

Gene Techno Science Co., Ltd.

Financial Results for Fiscal Year Ended March 2020

May 25, 2020

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



Overview of Financial Highlight in FY2020

Financial Highlight

Financial Highlight in FY2020

- ✓ Financial results was **in line with the forecast**
- ✓ Allocated 298 million yen of cost of goods sold excluding provision for order loss. **Adjusted gross profit fully absorbed SG & A expenses excluding R & D expenses**
- ✓ The **reduction of 300 million yen compared to the forecast** due to carrying over of R&D expenses into the subsequent period
- ✓ Net loss was **almost as expected**
- ✓ No impact on business performance due to the COVID-19 pandemic

Financial Results for FY2020 - Consolidated

Financial Results for FY2020 (From April 1, 2019 to March 31, 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				
<div style="background-color: #f4a460; padding: 5px; border-radius: 10px; display: inline-block;">Consolidated</div> Results for FY2020	1,077	1,585	898	△1,161	△1,187	△7,316	△264.65
(Reference) Forecasts for FY2020	1,050		1,200	△1,220	△1,260	△7,260	

Key Points

- Filgrastim biosimilars achieved the sales target as planned.
- Income of milestone and royalty in the progress of the development was included.

- R&D spending was mainly on the biosimilar operations.
- Reduced 300 million yen due to the carrying over of the biosimilar and the biotech business expenses into the subsequent period

- Allocated a goodwill of ca. 5,938 million yen in relation to the acquisition of 100% ownership of ACTE at the 1Q of FY2020
- A loss in relation to the acquisition of JRM at the 4Q of FY2020

Financial Results for FY2020-Individual performance (pro forma amount)

Financial Results for FY2020 (From April 1, 2019 to March 31, 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 for the year (in millions of yen)
		Total	R&D expenses included			
GTS						
Results for FY2020 (A)	964	1,489	(855)	△969	△1,007	△7,316
Results for FY2019 (B)	1,021	1,414	(945)	△805	△816	△856
(Reference) Changes (A – B)	△57	74	△89	△164	△191	△6,460
ACTE & Remcare						
Results for FY2020	113	128	42	△223	△223	50

Key Points

- Impairment loss of 5,938M JPY was recorded for 1Q/FY2019 in relation to the one-time depreciation of goodwill
- loss on valuation of shares of 149 million yen due to acquisition of 100% ownership of Japan Regenerative Medicine Co., Ltd.

※ **GTS only and ACT E& Remcare only** figures are not subject to the full-year review.

※ As to Japan Regenerative Medicine Co., Ltd., since the deemed acquisition date is the end of the current consolidated fiscal year, the income statement is not consolidated.

Financial Forecast for FY2021

		Sales (Million yen)	Operating profit (Million yen)	Ordinary profit (Million yen)	Net income attributable to owners of the parent ※ (Million yen)	Net profit per share (yen)
Consolidated	Forecast for FY2021	972	△1,665	△1,681	△1,684	△60.31
Consolidated	Actual in FY2020 (reference)	1,077	△1,161	△1,187	△7,316	△264.65

