

CellSeed Inc.

Fiscal 2022 First-Half Earnings Results Presentation



JASDAQ Growth Stock Code:7776

- **Company Profile**

- **Financial Summary Second Quarter of Fiscal Year**

Ending December 31, 2022

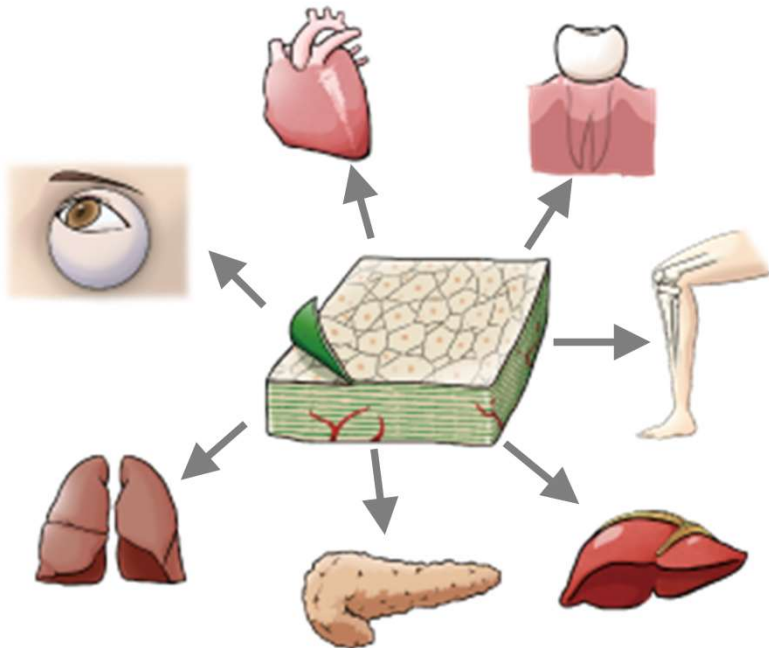
- **Progress of each business**

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

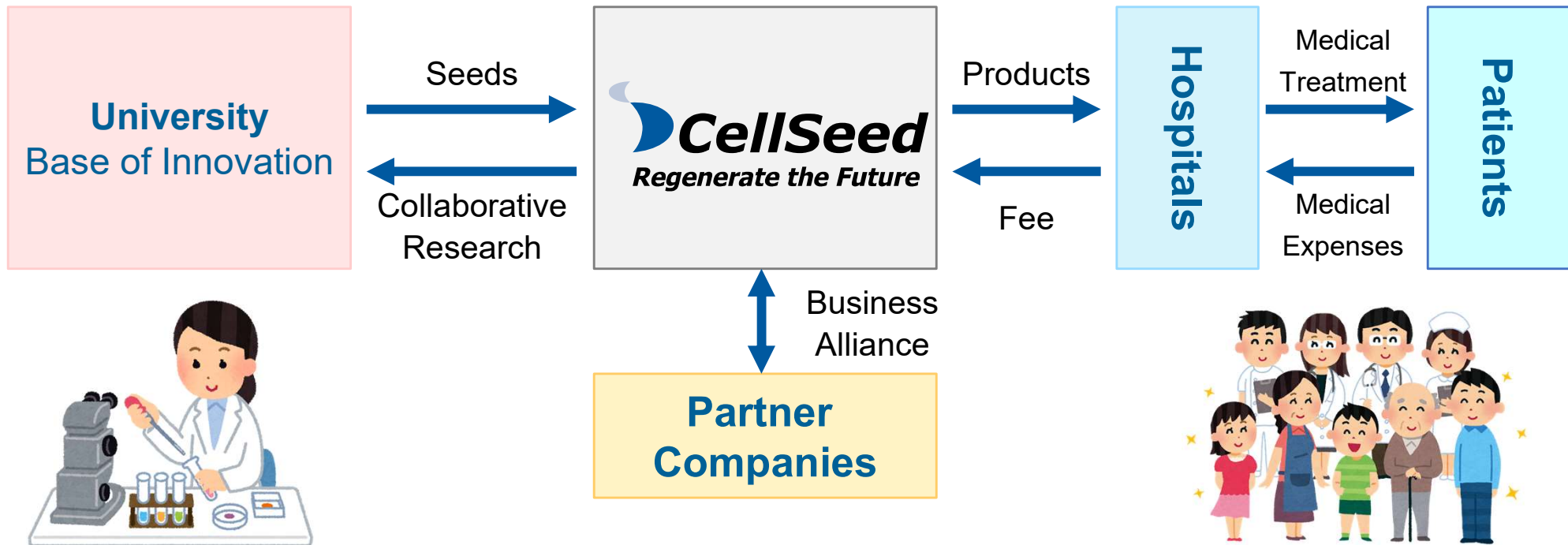


CPC

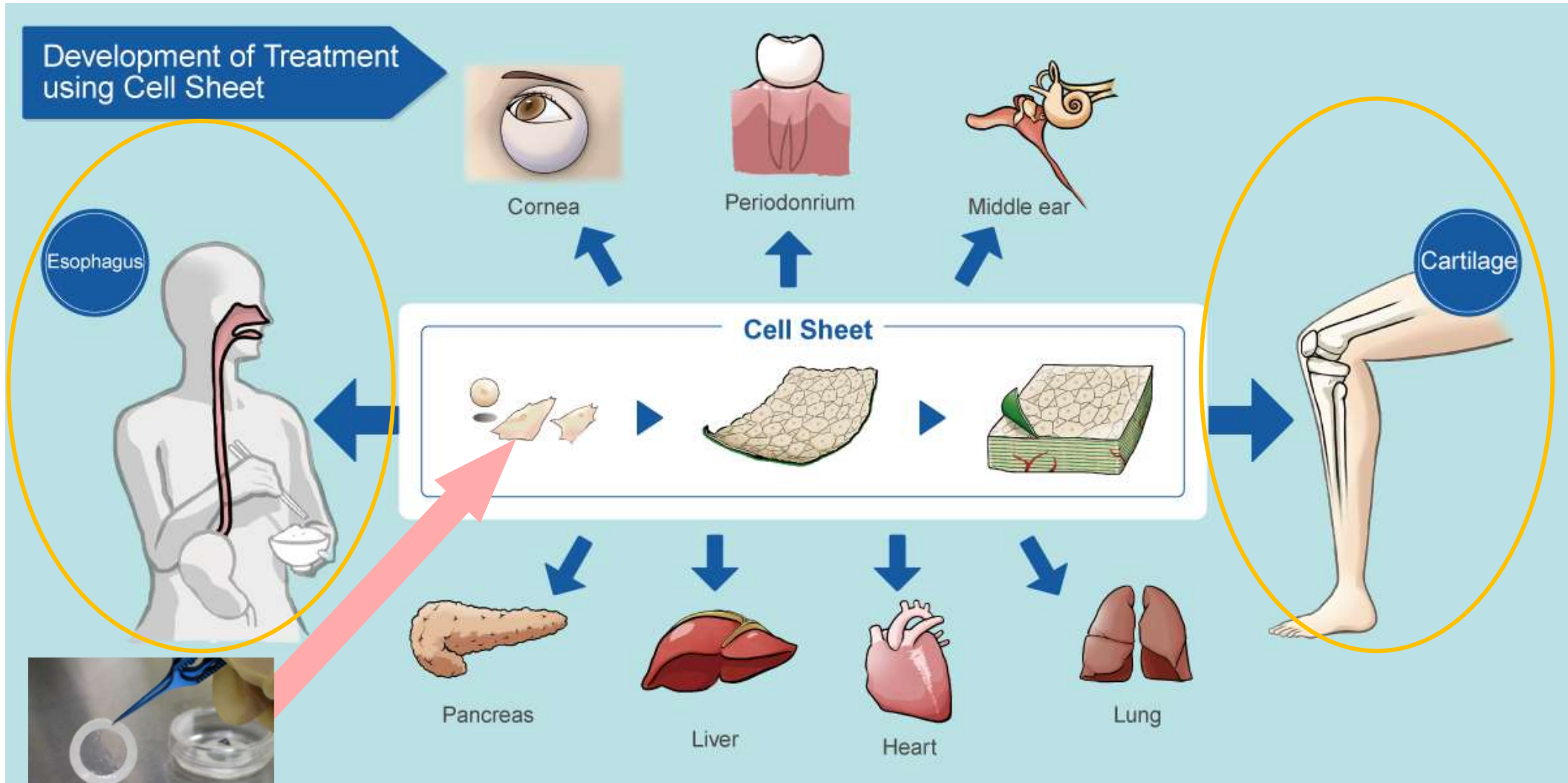
Our Business Model

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 12/2022

