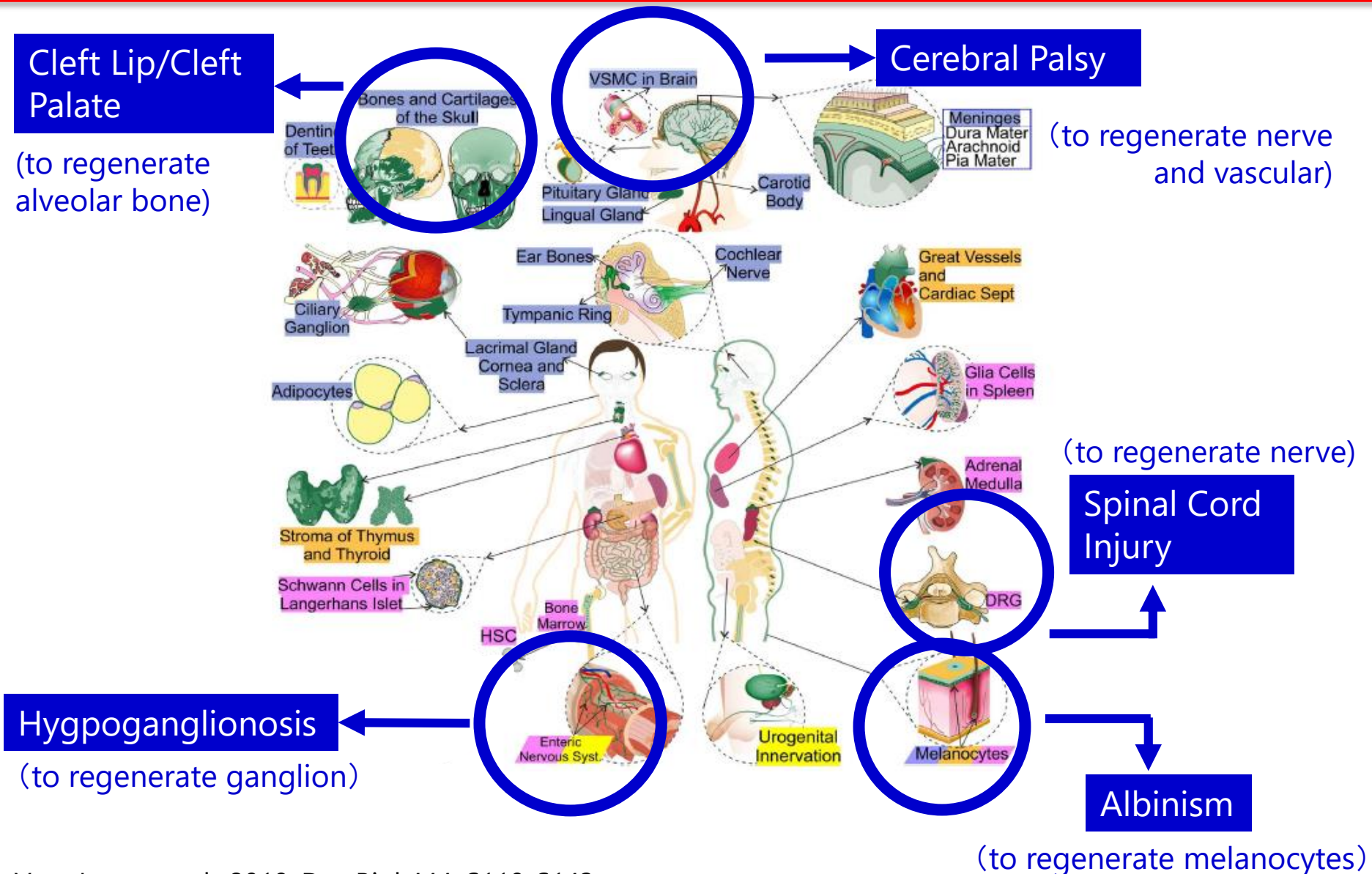
- One type of dental pulp stem cells that extracts from a dental pulp cavity (Stem cells from human exfoliated deciduous teeth).
- Possible to extract from the deciduous teeth, **which has many sampling timings, and less burden on the donor.**



