GENE TECHNO SCIENCE

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Security Code：4584

Gene Techno Science Co., Ltd.

Financial Results for 2Q/FY2020
(Fiscal Year Ending March 2021)

November 6, 2020

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Cautionary Statement

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.

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1. Introduction

2. Business Highlight in 2Q/FY2020

- Application for manufacturing and marketing approval of GBS-007
- Joint Research with Hokkaido University and Spinal Injuries Center for Non-Union Fractures
- Acceleration toward application for manufacturing and marketing approval of JRM-001 (by mid FY 2023)

3. GTS3.0 Business Development

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Introduction

Business 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－

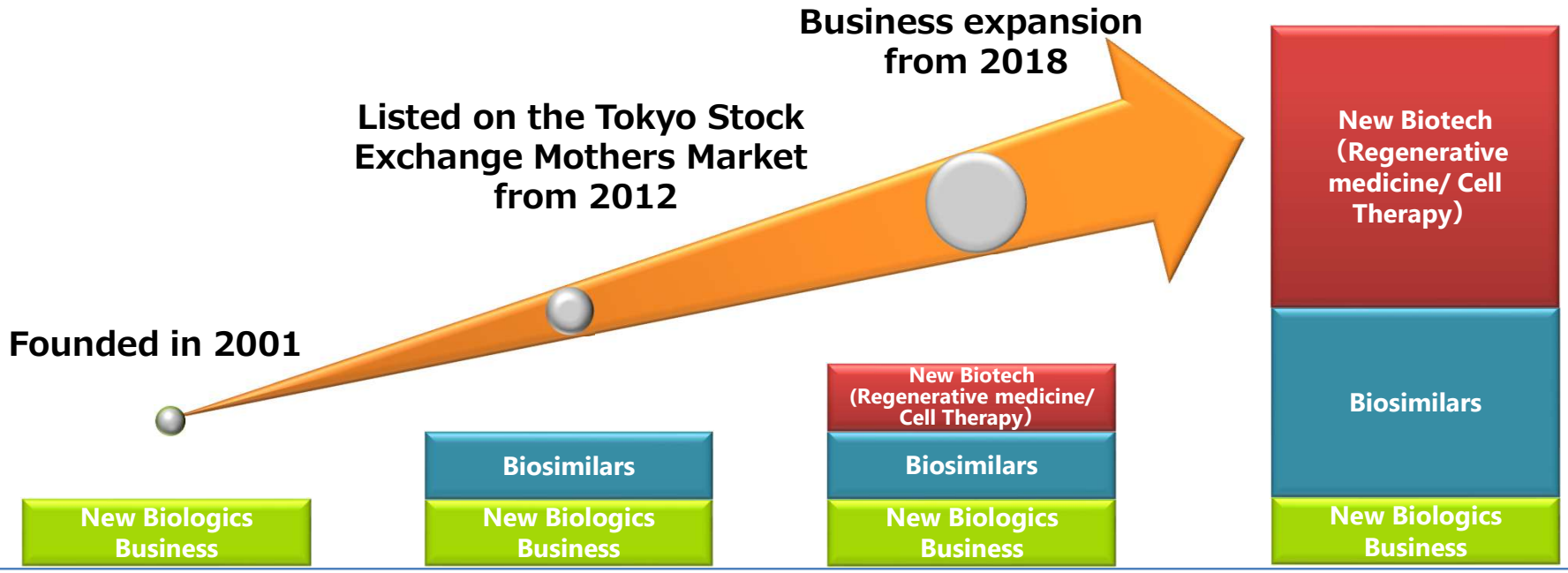
Targeting diseases which has less accessibility for sufficient medical treatment, and exploring the new therapeutic area

Target Area

- Pediatric diseases (Including juvenile one)
- Orphan disease
- Intractable disease
- Asia-endemic disease

Creating new treatment methods with new biotech Business (Regenerative medicine)

Our Business Growth and Expansion



GTS1.0

- ✓ Started a business as a startup from Hokkaido University
- ✓ Acquisition of basic biotechnology

