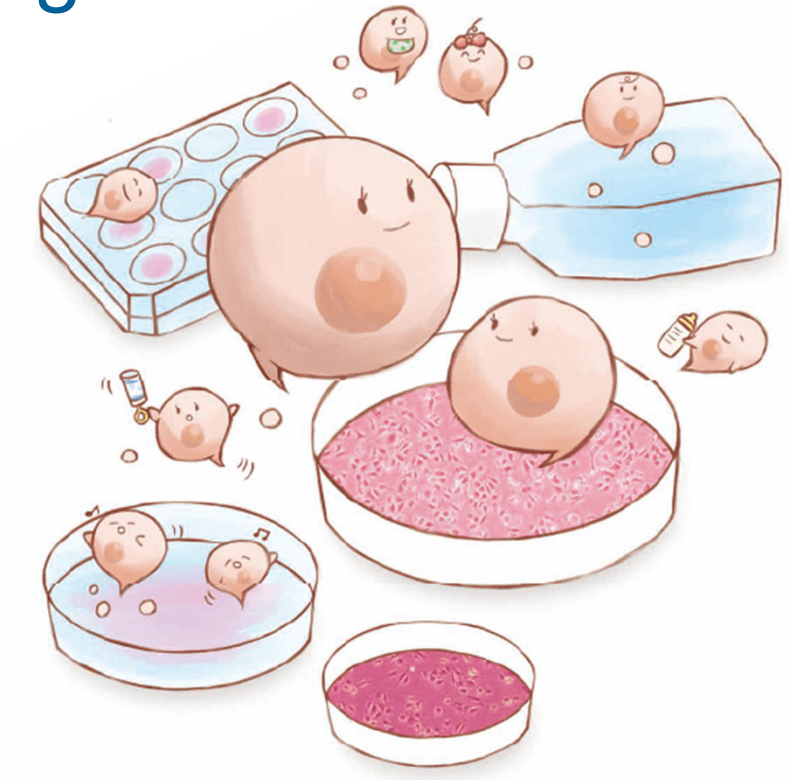
CellSeed Inc.

Fiscal 2021First-Half Earnings Results

Presentation



Stock Code:7776

Contents

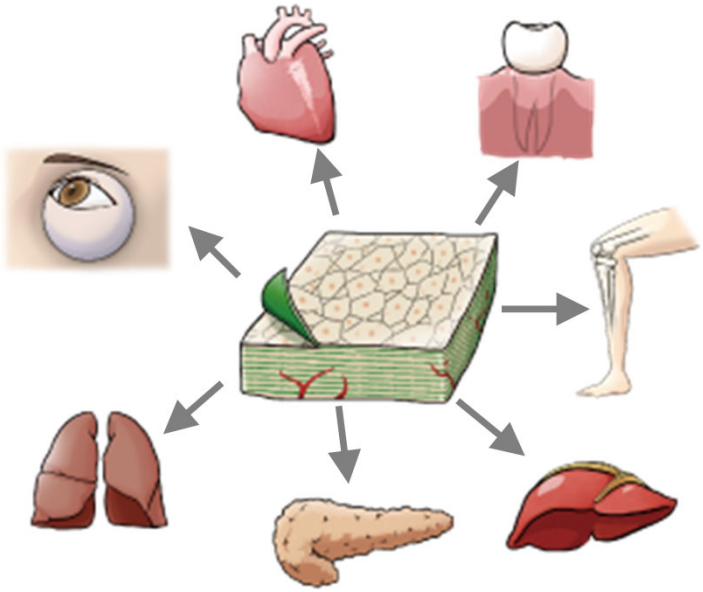
- Company Profile
- Financial summary FY 12/2021
- Progress of each business

CellSeed Inc. Corporate Information

Established	May, 2001
Core competence	Cell Sheet Engineering based on Temperature Responsive Polymers
Listed	JASDAQ（7776) in 2010
Business	

Regenerative Medical Products Business

- Commercialization of Cell Sheet Therapies



Regenerative Medicine Supporting Business

- Intelligent Culture Ware as Research Tools

UpCell®

- Contract Manufacturing Services・ Consulting

CPC

20th anniversary of the foundation of CellSeed

2001
CellSeed founded

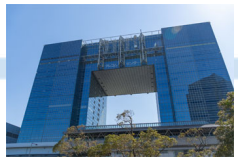
2004
RepCell® and HydroCell® launched

2007
UpCell® launched

2010
Listing on JASDAQ

2015
CellSeed Sweden AB established in Stockholm

2016
- Head office relocation to the Telecom Center Building
- Clinical trial on epithelial cell sheets for esophageal regeneration initiated
- Cell Processing Facility established