	FY2022 Non-Consolidated (January 2022 - December 2022)	FY2021 Consolidated (January 2021 - December 2021)
	Amount (Millions of Yen)	Amount (Millions of Yen)
Net sales	74	81
Operating profit	-348	-466
Ordinary profit	-352	-477
Net Income	-357	-486

As quarterly financial statements are prepared from the first quarter of the fiscal year ending December 31, 2022, figures for the second quarter of the fiscal year ending December 31, 2021 and percentage change from the same period of the previous year are not shown.

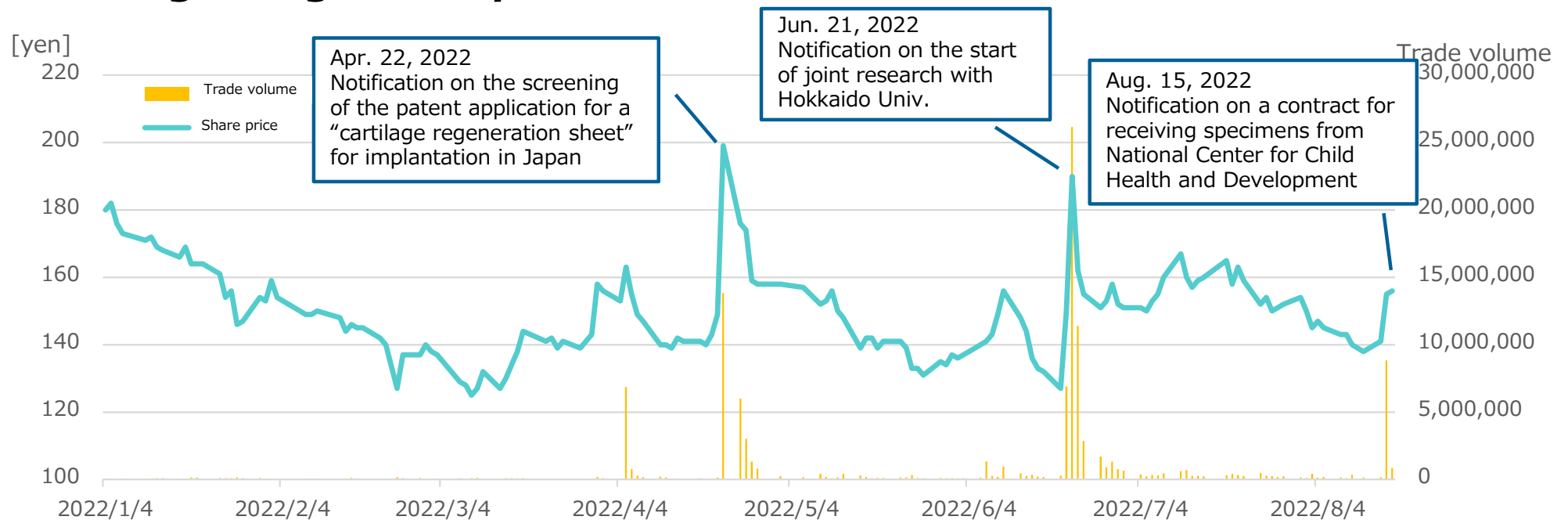
- Cemented the cooperation with existing distributors for sales promotion of devices and conducted active sales promotion campaigns.
- Regarding the commissioned manufacturing of autologous cartilage cell sheets, we posted sales from 1 case in the cumulative second quarter. From the third quarter, we plan to post sales from multiple cases.
- Regarding allogeneic cartilage cell sheets, we will proceed with development while receiving support of AMED, and prepare for the submission of a clinical trial notification at the end of 2022.