Key Points

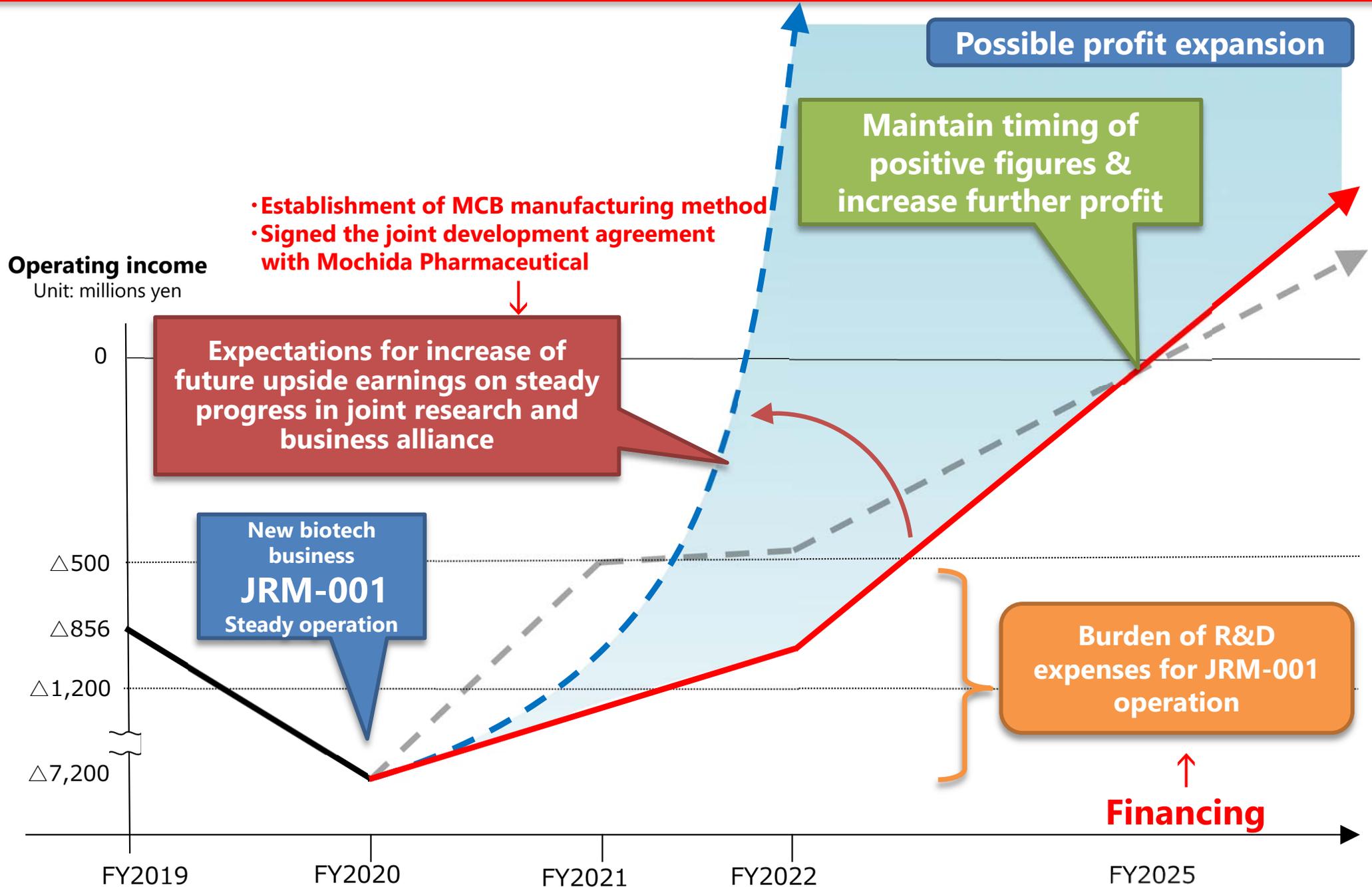
1. Sales : **Maintain almost the same level as the previous year**
2. R&D : **1,720 million yen** (for 898million yen FY 2020)
Mainly due to R&D expenses for JRM-001 (new) and Biosimilars (carried over from FY2020)
3. Not reflect the impact of the business performance due to COVID-19 pandemic

Financial Forecast for FY2021-Consolidated (Year-on-year comparison)

Unit : thousands yen

Subject	Results for FY2020	Key Points	Forecast for FY2021	Key Points
Gross sales	1,077,737		972,000	<ul style="list-style-type: none"> ✓ Maintain sale of Filgrastim the same level as the previous year ✓ Exclude potential milestones
Cost of goods sold	653,158	<ul style="list-style-type: none"> ✓ Included provision for cost increase in relation to MCB establishment ✓ Maintained COGs ratio of Filgrastim as the previous year. 	149,000	<ul style="list-style-type: none"> ✓ Reduce Filgrastim manufacturing cost ✓ Reduce the COGs ratio
Gross profit	424,579		823,000	
Selling, general and administrative expenses	1,585,975		2,495,000	
Other expenses	687,817		775,000	<ul style="list-style-type: none"> ✓ Maintain fixed cost as the previous year
R&D expenses	898,158	<ul style="list-style-type: none"> ✓ Reduced 300 million yen due to the carrying over of BS business expenses into the subsequent period 	1,720,000	<ul style="list-style-type: none"> ✓ Include about 420M yen of R&D expenses for JRM-001 ✓ Transfer 300M yen from the previous year
Operating profit	△1,161,396		△1,672,000	