2017
- Approval to manufacture specified cell processing products acquired
- Out-licensed esophageal regeneration epithelial sheet and chondrocyte sheet to MetaTech

2018
Start of regenerative medicine contract services

2020
Establishment of joint venture in Taiwan

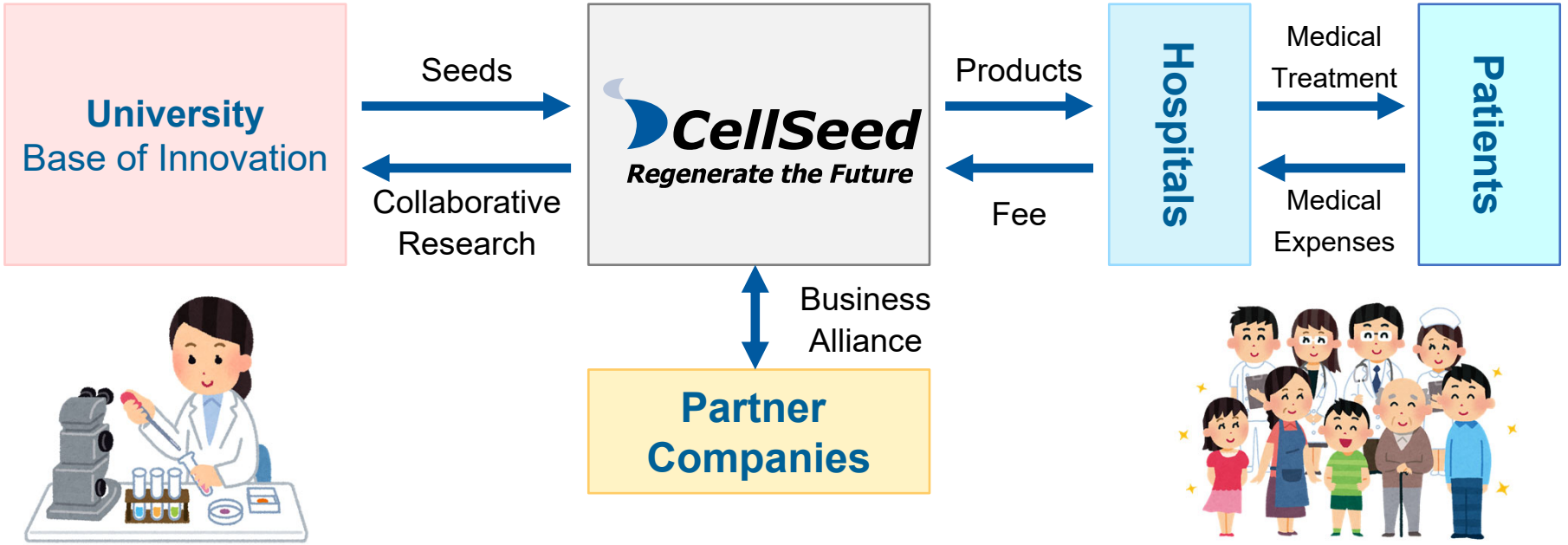
日生細胞生技
UP CELL BIOMED

2021
20th anniversary of the foundation of CellSeed

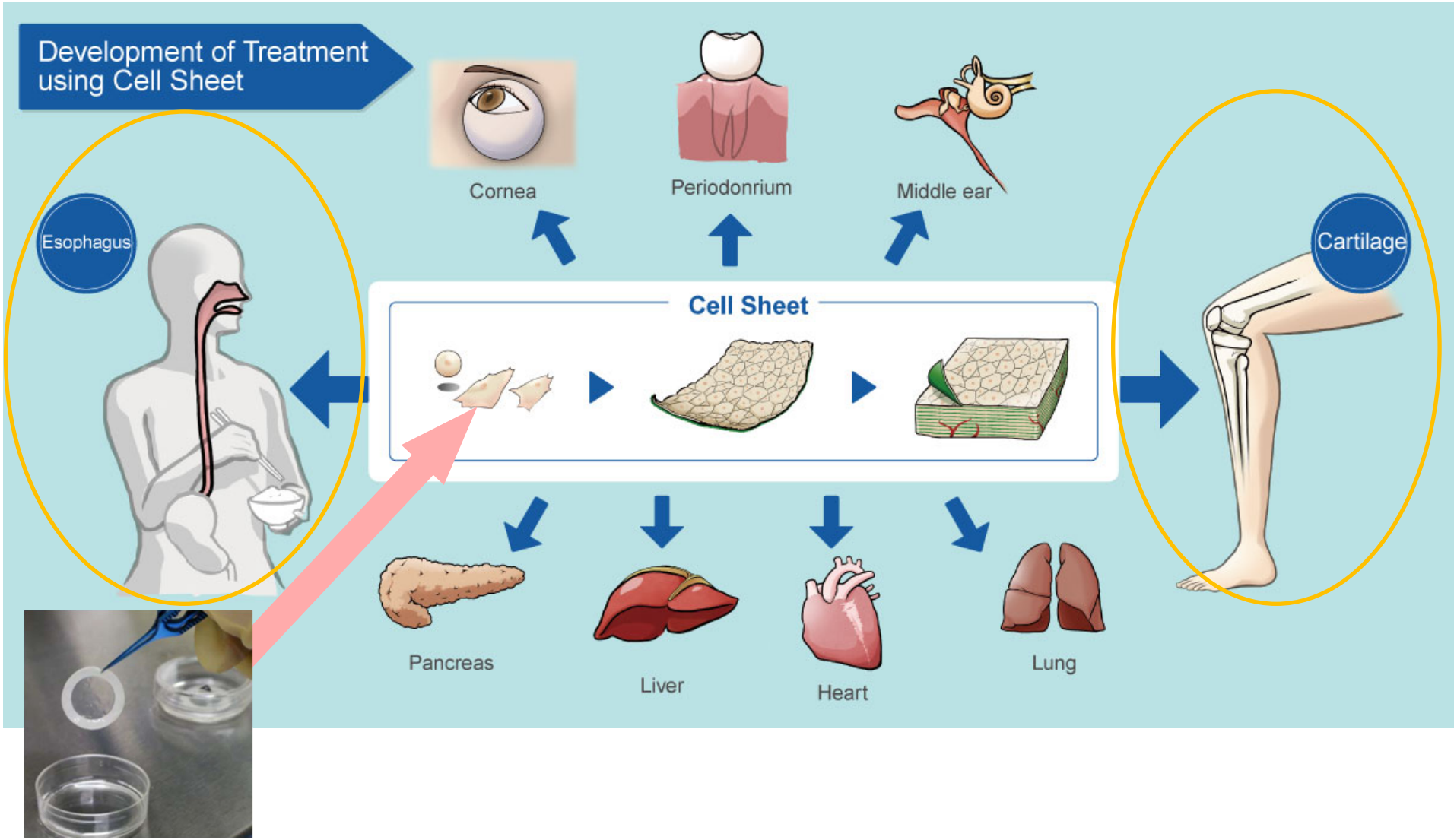
Our Business Model

Mission

We take the initiative of contributing to global health care in the valuable and innovative field of regenerative medicine.



Development of Treatment Using Cell Sheet Engineering



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Half-year financial summary FY 12/2021

	First Half of the FY2021 Consolidated (January 2021 - June 2021)			First Half of the FY2020 Consolidated (January 2020 - June 2020)
	Amount (Millions of Yen)	Change (Millions of Yen)	Change from Previous Period (%)	Amount (Millions of Yen)
Net sales	81	23	39.9	58
Operating profit	-466	-125	–	-340
Ordinary profit	-477	-135	–	-341
Profit attributable to owners of parent	-486	-145	–	-340

- As we enhanced collaboration and conducted active sales promotion for devices, especially overseas sales grew, and sales hit a record high.
- Tokai University entrusted us with the production of autologous cartilage cell sheets like last year, and sales from the two cases were posted.
- We performed additional clinical trials for the epithelial cell sheet for esophageal regeneration, to apply for the production and sales in 2025.