Completion of exercise of the 22nd share acquisition right (with the exercise price correction provision)

On June 22, 2022, we completed the exercise of all of the 22nd share acquisition rights issued on Jan. 5, 2022 with the allocatee being Barclays Bank PLC.

Exercise price	116-170 yen per share
No. of share acquisition rights exercised	44,000
Exercised by	Barclays Bank PLC
No. of shares issued	4,400,000
Total exercise price	610,121 thousand yen

- Variation in share price from the beginning of the year**



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- Progress of each business

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 <i>RepCell</i> ® and <i>HydroCell</i> ®
2007	Released <i>UpCell</i> ®.
2010	Released cellZscope®.
2011	Released ThermoPlate®.
2015	The regenerative medicine product Heart Sheet (Terumo Corporation) approved. (<i>UpCell</i> ® was adopted as its component)
2017	Released <i>HydroCell</i> ® 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	<ul style="list-style-type: none"> 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.
2022	Plan to start sales of the new product <i>UpCell</i> ® flasks

UpCell[®]

This cultureware maintains the physiological activity of cells and retains a high level of antigen proteins on the cell surface while serving as a cell culture dish for the recovery of the cell sheet.



RepCell[®]

In addition to the same characteristics as those of UpCell[®], this cultureware allows for the recovery of cells in a single cell or small colonies using the surface grid wall.



HydroCell[®]

Using proprietary technology, nano-surface design, super-hydrophilic polymers are fixed to the surface of this cultureware, which forms spheroids of iPS cells and cancer cells.



cellZscope

This is a type of cultureware that is most suitable for research into the effect of drugs and poisons for the evaluation of cell layer barrier functions.



The new product *UpCell*[®] to be released in Oct.

UpCell[®] Flask



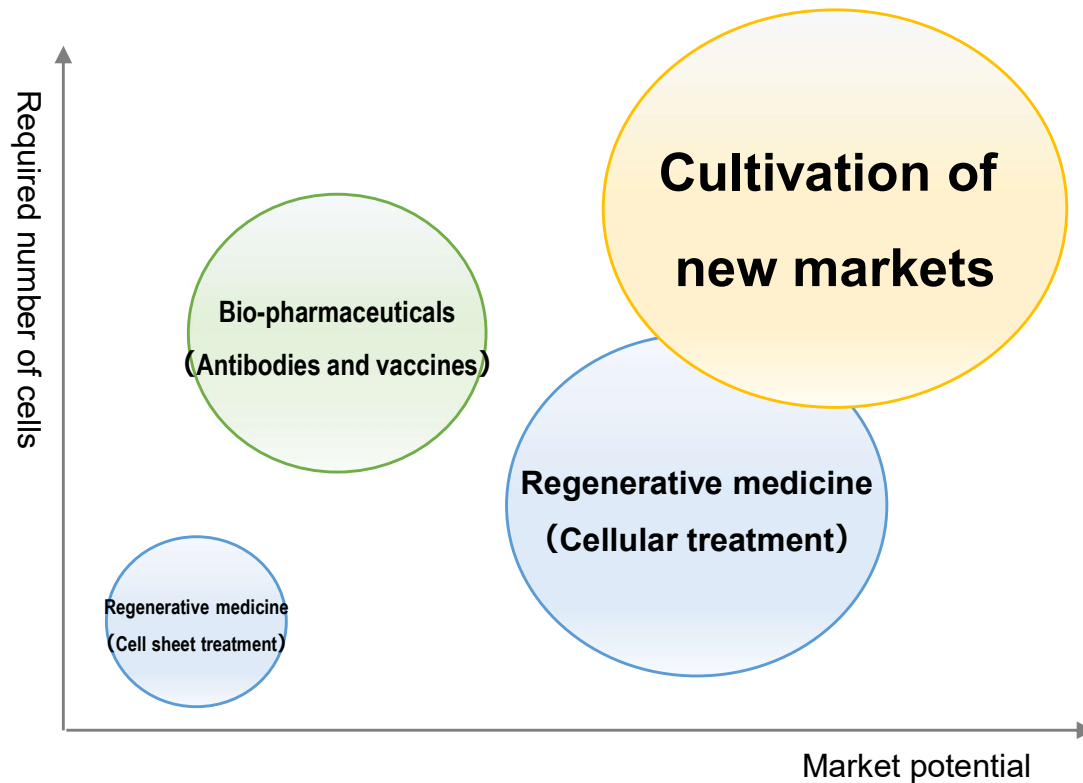
Cell Culture Insert for *UpCell*[®] 6 Well