GTS2.0

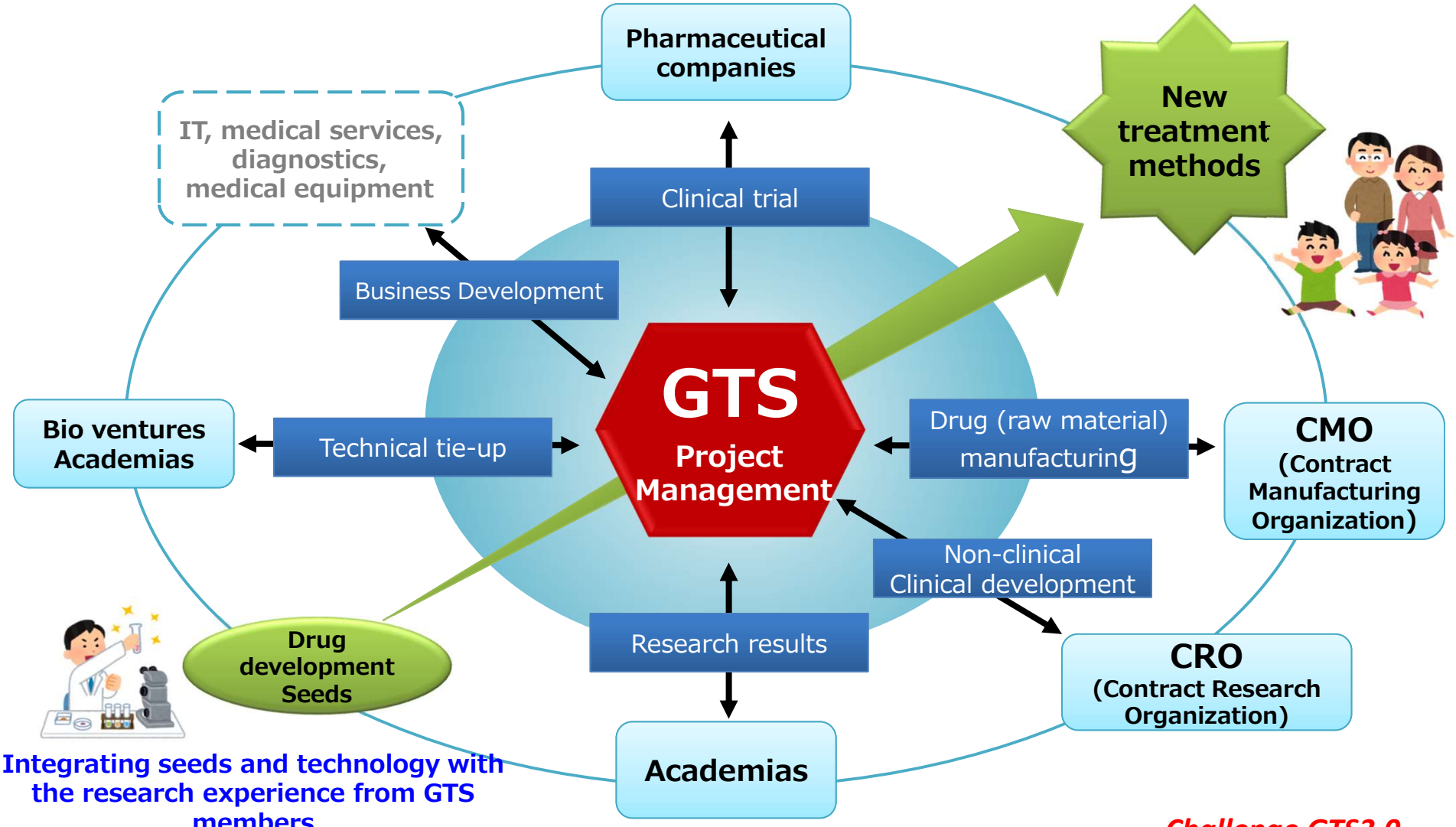
- ✓ Launched one biosimilar product
- ✓ Listed on the Tokyo Stock Exchange Mothers Market

GTS3.0～

- ✓ Development of accumulated biotechnology
- ✓ Full-scale entry into cell therapy
- ✓ Stable profit in bioshimilar business