	Bone Marrow	Adipose	Umbilical cord	Dental Pulp (SHEDs)
Type of Bank	Public	Private	Public/private	Private
Age of Donor	20 to 55 yrs old	Mostly over 20yrs old	0 yr old	5 to 12 yrs old
Timing of Extraction	When transplantation	When surgery	Time of birth	Usually 20 times
Burden on Donor	High	High	Very low	Low
Proliferating Ability	High	High	Research stage	Very high



# Target Diseases in GTS Cell Therapy Business



# Establishment of Scientific Advisory Board

- ✓ Appointed two new scientific advisors
- ✓ Established Scientific Advisory Board

Appoint experts with specialized academic knowledge in the regenerative medicine business and establish a system to incorporate advices from a wide range of business experience

## Scientific Advisory Board

**Tomoaki  
Taguchi**

Professor  
Department of Pediatric Surgery  
Graduate School of Medical Sciences  
Kyushu University

**Takayoshi  
Yamaza**

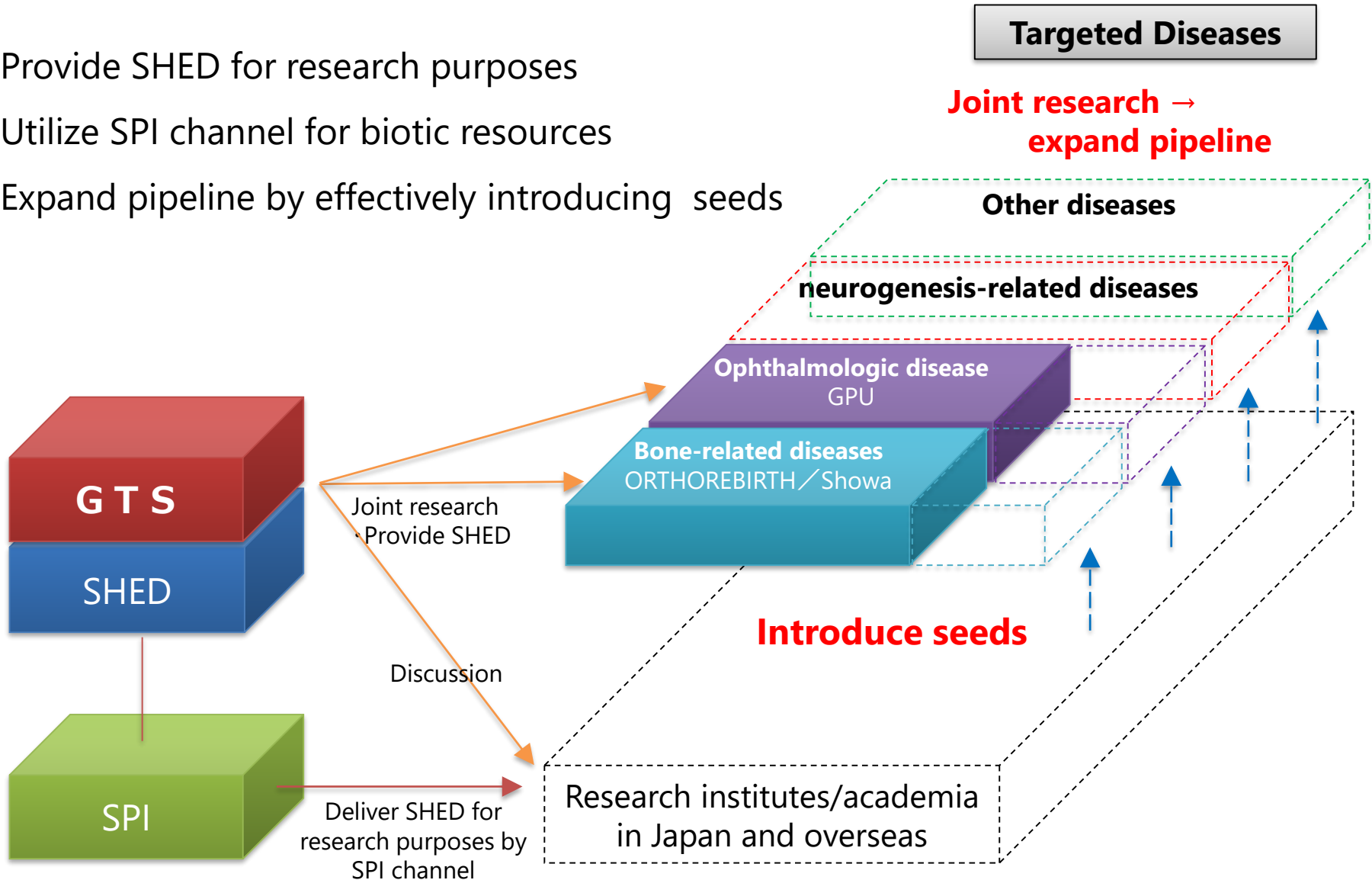
Associate Professor  
Department of Molecular Cell  
Biology and Oral Anatomy  
Graduate School of Dental Science  
Kyushu University