Differences between the estimates and results in the second quarter of the term ending Dec. 2021

[unit: million yen, rounded down to the nearest million]

	Net sales	Operating profit	Ordinary profit	Profit attributable to owners of parent
Previously announced estimates (announced on Feb. 14, 2021)	50	-587	-601	-601
Results (announced on Aug. 12, 2021)	81	-466	-477	-486

- **Reasons for the differences**

The commissioned production of cell sheets was partially delayed, but the sales of cell cultureware hit a record high, as overseas sales exceeded the initial forecast. Regarding profit, operating profit, ordinary profit, and profit attributable to owners of parent exceeded the previous estimates, as the costs for outsourcing development fell below the estimate and our cost control reduced the expenses for R&D, manufacturing, and SGA.

The sales and profit in the cumulative second quarter exceeded the previous forecasts, but the full-year earnings forecast is unchanged from the forecast announced on Feb. 12, 2021, because the outlook remains uncertain due to the spread of COVID-19, etc.

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Cell cultureware in the regenerative medicine supporting business

CellSeed Regenerate the Future

Temperature-responsive cell cultureware invented by Professor Okano of Tokyo Women's Medical University in 1989 can detach cells just by lowering its temperature. This feature enabled us to collect intact cell sheets for the first time in the world. As temperature-responsive cell cultureware are sold all around the world, many researchers are actively researching and developing treatment methods using cell sheets.

UpCell®

HydroCell®

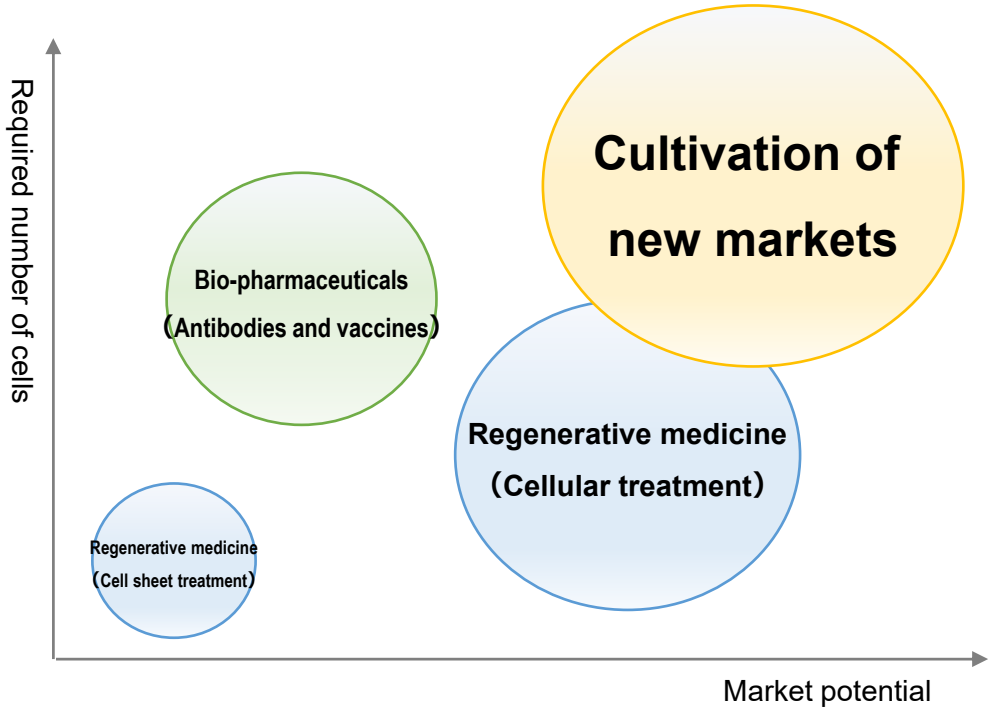
1989	Professor Okano of Tokyo Women's Medical University invented temperature-responsive cell cultureware.
2004	Released RepCell® and HydroCell®
2007	Released UpCell®.
2010	Released cellZscope®.
2011	Released ThermoPlate®.
2015	The regenerative medicine product Heart Sheet (Terumo Corporation) approved.（UpCell® was adopted as its component）
2017	Released HydroCell® flasks.
2019	Overseas sales via Thermo Fisher Scientific increased 200% from the previous year.
2020	The sales of devices exceeded 100 million yen for the first time.
2021	・Reached an agreement for extending the period of the sales contract with Thermo Fisher Scientific until 2025. ・Established facilities for developing and manufacturing cell cultureware.