- For *UpCell*[®] Flask, we plan to release products whose culture area is larger than that of the existing *UpCell*[®] Dish. It is possible to collect a larger amount of intact cells, so this is suited for research into immunity and cellular therapy.
- With culture in an environment close to the living-organism environment, such as co-culture with the cell culture insert for *UpCell*[®] 6 Well, it is possible to collect cell sheets with the biological function kept at a high level.

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



Time 24

Aomi Cell Cultureware Innovation Center

Time 24 Building, 4-32,
Aomi 2-chome, Koto-ku, Tokyo



Telecom Center Sta.

Head Office

15F (East Wing) Telecom Center Building
2-5-10, Aomi, Koto-ku, Tokyo

Cell Processing Facility

Telecom Center Building 6F
Total Floor Area 763 m²

(Facility Number:FA3160008)

Cell control room



Cell control room



Telecom Center

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.



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.

■ Pediatric autologous epithelium cell sheet

- For children after surgery for congenital esophageal atresia



*The above are the projects that can be disclosed.

Pipeline Progress

Regenerative medicine

The Act on the Safety of Regenerative Medicine

Clinical research

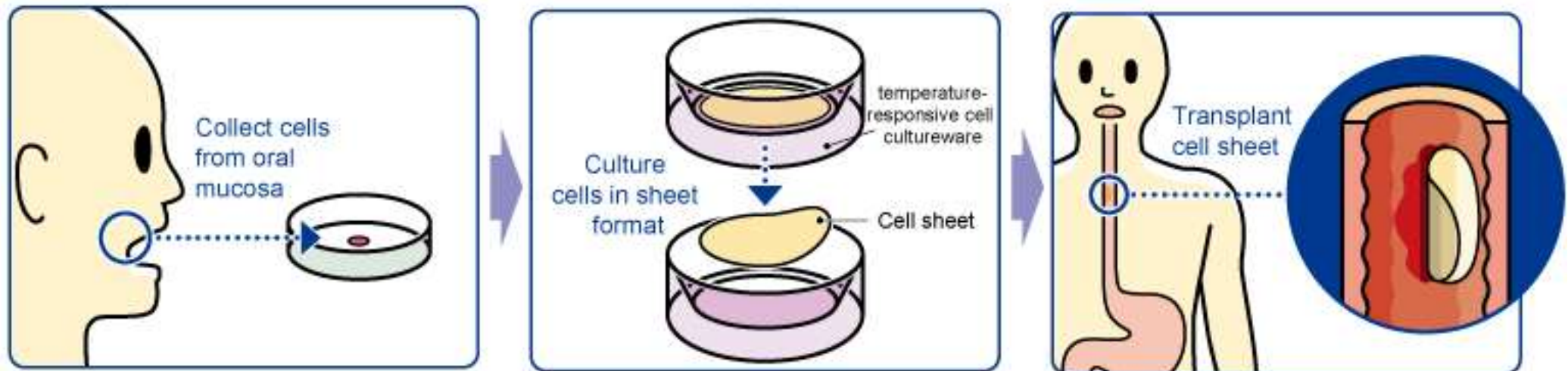
Self-funded medical treatment

The Act on Pharmaceuticals and Medical Devices

Manufacturing and sales