Strengthen our cell  
therapy business with  
SAB



# Positioning of SPI in Cell Therapy Business

- ✓ Provide SHED for research purposes
- ✓ Utilize SPI channel for biotic resources
- ✓ Expand pipeline by effectively introducing seeds





# Investment in Heartseed Inc.

- Established in Nov 2015 as a venture company spun out from Keio University
- Aim to deliver fundamental treatment to patients with severe cardiac failure through “myocardial regenerative medicine”.
- Developed technology for generating ventricular cardiomyocytes differentiated and induced from iPS cells to supply as highly purified regenerative medicine products for patients with severe cardiac failure, and is currently working toward commercialization.

Investment in Heartseed, a promising regenerative medicine venture, and explore the possibility of collaboration through the technologies of two companies.

<b>General Information</b>	Established	November 30, 2015	
	Business	Myocardial regenerative medicine using iPS cells	
	Capital	1,800million JPY (as of Aug. 31, 2019)	
	Location	HQ	12-9, Daikyo-cho, Shinjuku-ku, Tokyo 160-0015, JAPAN
<b>Management</b>	Directors	Director, CEO	Keiichi Fukuda
		Director, COO	Kikuo Yasui
		Director, R&D	Takumi Akiyama
	Outside Director	Yutaro Kasai, Toshiharu Furukawa	
	Auditor	Tomoyuki Kikugawa	
<b>Share holders</b>	Founders / Employees / Angel Bridge / Astellas Venture Management / Shibuya Corp.		

### GTS Cell Therapy Platform

Cardiac stem cells

Stem cells from human exfoliated deciduous teeth

Heartseed iPS cells



# Product Pipeline Update



# Pipeline Update

## (1) Biosimilars

Project	Therapeutic Area	Development Research	Clinical Trial		Application/Marketing/Approval/Launch	Partner
			Phase 1	Phase 3		
<b>GBS-001</b> Filgrastim	Oncology					Fuji Pharma Co., Ltd. Mochida Pharmaceutical Co., Ltd.
<b>GBS-004</b> Bevacizumab	Oncology					
<b>GBS-005</b> Adalimumab	Immunological disease					Terminating an agreement with Changchun Changsheng Life Sciences Limited (China) and searching new partners
<b>GBS-007</b> Ranibizumab	Ophthalmic disease					Senju Pharmaceutical Co., Ltd. License out to Ocumension Therapeutics (China and Taiwan)
<b>GBS-008</b> Palivizumab	Infectious disease					
<b>GBS-010</b> PEG-filgrastim	Oncology					
<b>GBS-011</b> Darbepoetin alfa	Renal disease					Sanwa Kagaku Kenkyusho Co., Ltd. Received marketing approval in Sep 2019.


## (2) New Biologics

Project	Therapeutic Area	Basic Research	Development Research	Clinical Trial			Application/Marketing/Approval/Launch	Partner
				Phase 1	Phase 2	Phase 3		
<b>GND-001</b> Anti alpha-9 integrin antibody	Immunological disease, Oncology							Kaken Pharmaceutical Co., Ltd.
<b>GND-004</b> Anti RAMP2 antibody	Ophthalmic disease, Oncology							Looking for partners
<b>GND-007</b>	Immunological disease							



# Pipeline Update

## (3) New Biotech Business (Cell Therapy)

Project	Basic Research	Clinical Trial	Conditional and Time-limited Authorization ※	Marketing (Further confirmation on safety and efficacy)	Marketing Authorization	Marketing Continues	Partner
<b>GCT-101</b> Cell therapy using SHED for alveolar cleft							Orthorebirth Co., Ltd.
<b>JRM-001</b> Cell therapy using cardiac stem cell for hypoplastic left heart syndrome							Japan Regenerative Medicine Co., Ltd.
Stem Cell from Human Exfoliated Deciduous Teeth	Bone-related Diseases		UPDATE!!				Showa University School of Medicine
	Ophthalmologic Diseases		UPDATE!!				Gifu Pharmaceutical University

※ Expedited approval system for regenerative medicine  
Post-marketing safety measures must be taken, including prior informed consent of risk to patients.