CellSeed Temperature Sensitive Cell Cultureware Lineup

UpCell® Cell Sheet Recovery (Temperature Sensitive)	**RepCell ®** Cell Recovery (Temperature Sensitive)	**HydroCell ®** Ultra-Low Adhesion Cell Cultureware
● Temperature-responsive cell cultureware for "Cell Sheet" engineering	● Temperature-responsive cell cutureware for cell collection	● Low cell binding cultureware
	 3 x 3 mm Grid Wall	

Cultivation of new markets for cell cultureware

Recently, the production of bio-pharmaceutical products using mass-cultured cells, the immunotherapy using cells, and initiatives for solving food and environmental issues have been active. In the generally used cell collection technology, proteolytic enzymes are used, so cells are damaged when collected. Accordingly, it is difficult to keep the intrinsic functions and components of cells intact. However, by using our products, it is possible to collect cells without damaging them and utilize all functions and components of cells as they are. Therefore, our products are attracting attention, because they are expected to improve industrial efficiency and effectiveness in new markets.



Temperature-responsive cell cultureware

Reference info: Forecast for the global market of regenerative medicine 2025/2030/2035 (100 million yen)
Tissue transplantation (cell sheets); 812/895/885
Cell transplantation (cell therapy); 13,476/24,695/36,033
Source: Survey on the market of regenerative medicine and gene therapy in fiscal 2019 Arthur D. Little Japan Final Report, P144

Reference info: Forecast for sales of bio-pharmaceutical products 2020 (100 million yen)
2020; 300,000
Source: Issues in the bio-pharmaceutical industry and suggestions for further development Japan Pharmaceutical Manufacturers Association, Office of Pharmaceutical Industry Research, Research Paper, No.71, P8

System for enhancing the sales of devices

In order to expand overseas sales channels, we will strengthen our sales structure. In addition, in order to offer consistent quality and services and satisfy customers further, we developed a quality management system and obtained the international certificate of ISO9001:2015.

- **Strengthening of the sales structure**

  - Extended the period of the basic sales contract for cell cultureware and cemented the cooperation with Thermo Fisher Scientific, a general scientific service provider, headquartered in Massachusetts, the U.S.

- **Acquisition of ISO 9001: 2015 Certification**

  - Date of registration : January 6, 2020
  - Period of validity : January 6, 2023
  - Scope of registration : Design and manufacturingcontrol of cell cultureware Sales of special cell monitoring devices and measuring instrumen

Establishment of development and manufacturing facilities

In response to the growth of overseas sales volume, we decided to construct facilities for developing and manufacturing cell cultureware. We plan to start the operation of the facilities in the 4th quarter of FY12/21.

- **Outline of facilities**

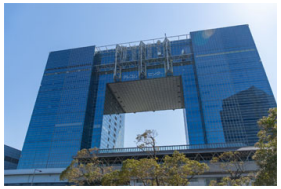
Name	CellSeed Inc. facilities for developing and manufacturing new cell cultureware
Location	TIME24 Bldg., 2-4-32 Aomi, Koto-ku, Tokyo
Business description	Development and manufacturing of flasks

TIME24 Building

New facilities

Telecom Center Sta.

Telecom Center Building



Head office and CPC

Regenerative Medicine Supporting Business

CellSeed
Regenerate the Future

1 Development of Manufacturing Methods and Contract Manufacturing for Cell Sheet Products

- Development of cell sheet manufacturing methods
- Contract manufacturing of cell sheet products
- Quality testing of cell sheets, etc.

2 Facility Management and Application Support

- Support for preparing and submitting applications
- Support for document creation/consulting
- Support for operation and maintenance of facilities equipment/management system, etc.

3 Training of Cell Culturing Technicians

- Cell sheet culturing training
- Cell sheet harvesting training, etc.

Commissioned projects in our regenerative medicine service

CellSeed Regenerate the Future

For the regenerative medicine service, we obtained the permission to manufacture specific processed cells (facility No. FA3160008) in March 2017 and the permission to manufacture products for regenerative medicine in October 2018 and have undertaken various projects so far. We will continue the commissioned production of cell sheets, while giving top priority to quality.

Autologous cartilage cell sheets

- Tokai University entrusted us with the manufacturing of autologous cartilage cell sheets, as the university started advanced medicine B with these sheets.