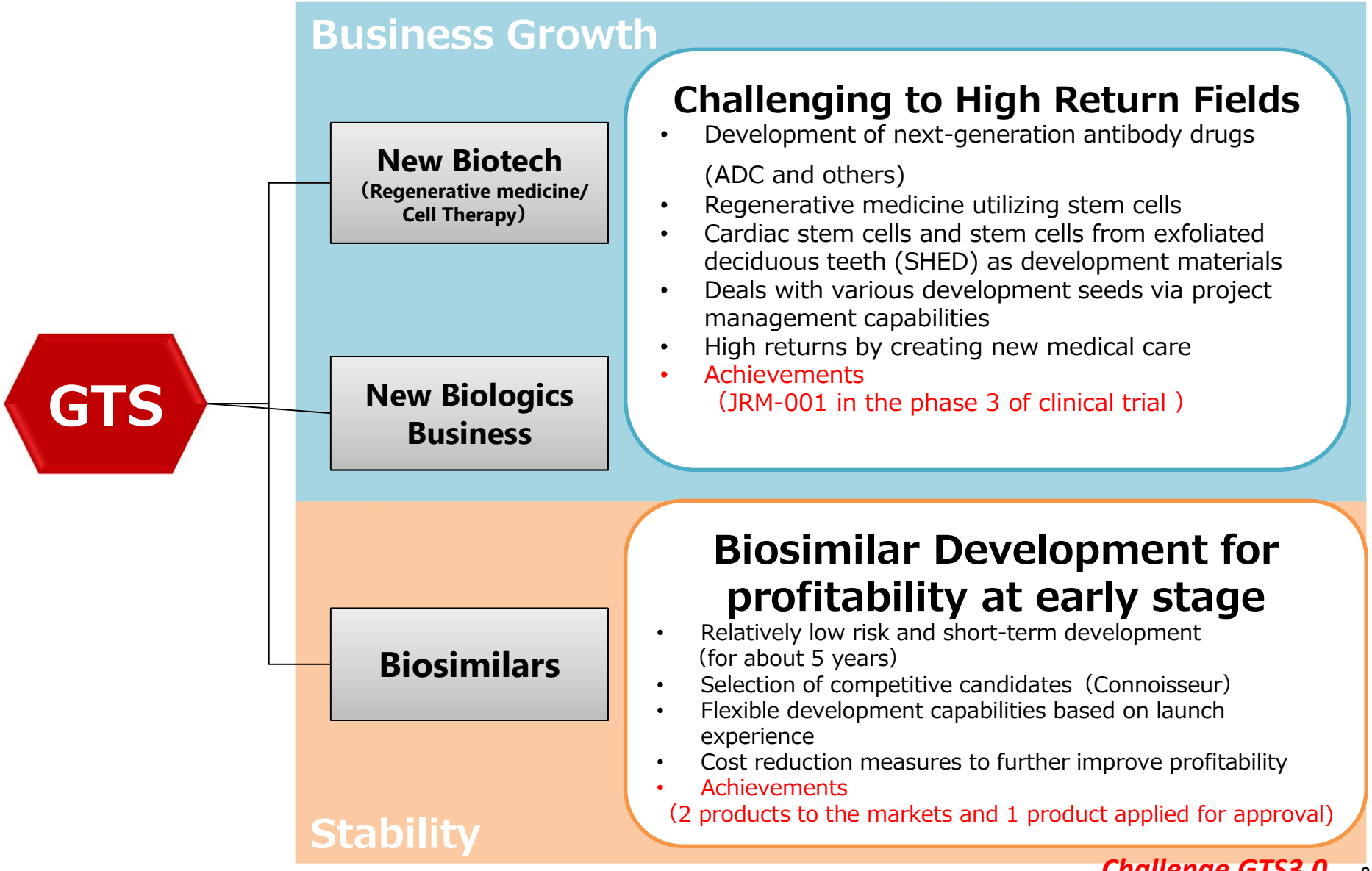
Our strength : Virtual Management

Evolving development capabilities through a virtual management backed by our expertise and external partners



Integrating seeds and technology with the research experience from GTS members

Our strength: Hybrid Business Model



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Overview of Business Highlight in 2Q/FY2020

Business Highlight for 2Q/FY2020

New Biotech
(Regenerative medicine/ Cell Therapy)

- Launched clinical research with the University of Tokyo Hospital to establish a supply system of deciduous tooth as a raw material for the production of SHED
- Concluded a joint research agreement with Hokkaido University and Spinal Injuries Center for non-union fractures+ Adopted for the NOASTEC (Northern Advancement Center for Science &Technology) Research and Development Subsidy Program
- Accelerate toward application for manufacturing and marketing approval of JRM-001 (by mid FY 2023)

Biosimilars

- Terminated the partnership of Adalimumab biosimilars due to dissolution of Changchun Changsheng Life Sciences Limited, GTS's joint development partner in China
- Senju Pharmaceutical Co., Ltd. applied for manufacturing and sales in Japan of the biosimilar product in the field of ophthalmic treatment to the Ministry of Health, Labour and Welfare

New Biologics Business

- Excluded Anti-human α9 integrin antibody from the pipeline due to cancellation of license agreement between Kaken Pharmaceutical and GTS

Cell Bank/ Culture Supernatant

- Establishment of new SHED business structure for strengthening cooperation with Dojin Group (Postponed the execution date of the share transfer of Advanced Cell Technology and Engineering to December 31, 2020 to further improve the cooperation system)

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Application for manufacturing and marketing approval of GBS-007