Roadmap in GTS3.0



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

Analysis of profit structure (Comparison with previous roadmap)

Analyzing profit structure excluding temporary special factors such as provision for cost increase related to MCB establishment and carrying over of R&D expenses

- Exclude d355M yen of provision for cost increase related to MCB establishment
+ Include 300M yen of the carrying-over of R&D expenses in relation to, mainly, Biosimilars

Unit: thousands yen

Subject	FY2019	FY2020		FY2021	
	Result	Adjusted result	Result	Adjusted result	Forecasts
Gross sales	1,021,703	1,077,737 ←	1,077,737	972,000 ←	972,000
Cost of goods sold	412,386	298,158 ←	653,158	149,000 ←	149,000
Gross profit	609,316	779,579 ←	424,579	823,000 ←	823,000
Selling, general and administrative expenses	1,414,879	1,885,975 ←	1,585,975	1,750,000 ←	2,495,000
Other expenses	469,651	687,817 ←	687,817	775,000 ←	775,000
R&D expenses	945,228	1,198,158 ←	898,158	1,000,000 ←	1,720,000
Operating profit	△805,562	△ 1,106,396 ←	△1,161,396	△ 927,000 ←	△1,672,000



While R & D expenses is higher than expected due to SHED Project progress and business collaborations, gross profit from BS business steadily increases.

- Exclude 420 million yen of R&D expenses for JRM-001
- Exclude 300 million yen of R&D expenses carried over from FY2020



Overview of Business Highlight in FY2020

Business Highlight of FY2020

New Biologics Business

- Continuation of out-licensing activities for anti-RAMP2 antibody
- Joint research with Sapporo Medical University on anti-cancer drug using antibody with cancer cell invasion ability
- Joint research with Mab Genesis for the acquisition of new antibody with cancer cell killing effect

Biosimilars Business

- Obtained marketing authorization for biosimilar of darbepoetin alfa bio → Sales release
- Signed a joint development agreement with Kishi Kasei Co., Ltd. on biosimilar of Aflibercept
- End of observation period for final patient in Phase 3 clinical trial of GBS-007 developing with Senju Pharmaceutical Co., Ltd.

New Biotech Business (Regenerative medicine)

- Signed a joint research and development agreement with ORTHOREBIRTH on cleft lip and palate
- Signed an industry-academia partnership agreement with Showa University on regenerative medicine
- Signed a joint research agreement with Gifu Pharmaceutical University on eye-related diseases
- Signed an agreement with Summit Pharmaceuticals International Corporation regarding the distribution of dental pulp mesenchymal stem cells
- Invested in Heartseed
- Signed a four-party joint research agreement with Tokyo Metropolitan Institute of Medical Science, Nagoya University Hospital, and Tokyo Medical and Dental University to create a treatment method for cerebral palsy using stem cell from human exfoliated deciduous Teeth (SHED)
- Executed the acquisition of 100% ownership of Japan Regenerative Medicine Co., Ltd.
- Signed a joint research agreement with Oita University to create a treatment method for peripheral nerve palsy using stem cell from human exfoliated deciduous teeth (SHED)
- Signed a joint research agreement with Nagoya University to create a treatment method for spinal cord injury using stem cell from human exfoliated deciduous teeth (SHED)
- Established master cell bank (MCB) manufacturing method for regenerative medicine products based on business alliance with Nikon Corporation
- Signed a joint development agreement with Mochida Pharmaceutical Co., Ltd. for regenerative medicine products such as congenital isolated hypoganglionosis.

Others

- Executed the acquisition of 100% ownership of Advanced Cell Technology and Engineering (ACTE)
- Review of financing methods
- Established Remcare
- Appointment of academic advisor
- Borrowing of fund from Mizuho Bank
- Business alliance agreement with Eil Inc. for business development in the regenerative medicine and healthcare fields
- Business alliance agreement with Dojin Group for business development in regenerative medicine and healthcare fields

Key Business Highlight of FY2020

Improving pipeline of SHED for full-scale promotion of regenerative medicine business

Biosimilar Business

■ Completed Phase 3 clinical trial of GBS-007

- ✓ End of observation period for final patient in Phase 3 clinical trial of GBS-007 developing with Senju Pharmaceutical Co., Ltd.