Cell sheets for treating liver disease

- Conclusion of a contract for the transfer of technologies for clinical trials and manufacturing of cell sheets for treating liver disease with KanonCure in Nov. 2020.

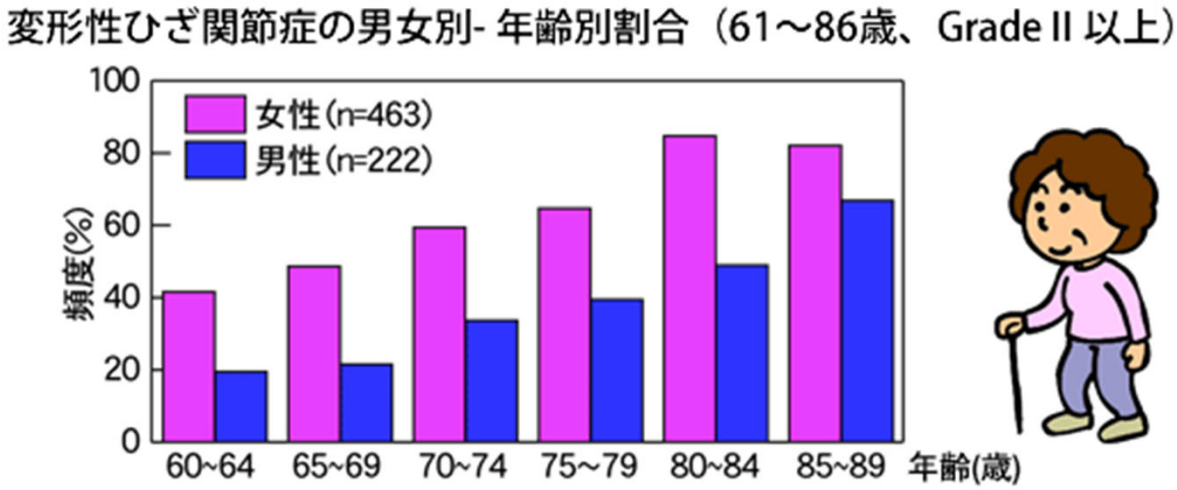
Periodontal ligament cell sheets

- The first project for commissioned manufacturing of cell sheets for clinical trials led by medical doctors

*The above are the projects that can be disclosed.

Chondrocyte Sheet

- Disease characteristics
  - Causes：ageing・obesity traumatic
  - No treatment to regenerate lost cartilage is available
- In Japan, estimated number of potential patients about 30 million persons of which, about 10 million shows symptoms.



Go Omori, Yoshio Koga and others From epidemiological survey for osteoarthritis of the knee

Overview of Chondrocyte Sheet Project

CellSeed Regenerate the Future

◆ Clinical Research at University

Tokai University School of Medicine

Prof. Masato Sato, School of Medicine, Tokai University

<Autologous Cartilage Sheets>

- 2010 Clinical study started, 8 cases completed
- 2020 Advanced Medicine B started