Application for manufacturing and marketing approval of GBS-007

■ Outline	Biosimilar of Anti-VEGF antibody drug Ranibizumab as a medicine for age-related macular degeneration
■ Target disease Age-related macular degeneration	A disease in which waste products accumulate in the macula, which controls eyesight in the eyeball, or new blood vessels form in the macula with aging, making it difficult to see
■ Development Partner Senju Pharmaceutical Co., Ltd.	One of the leading domestic companies in the field of ophthalmology, which handles a wide range of medical drugs for ophthalmology and otolaryngology.
■ Targeted Market	Targeting the domestic market for existing treatments for age-related macular degeneration Lucentis About 25 billion yen (Domestic) Eylea About 600 billion yen (Domestic)
■ Outlook	Aiming at manufacturing and marketing approval Actively promote not only domestic but also overseas expansion, which has a larger market

Biosimilar Business
Launch of the third product with more reality

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Joint Research with Hokkaido University and Spinal Injuries Center for Non-Union Fractures

New treatment method for the elderly with SHED

■ Non-union fractures are especially common in the elderly people and cause bedridden and long-term care

■ Fractures of the spine (vertebral body) is the common due to age-related osteoporosis.

Number of osteoporosis patients (Domestic): About 13 million patients	**Male: 3 million patients** **Female: 9.8 million patients**
Estimated number of non-union fractures among osteoporosis patients	About 0.1 million patients/year

Developing new regenerative medicine for non-union fractures

GTS ✖ **Specialists**
・Department of Orthopaedic Surgery, Faculty of Medicine, Hokkaido University
・Spinal Injuries Center
✖ **SHED** (Excellent bone regeneration ability)

(Source) Created based on Osteoporosis Prevention and Treatment Guidelines 2015 by GTS

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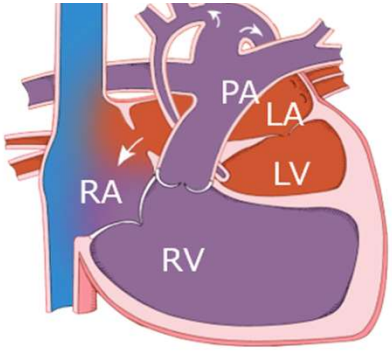
Significant acceleration toward application for manufacturing and marketing approval of JRM-001 (by mid FY 2023)

～New manufacturing partner in Phase 3 clinical trial of JRM-001～

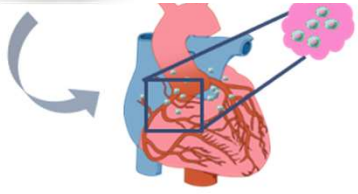
New Biotech : JRM-001 (Cardiac stem cells)

Single ventricle physiology
Hypoplastic left heart syndrome (HLHS)

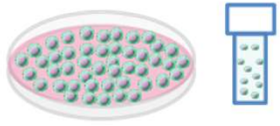


Though a common treatment is surgery, cardiac hypofunction and heart failure frequently appears after surgery.

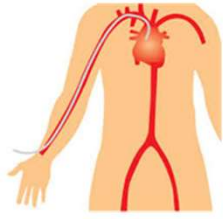
①Taking a small amount of heart tissue during surgery



②Isolation and culture of cardiac stem cells



③Catheterization in the coronary artery



④ Recovery of heart function

Improvement of heart function and heart failure, and physical development

Cardiac Stem Cells (CSCs)

・Low tumor resistance and high safety
・In addition to the ability to differentiate into various cell tumors, it has the ability to secrete factors that contribute to the regeneration of heart function.

Pediatric Congenital Heart Diseases

・Estimated number of patients is between 400 and 500 patients per year.
・HLHS is known as a typical single ventricle physiology.

JRM-001

・Cell therapy for improvement of heart function after surgery.
・Conducting a verified clinical trial
・Designated as an item subject to the first screening system.

Acceleration toward application for manufacturing and marketing approval of JRM-001 (by mid FY 2023)

Highlight of JRM-001

Accelerating the phase 3 clinical trial and more profit growth is expected.

■ Accelerating the phase 3 clinical trial with J-TEC

・Japan Tissue Engineering Co., Ltd. (J-TEC) as a manufacturing partner
・ Development of JRM-001 significantly accelerates with plenty of J-TEC's achievements in commercializing products of regenerative medicine from the patient's tissue

■ Focusing on applying for the domestic manufacturing and marketing approval of this product by mid FY2023

・ Scheduled to be launched as a new regenerative medicine product in FY 2024

■ Providing the "world's first" regenerative medicine product and contribution to our sales

・ Existing treatment: surgery
→ Improving therapeutic effect in combination with JRM-001

(Reference) Cost of existing surgery is about 18 million yen/patient

■ Providing this treatment method to not only for domestic patients but also for patients overseas and other individuals

Our ESG Action: Social impact by aiming at providing comprehensive healthcare solutions for patients as well as families and caregivers