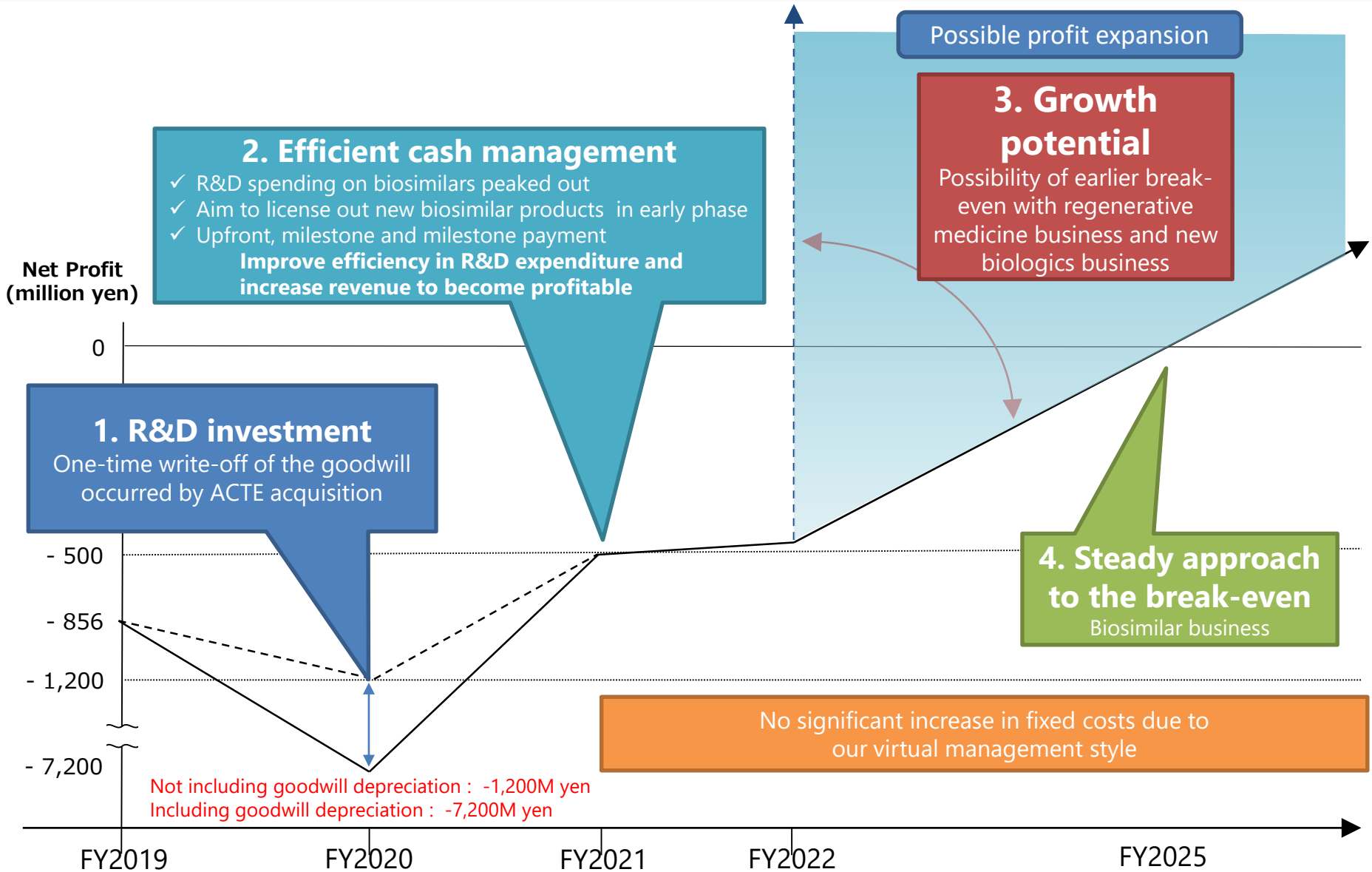
### Other Partners

Category	Partner	Project
<b>Business Succession</b>	Juntendo University Juntan Bio Co., Ltd.	Induction of immune tolerance for organ transplant
<b>Investment</b>	Sapporo Medical University Minerva Medica Co., Ltd.	Cell therapy using mesenchymal stem cell derived from bone marrow for diabetic nephropathy
	Heartseed Inc.	Myocardial regenerative medicine using iPS cells