<Allogeneic Cartilage Sheets>

- 2017 Clinical study started
- 2019 10 cases completed

Started medial treatment in Tokai University as Advanced Medicine B

Basic Development Agreement

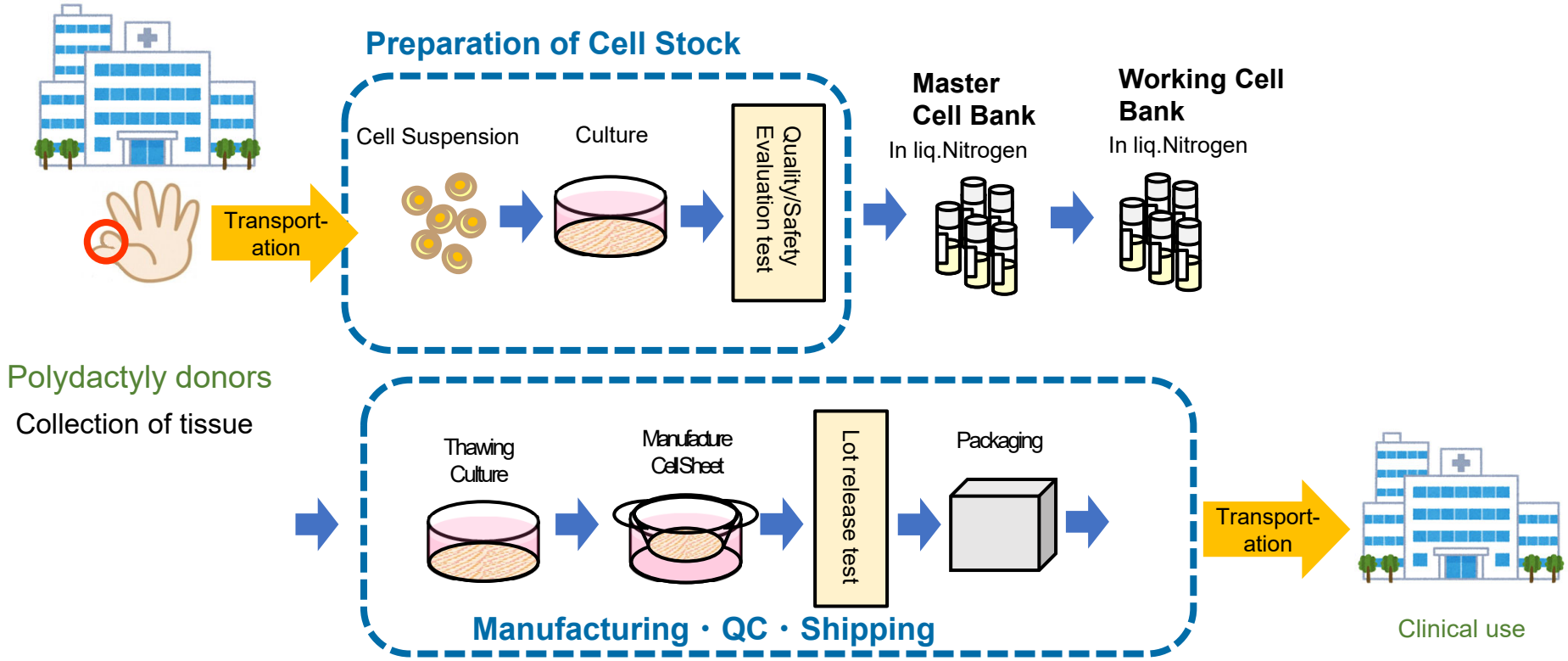
◆ Development for regulatory approval by companies

Japan ⟷ **CellSeed** *Regenerate the Future* ⟷ **MetaTech** 三顧股份有限公司 **Taiwan**

- **<Autologous Cartilage Sheets>**
  Contracted manufacturing of autologous cartilage cell sheets for advanced medicine started
- **<Development of Allogeneic Cartilage Sheets>**
  Acquired cartilage cell for commercial purposes from National Center for Child Health and Development

- Licensed out to MetaTech Inc., Taiwan.
- Started the commercialization of autologous cartilage sheets based on Taiwanese law (laws applicable to Japan's Advanced Medicine B), and conducted transplant surgery on 10 patients