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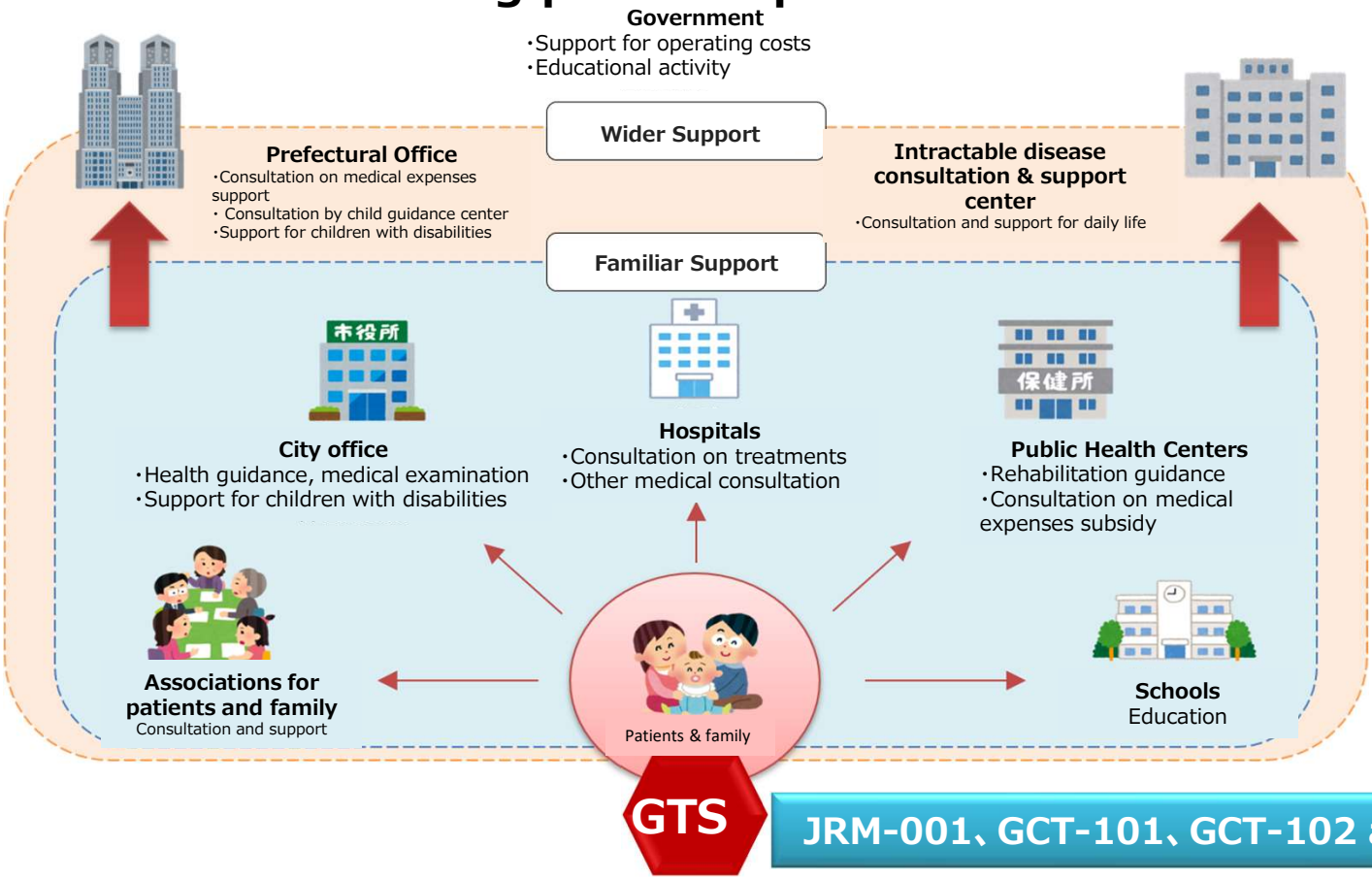
Environment surrounding pediatric patients



Providing new treatments for pediatric diseases for reduction of the burden on patients and their families, and contributing to society

Approaching realization of this target with JRM-001

(Source) Created based on basic documents on disease countermeasures for children with chronic specific diseases in children from Ministry of Health, Labour and Welfare

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GTS3.0　Business Development

GTS3.0 Risks for realization and our strategies

What is GTS3.0？

From University-launched venture company to become a new growing biotech engineering company