New biotech business

■ Executed the acquisition of 100% ownership of Japan Regenerative Medicine Co., Ltd. (JRM)

- ✓ Signed stock transfer agreement. Added JRM's regenerative medicine product "JRM-001" using cardiac stem cells in the pipeline

New biotech business

■ Started joint research with Oita University and Nagoya University

- ✓ Signed a joint research agreement with Oita University for peripheral nerve palsy and Nagoya University for spinal cord injury to create treatment methods using stem cell from human exfoliated deciduous teeth (SHED)

New biotech business

■ Established master cell bank manufacturing (MCB) method based on business alliance with Nikon Corporation

- ✓ Established master cell bank (MCB) manufacturing method to commercialize SHED as Regenerative medicine products.

New biotech business

■ Signed a joint development agreement with Mochida Pharmaceutical Co., Ltd.

- ✓ Signed a joint development agreement to create treatment methods with SHED for specific rare diseases and intractable diseases in the digestive tract area, such as congenital isolated hypoganglionosis



Financing Status

Financing performance of FY2020

Accelerating to accomplish GTS3.0 with financing

Classification	Investor	Amount
Long-term debt	Mizuho Bank	600M yen
2 nd Convertible bond	CVI Investments, Inc.	600M yen
9 th Stock options (Selling price)		3M yen
3 rd Convertible bond		600M yen
10 th Stock options (Selling price)		4M yen
Total ①		1,808M yen

9 th Stock options (Not exercised)	CVI Investments, Inc.	307M yen
10 th Stock options (Not exercised)		780M yen
Expected total amount②		1,087M yen
① + ②		2,895M yen

Note: The expected total amount for the 9th and 10th stock acquisition rights is calculated based on the exercise price as of today.



GTS3.0 Business Development



GTS 3.0

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

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



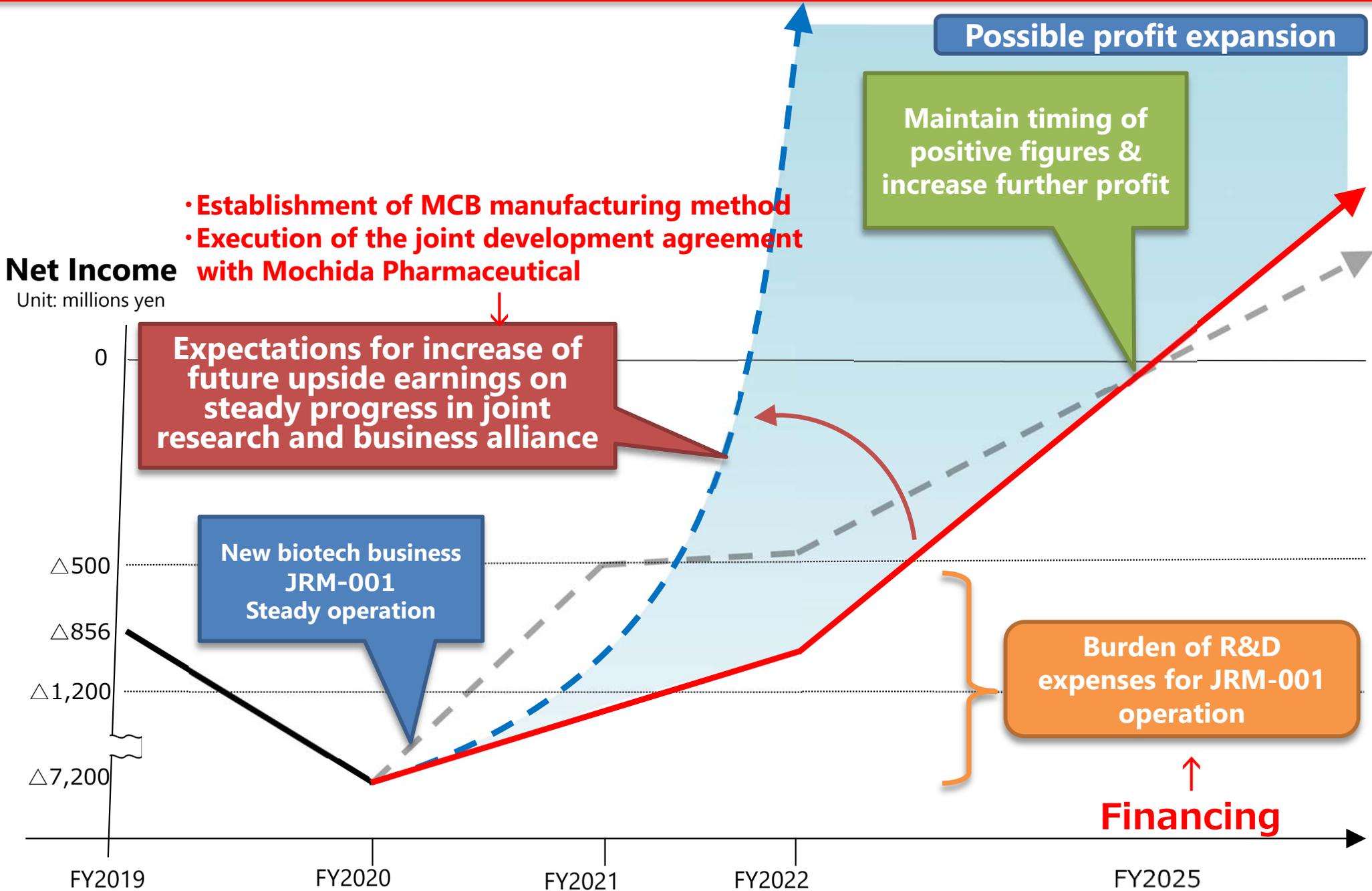
**Targeting diseases which has less accessibility
for sufficient medical treatment, and
exploring the new therapeutic area**