Allogeneic chondrocyte sheets



Allogeneic chondrocyte sheets

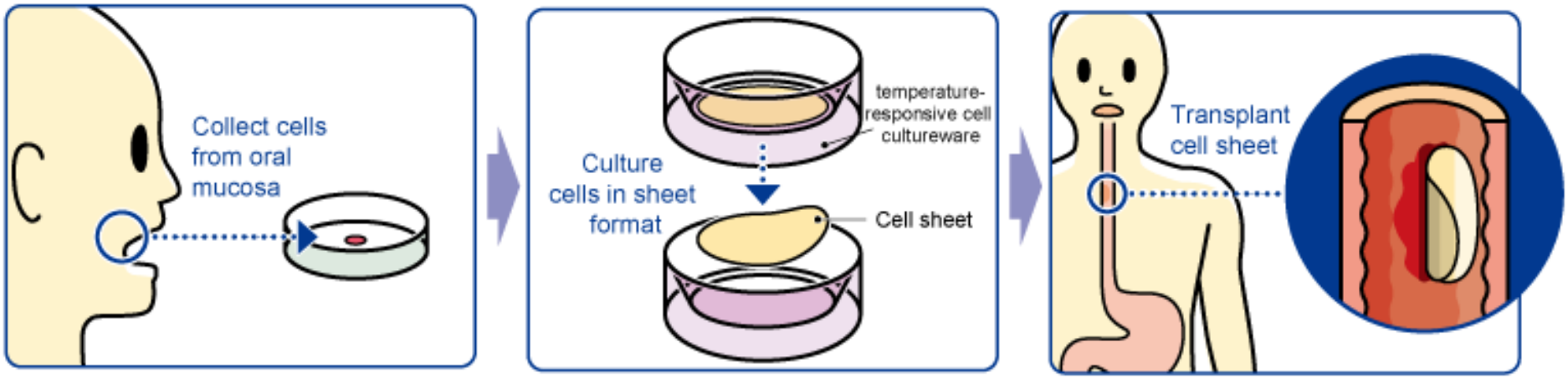
Clinical Research at Tokai University	Completed in December 2019 transplants of 10 cases
Development at CellSeed	Transfer of the cell bank and cell sheet manufacturing technology from Tokai University to CellSeed
Sep. 2018 Adopted as the ancillary project of AMED	Adopted as “a project for developing fundamental evaluation technologies for industrializing regenerative medicine (support for acceleration of development of regenerative medicine seeds)”; project period: Oct. 2018 to Mar. 2021
Dec. 2020 Acquisition of cartilage cells for commercial use	Acquired cartilage cell for commercial purposes from the National Center for Child Health and Development
Jul. 2021 Adopted as the ancillary project of AMED	Adopted as “a project for developing fundamental evaluation technologies for industrializing regenerative medicine (project for promoting the industrialization of regenerative and cell medicine and gene therapy)”; project period: Aug. 2021 to Mar. 2023

We plan to submit a clinical trial plan at the end of 2022.

Epithelial Cell Sheet for Esophageal Regeneration
(CLS2702C/D)

CellSeed
Regenerate the Future

- A medical treatment developed by Tokyo Women's Medical University as a regenerative treatment for esophageal cancer (to heal esophageal wound and prevent stricture)
- Cell sheet is on a temperature-responsive cell culture ware and then transplanted into the ulcerated area in the esophagus after endoscopic surgery for esophageal cancer



Clinical Research and Clinical Trials of Esophageal Cell Sheet

CellSeed Regenerate the Future

Clinical Research at Universities

2008－2014＜Japan＞

Tokyo Women's Medical Univ.	10case
Tokyo Women's Medical Univ. and Nagasaki Univ.	10case

＜Europe＞

Karolinska University Hospital	10case

Tokyo Women's Medical University

Basic Development Agreement

2017.4
Business alliance agreement signed with Taiwan's MetaTech(AP) Inc.

Clinical Trials sponsored by CellSeed

"SAKIGAKE Designation" in Feb. 2017

Japan ⟷ **CellSeed** Regenerate the Future ⟷ **Taiwan (MetaTech)** **Europe (Sweden)**

- 2016 Apr. Submitted a notification of clinical trial plan
- 2019 Mar. Completed the clinical trial in Japan
- 2020 Oct. Additional clinical trial plan notification submitted
- 2021 Feb. First medical case recorded

- 2016 Consulted with European Medicines Agency (EMA)
- 2017 Licensed out the product to MetaTech in Taiwan
- 2018 Submitted a notification of a clinical trial in Taiwan
- 2020 Suspended the clinical trial in Europe

The 2nd Cell Sheet Engineering Innovation Forum

We plan to stream the 2nd forum on cell sheet engineering innovation live on Nov. 1, 2021.

- **Speakers**

Tatsuya Shimizu, Ph,D., M.D.

Professor, Tokyo Women's Medical University, Director, Institute of Advanced BioMedical Engineering and Science

Yuji Miyahara, Ph,D.,

Professor, Tokyo Medical and Dental University, Director, Institute of Biomaterials and Bioengineering

Ryoichi Sakiyama, Ph,D.,

Associate Professor, Osaka Institute of Technology Department of Biomedical Engineering

Kohji Nishida, Ph,D.,

Senior Professor, Graduate School of Medicine, Osaka University

The 19th share acquisition right with a provision for revising exercise price exercised

All of the 19th share acquisition rights issued on August 6, 2020 to Barclays Bank PLC were exercised on July 29, 2021.

Exercise price	211-327 yen/share
No. of share acquisition rights exercised	35,000
Exercised by	Barclays Bank PLC
No. of shares issued	3,500,000
Total exercise price	862,092 thousand yen

CellSeed

Regenerate the Future

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