- **Development system : Establishment of a development system for next-generation medical care with innovation in medical technology**
  - Promoting various development seeds with accumulated biotechnology
  - Establishing a development system utilizing parterning
  - Utilizing cardiac stem cells and SHED for regenerative medicine
- **Strategic field : Challenging to create new treatment methods targeting pediatric diseases**
  - Shifting from the development of medical treatments for popular diseases to the treatments for rare and intractable diseases
  - Targeting multiple markets of 5 to 10 billion yen
- **Financing capability : Success of BS business and shift to debt financing**
  - Established a stable profitability in the BS business, which has relatively low development risk and is expected early profits
  - Challenging high-return fields based on our stable management
- **Development partner : Potentials for cardiac stem cells and SHED**
  - Executed many business alliances with academias and companies for regenerative medicine
  - Expanding alliance activities for overseas expansion

GTS3.0: Business portfolio

Business Growth | Expansion of profitability | Realization of profitability

Regenerative Medicine

Stem Cell from Human Exfoliated Deciduous Teeth (SHED)

- **ORTHOREBIRTH** — Cleft lip and palate
- **Mochida Pharmaceutical** — Congenital Isolated Hypoganglionosis
- **Showa University School of Medicine** — Bone-related Diseases
- **Tokyo Metropolitan Institute of Medical Science / Nagoya University Hospital Tokyo Medical and Dental University** — Cerebral Palsy
- **Gifu Pharmaceutical University** — Ophthalmologic Disease
- **Oita University** — Peripheral nerve palsy
- **Nagoya University** — Spinal cord injury
- **Hokkaido University and Spinal Injuries Center** — Non-Union Fractures

Cardiac stem cell

JRM-001
Hypoplastic left heart syndrome ／ Functional monoventricular disease

Antibody drug

Biosimilar

- **GBS-001** Oncology
- **GBS-007** Ophthalmic disease
- **GBS-011** Renal disease
- **GBS-004** Oncology
- **GBS-008** Infectious disease
- Kishi Kasei Co., Ltd. **GBS-012** Ophthalmic disease
- **GBS-005** Immunological disease
- **GBS-010** Oncology

New Antibody/ Manufacturing Method Development

- **GND-004** Oncology
- **Sapporo Medical University** Oncology
- **GND-007** Immunological disease
- **MabGenesis** Oncology

Business alliance

- Nicon
- Showa University Industry-academia partnership
- Summit Pharmaceuticals International Corporation
- Eil
- Dojin Group
- SOLA
- chromo-center
- GPC

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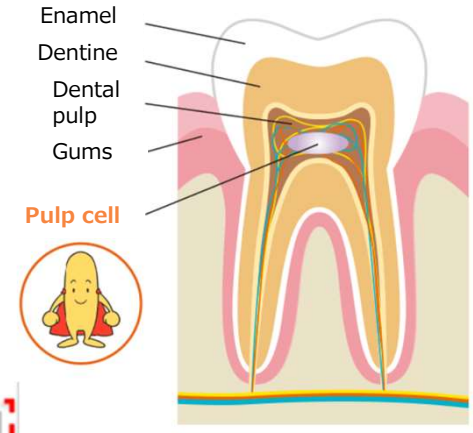
New Biotech Development : SHED

Target diseases		Partner	Symptoms	Treatment methods	Number of patients	Therapeutic target
Cleft lip and Palate	Pediatric disease	ORTHOREBIRTH	Eating and speech disorder	Lip plasty＋ Ilium transplant	2,000 newborn babies per year	Mandible regeneration
Congenital Isolated Hypoganglionosis	Pediatric disease	Mochida Pharmaceutical	Intestinal obstruction	Intestinal resection, artificial anus construction	100 children （Designated intractable disease 101）	Ganglion regeneration
Cerebral Palsy	Pediatric disease	Tokyo Metropolitan Institute of Medical Science, Nagoya University and Hospital Tokyo Medical and Dental University	Acroparalysis	None	2,000 newborn babies per year	Nerve and blood vessel regeneration
Spinal Cord Injury		Nagoya University	Loss of motor, sensory, perceptual function	None	5,000 persons per year (100,000 patients in total)	Nerve regeneration
Peripheral Nerve Palsy		Oita University	Dyskinesis and sensory dysfunction	Nerve reconstruction	8,000 surgeries per year	Peripheral nerve regeneration
Non-Union Fractures		Hokkaido University and Spinal Injuries Center	Chronic pain, gait disturbance	Surgery	100,000 patients per year	Bone regeneration
Bone-related Disease		Showa University School of Medicine				
Ophthalmologic Disease		Gifu Pharmaceutical University				