Target Area

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

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

Roadmap in GTS3.0



GTS3.0: Business portfolio (as of FY 2019)

Regenerative
Medicine

Stem Cell from Human Exfoliated
Deciduous Teeth (SHED)
(Acquisition of ACTE)

Cardiac stem
cell
(Outside of own
portfolio)

JRM-001
Hypoplastic left heart
syndrome /
Functional
monocentric disease

Business
alliance

Antibody
drug

Biosimilar

GBS-001
Oncology

GBS-007
Ophthalmic
disease

GBS-011
Renal disease

GBS-004
Oncology

GBS-008
Infectious
disease

GBS-005
Immunological
disease

GBS-010
Oncology

New Antibody/ Manufacturing Method Development

GND-001
Oncology

GND-004
Ophthalmic
disease

GND-007
Immunological
disease

SOLA

chromo-
center

GPC

GTS3.0: Business portfolio (as of FY 2020)

Regenerative
Medicine

Stem Cell from Human Exfoliated Deciduous Teeth (SHED)

- ORTHOREBIRTH** (NEW)
Cleft lip and palate
- Mochida Pharmaceutical Co., Ltd.** (NEW)
Congenital Isolated Hypoganglionosis
- Showa University School of Medicine** (NEW)
Bone-related Diseases
- Gifu Pharmaceutical University** (NEW)
Ophthalmologic Disease
- Tokyo Metropolitan Institute of Medical Science** (NEW)
Nagoya University Hospital (NEW)
Tokyo Medical and Dental University (NEW)
Four-party joint research
Cerebral Palsy
- Oita University** (NEW)
Peripheral nerve palsy
- Nagoya University** (NEW)
Spinal cord injury

Cardiac stem cell

JRM-001 (NEW)
Hypoplastic left heart syndrome / Functional monoventricular disease

Business alliance

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

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.** (NEW)
- GBS-005** Immunological disease
- GBS-010** Oncology
- GBS-012** Ophthalmic disease

New Antibody/ Manufacturing Method Development

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



Pipeline Update

■ GND-001 (Anti-human α 9 integrin antibody)

- ✓ Excluded from the pipeline due to cancellation of license agreement between Kaken Pharmaceutical and GTS

■ GBS-005 (Adalimumab biosimilars)

- ✓ Terminated the partnership due to dissolution of Changchun Changsheng Life Sciences Limited, GTS's joint development partner in China.
- ✓ Continue out-licensing activities.