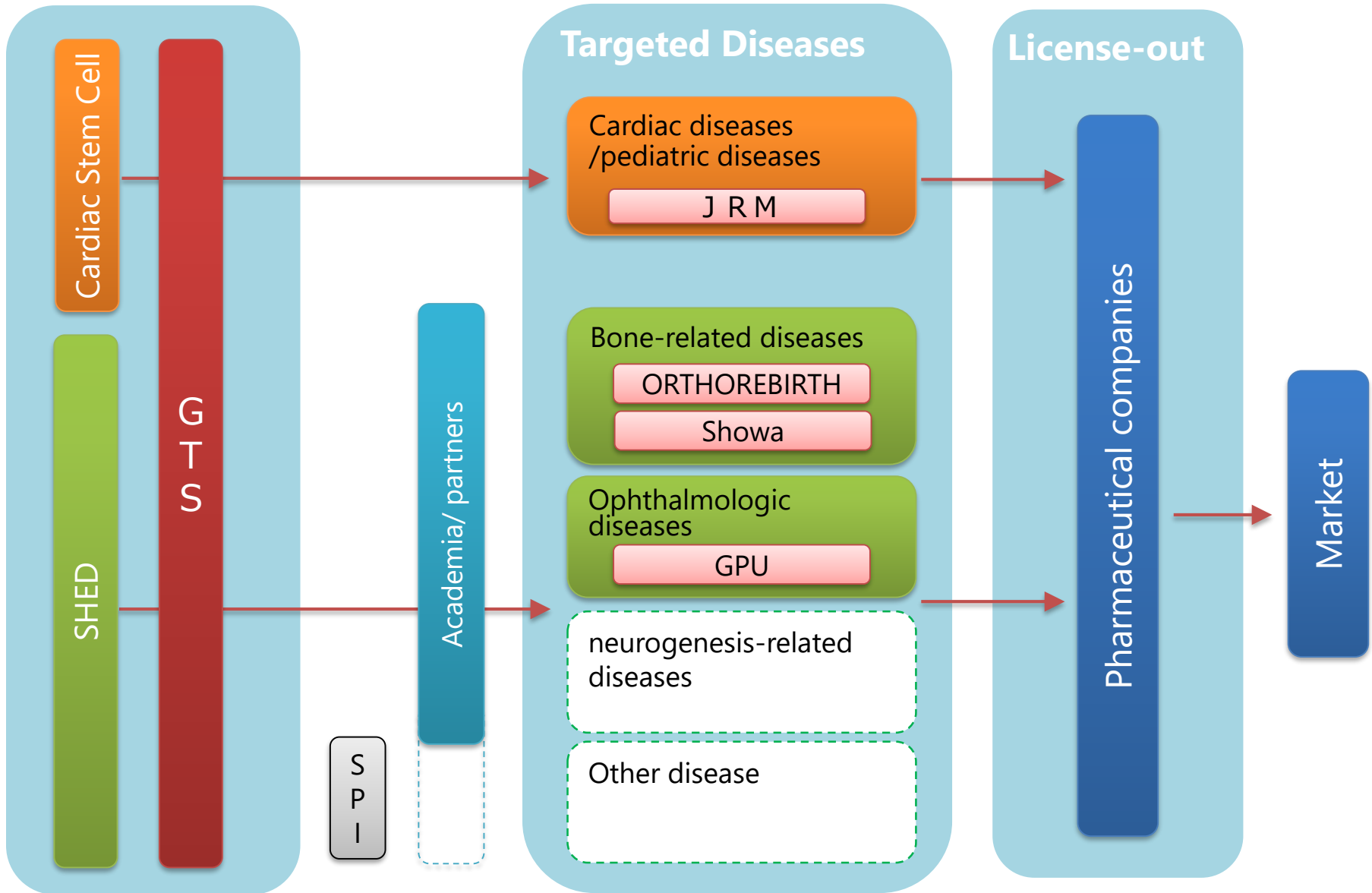


# Roadmap -from Biosimilars to Cell Therapy

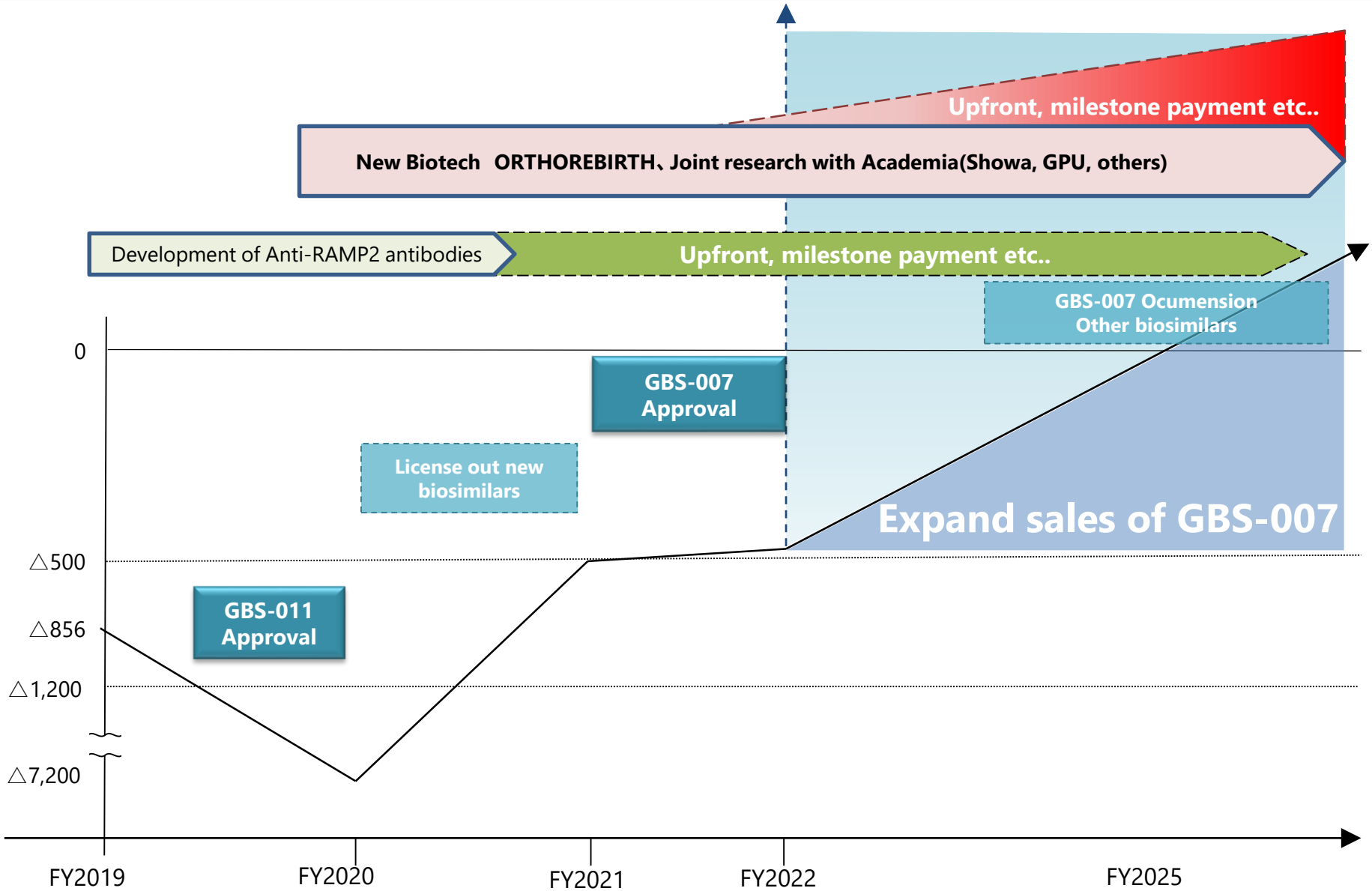
# Roadmap in GTS3.0



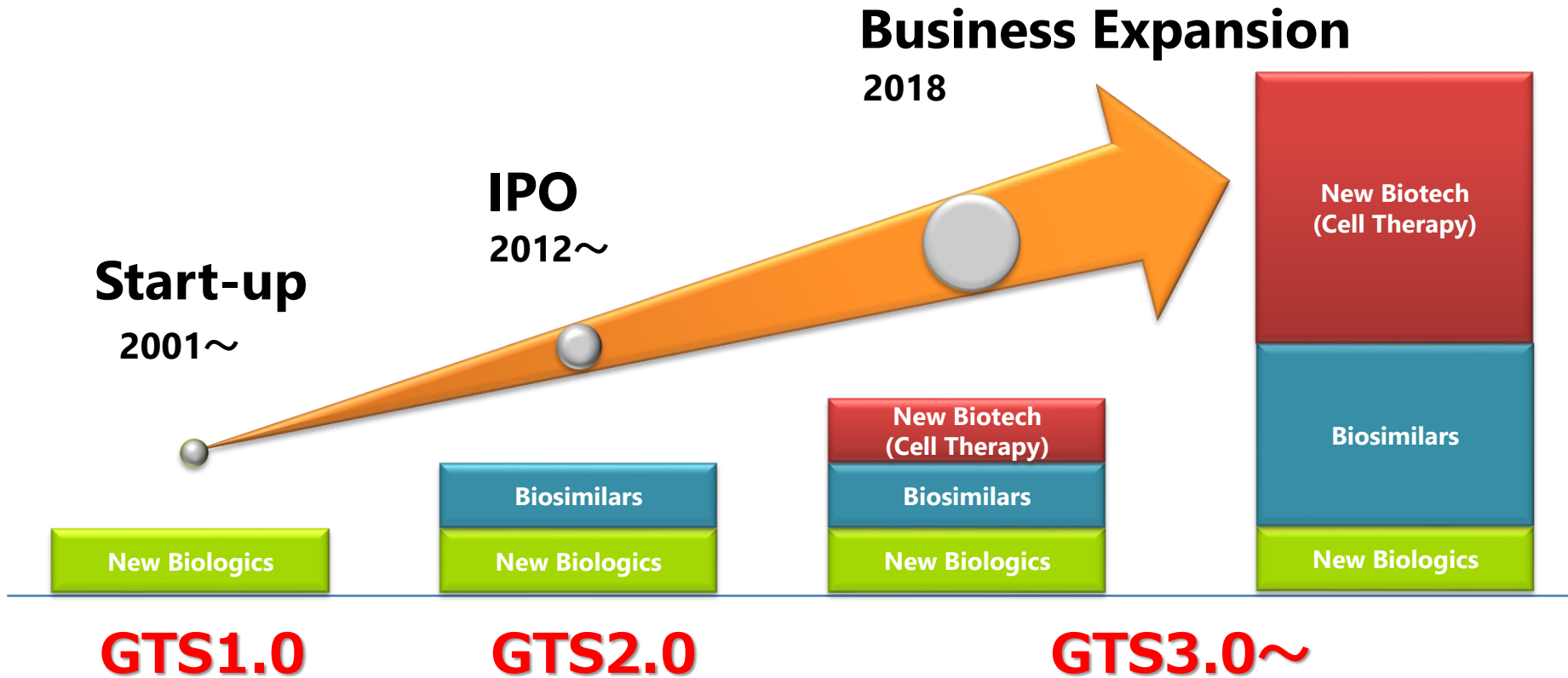
# Roadmap of Cell Therapy Business



# Action Plan in GTS3.0



# Shit in Business Strategy towards Cell Therapy



- ✓ Founded as a spin-out venture from Hokkaido Univ.
- ✓ Acquired basic biotech technology
- ✓ Launched one biosimilar product
- ✓ Listed at Mothers of TSE
- ✓ Strive for creating healthcare solutions based on the technology and accumulated experience/know-how
- ✓ Full-scale entry to cell therapy
- ✓ Realize steady profitability

# Gene Techno Science



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