GTS3.0 Potential for SHED

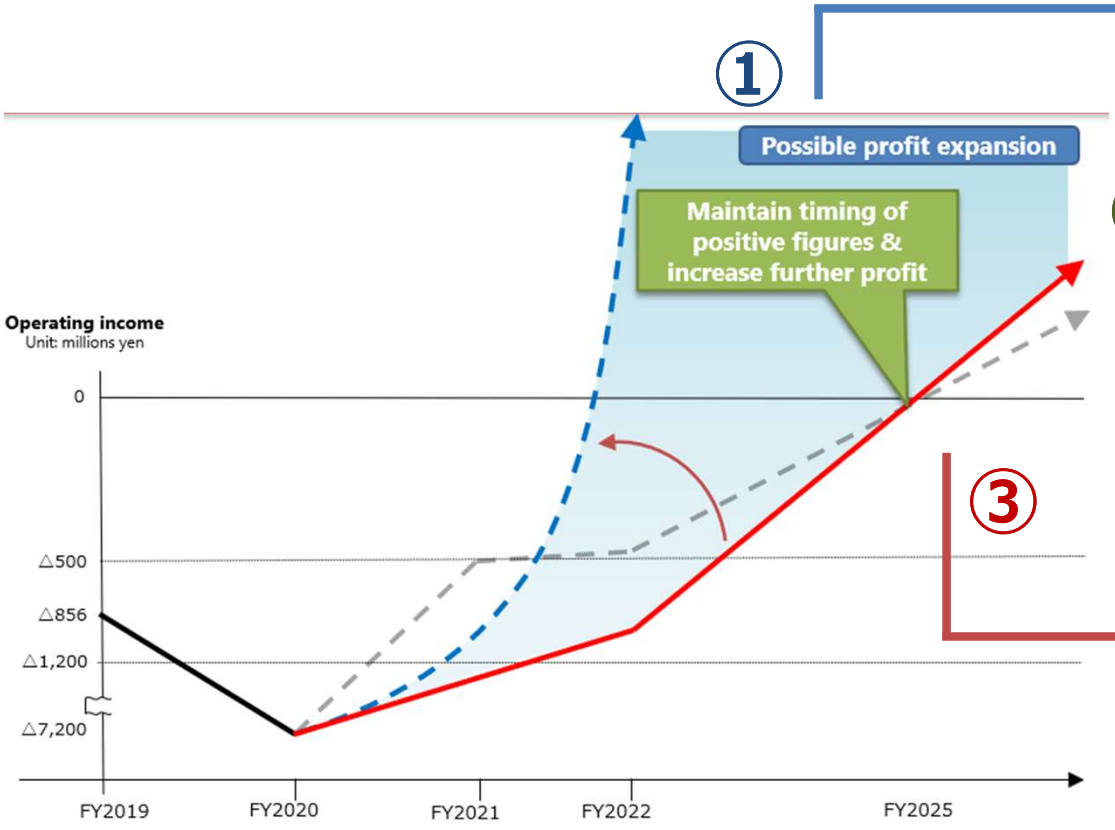
- Stem cells from the dental pulp inside the tooth (pulp cavity)
- Especially, stem cells from deciduous teeth (SHED) are active and have better regeneration ability.
- Stem cells from exfoliated deciduous teeth have more chances to obtain and less burden on the donors.



	Marrow	Fat	Cord Blood	SHED
Type of cell banks	Public	Private	Public and Private	Private
Age of the donors	Between 20 and 50 years old	Mostly estimated over 20 years old	0 years old	About between 5 and 12 years old
Chances	Timing of marrow transplanting	Timing of liposuction surgery	Timing of childbirth (Once)	Timing of falling out deciduous teeth (Generally 20 times per child)
Burden on the donors	High	High	Very Low	Low
Cell proliferation	High	High	Under study	Very Low

GTS3.0 Roadmap（Reproduction of Aug. 2020）

Roadmap is proceeding as scheduled
Aiming at stable and early profitability



① Business Growth

Pursuing upside with lump-sum contract payments and development milestones from new biotech and new biologics business

New biologics business increases the possibility of turning profitable between FY 2022 and 2025

② Expansion of Profitability

Sales of JRM-001 will contribute to profit expansion after 2025

Potential market of JRM-001

Number of target patient（Domestic） 500 patients

✓ Reference： Cost of alternative treatments is about 18 million yen/ patient

③ Stable Profitablity

Achieving profitability in 2025 with sales of BS business alone

GBS-001, 011, 007

Cell Bank/ Culture Supernatant

Expanding through business alliance with Dojin Group

※ The figures are based on net income at FY2020 because an extraordinary loss was incurred due to the amortization of goodwill.