Progress in each pipeline (Progress status of FY2020)

① Biosimilars Business

Project	Therapeutic Area	Development Research	Clinical Trial		Application/ Marketing/Approval/ Launch	Partner
			Phase 1	Phase 3		
GBS-001 Filgrastim	Oncology	[Progress bar: 100%]				Fuji Pharma Co., Ltd. Mochida Pharmaceutical Co., Ltd.
GBS-004 Bevacizumab	Oncology	[Progress bar: ~10%]				
GBS-005 Adalimumab	Immunological disease	[Progress bar: ~40%]				
GBS-007 Ranibizumab	Ophthalmic disease	[Progress bar: ~80%]			[Progress bar: ~10%]	Senju Pharmaceutical Co., Ltd. License out to Ocumension Therapeutics (China and Taiwan)
GBS-008 Palivizumab	Infectious disease	[Progress bar: ~20%]				
GBS-010 PEG-filgrastim	Oncology	[Progress bar: ~30%]				
GBS-011 Darbepoetin alfa	Renal disease	[Progress bar: ~90%]			[Progress bar: ~10%]	Sanwa Kagaku Kenkyusho Co., Ltd.
GBS-012 Aflibercept	Ophthalmic disease	[Progress bar: ~5%] NEW				Kishi Kasei Co., Ltd.

Progress in each pipeline (Progress status of FY2020)

② 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 <i>Anti RAMP2 antibody</i>	Ophthalmic disease, Oncology							
GND-007	Immunological disease							
New Antibody	Oncology	 NEW						Sapporo Medical University
	Oncology	 NEW						MabGenesis

Progress in each pipeline (Progress status of FY2020)

③ New biotech business (Regenerative medicine)

Project	Targeted disease	Basic Research	Clinical Trial	Conditional and Time-limited Authorization ※	Marketing (Further confirmation on safety and efficacy)	Marketing Authorization	Marketing Continues	Partner
Cardiac stem cell	JRM-001	Cell therapy using cardiac stem cell for hypoplastic left heart syndrome						Japan Regenerative Medicine Co., Ltd.
	GCT-101	Cleft lip and palate	NEW					ORTHOREBIRTH Co., Ltd.
Stem Cell from Human Exfoliated Deciduous Teeth (SHED)	GCT-102	Congenital Isolated Hypoganglionosis	NEW					Mochida Pharmaceutical Co., Ltd.
		Bone-related Diseases	NEW					Showa University School of Medicine
		Ophthalmologic Diseases	NEW					Gifu Pharmaceutical University
		Cerebral Palsy	NEW					<ul style="list-style-type: none"> •Tokyo Metropolitan Institute of Medical Science •Nagoya University Hospital •Tokyo Medical and Dental University
		Peripheral nerve palsy	NEW					Oita University
		Spinal cord injury	NEW					Nagoya University

※Expedited approval system for regenerative medicine

Post-marketing safety measures must be taken, including prior informed consent of risk to patients.



Appendix

Reserve for loss on orders

Allocated 355 million yen of provision for allowance for order loss for MCB manufacturing in cost of goods sold

- ✓ Improved Master Cell Bank (MCB) manufacturing method with GTS and JRM development experience and know-how, and established MCB manufacturing method in March
- ✓ Accelerating establishment of MCB and development of a stable supply system to license GCT-102 with Mochida Pharmaceutical Co., Ltd., as well as regenerative medicine product projects under joint research with academia to pharmaceutical companies.
- ✓ The provision for provision for order loss (cost of goods sold) is allocated in FY2020 including the above expenses.
- ✓ Furthermore, we started to establish a manufacturing method for final products using MCB as a raw material during FY2020 and will continue to strengthen collaboration with partner companies toward clinical trials at FY2021.

Pipeline (Other related companies)

Other related companies

Classification	Name of Company	Business Description
Investee	Heartseed	Myocardial regenerative medicine using iPS cells
	MINERVAMEDICA Co., Ltd. (Sapporo Medical University)	Research and development of diabetic nephropathy using bone marrow mesenchymal stem cells
Business Successor	JUNTEN BIO (Juntendo University)	Research and development of immune system diseases using induction of tolerance

Gene Techno Science



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