GTS3.0 Roadmap

Transforming into a new biotech engineering company pursuing high-return based on stable profits

- ✓ Launching GBS-007 Ranibizumab BS and JRM-001 in the next four years in addition to Filgrastim BS and Dalbepoetin alpha BS and steadily strengthening the profit base
- ✓ Pursuing further upside in the biosimilar business and aiming for early additional profits
- ✓ Reduction of manufacturing cost (Using the measures realized by Filgrastim BS to other products)
- ✓ Accelerating business alliances with regenerative medicine and new biologics business, pursuing further accumulation of profits based on the above stable profits for improvement of future corporate value

Strategic and financial mid-term plan will be announced in February, 2021 to show our commitments to surpass break-even point at earlier stage

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Pipeline Update

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Biosimilars

Project	Therapeutic Area	Development Research	Clinical Trial		Application/ Marketing/ Approval/ Launch	Partner
			Phase 1	Phase 3		
GBS-001 Filgrastim	Oncology					Fuji Pharma Co., Ltd. Mochida Pharmaceutical Co., Ltd.
GBS-004 Bevacizumab	Oncology					
GBS-005 Adalimumab	Immunological disease					
GBS-007 Ranibizumab	Ophthalmic disease				NEW!	Senju Pharmaceutical Co., Ltd. License out to Ocumension Therapeutics (China and Taiwan)
GBS-008 Palivizumab	Infectious disease					
GBS-010 PEG-filgrastim	Oncology					
GBS-011 Darbepoetin alfa	Renal disease					Sanwa Kagaku Kenkyusho Co., Ltd.
GBS-012 Aflibercept	Ophthalmic disease					Kishi Kasei Co., Ltd.

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New Biologics Business

Project	Therapeutic Area	Basic Research	Development Research	Clinical Trial			Application/ Marketing/ Approval/ Launch	Partner
				Phase 1	Phase 2	Phase 3		
GND-004 Anti RAMP2 antibody	Ophthalmic disease, Oncology							Looking for partners
GND-007	Immunological disease							
New Antibody	Oncology							Sapporo Medical University
	Oncology							MabGenesis Co., Ltd.

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New Biotech（Regenerative medicine/ Cell Therapy）

Project			Basic Research	Non-Clinical	Exploratory Clinical Trial (Ph1 Ph2)	Pivotal trial (Ph3)	Marketing Authorization	Launch (PMS※)	
Cardiac stem cell	JRM-001	Hypoplastic Left Heart Syndrome							

※Post Marketing Surveillance

Project			Basic Research	Clinical Trial	Conditional and Time-limited Authorization※	Marketing (Further confirmation on safety and efficacy)	Marketing Authorization	Marketing Continues	Partner
Stem Cell from Human Exfoliated Deciduous Teeth	GCT-101	Cell therapy using SHED for alveolar cleft							Orthorebirth Co., Ltd.
	GCT-102	Congenital Isolated Hypoganglionosis							Mochida Pharmaceutical Co., Ltd.
		Bone-related Diseases							Showa University School of Medicine
		Ophthalmologic Diseases							Gifu Pharmaceutical University
		Cerebral palsy							• Tokyo Metropolitan Institute of Medical Science • Nagoya University Hospital • Tokyo Medical and DentalUniversity
		Peripheral nerve palsy							Oita University
		Spinal cord injury							Nagoya University
		Fracture non-union							Hokkaido University Spinal Injuries Center

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

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Overview of Financial Highlight in 2Q/FY2020

Overview of Financial Highlight

Financial Highlight

◆Financial Highlight in 2Q/FY2020

✓Financial results was in line with the forecast

✓Since R&D expenses are scheduled to be recorded in the second half due to development schedules, there will be no change in earnings forecasts.

✓ R&D developments are proceeding well.

✓ No impact on business performance due to the COVID-19 pandemic

Consolidated Financial Results for the Second Quarter of the Fiscal Year Ending March 31, 2021

◆ Consolidated Financial Results for the Second Quarter of the Fiscal Year Ending March 31, 2021 (April 1, 2020 – September 30, 2020)

	Sales (in millions of yen)	Selling, general and administrative expenses (in millions of yen)		Operating profit (in millions of yen)	Ordinary profit (in millions of yen)	Net income attributable to owners of the parent (in millions of yen)	Net income per share (in yen)
		Total	R&D expenses included				
Consolidated							
Result for second quarter of the fiscal year ending Mar. 31, 2021	174	817	403	△682	△693	△696	△24.49
(Reference) Forecasts for the fiscal year ending Mar. 31, 2021	972		1,720	△1,672	△1,688	△1,691	

Key Points

- Sales of Filgrastim biosimilar is not recorded due to delivery schedule.
- Income of milestone and royalty in the progress of the development was included.

- R&D spending was mainly on the biosimilar operations.
- R&D developments are proceeding well.

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Biotech Engineering Company,
striving for value creation