Pipeline	Fundamental research	Clinical research	Clinical trials			Application /approval	Sales
			First phase	Second phase	Third phase		
Epithelial Cell Sheet for Esophageal Regeneration	Currently conducting clinical trials under the Pharmaceutical and Medical Device Act						
Autologous chondrocyte sheets	Under the Act on Securing Safety of Regenerative Medicine, we obtained approval and implemented treatment as advanced medical treatment B. We also accepted outsourcing for the manufacturing of cell sheets.						
Allogeneic chondrocyte sheets	Fundamental research/clinical research at Tokai University						
	Currently preparing for clinical trials under the Pharmaceutical and Medical Device Act						

- 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



Tokyo Women's Medical University

● 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
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Basic Development Agreement



● Clinical Trials sponsored by CellSeed

"SAKIGAKE Designation" in Feb. 2017

Japan



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

Taiwan (MetaTech) Europe (Sweden)

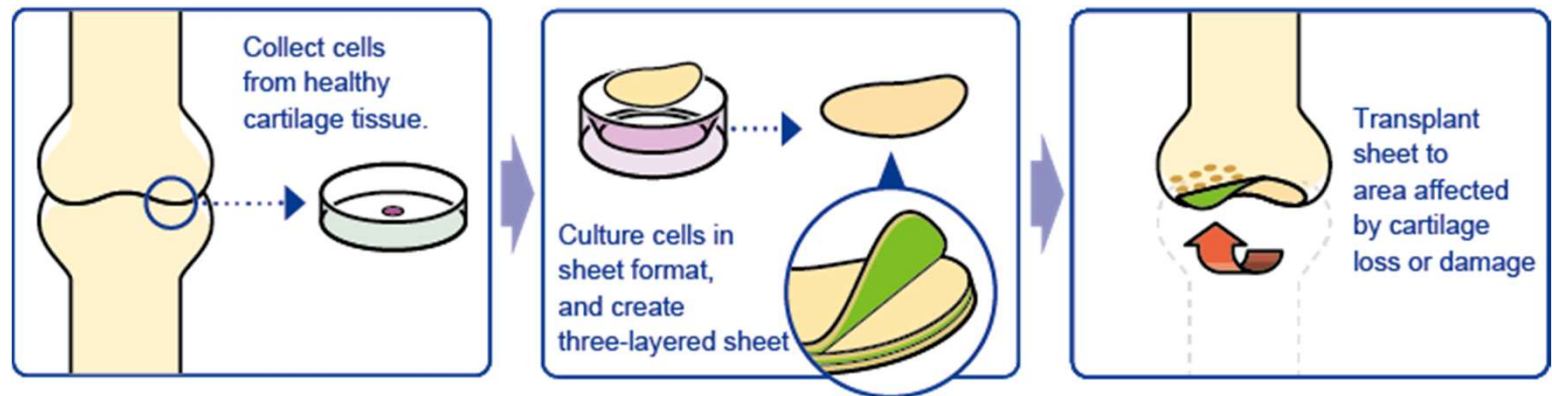
- 2016 Apr. Submitted a notification of clinical trial plan
- 2019 Mar. Completed the clinical trial in Japan
- 2020 Oct. Additional clinical trial plan notification submitted
- 2021 Feb. First medical case recorded

- 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

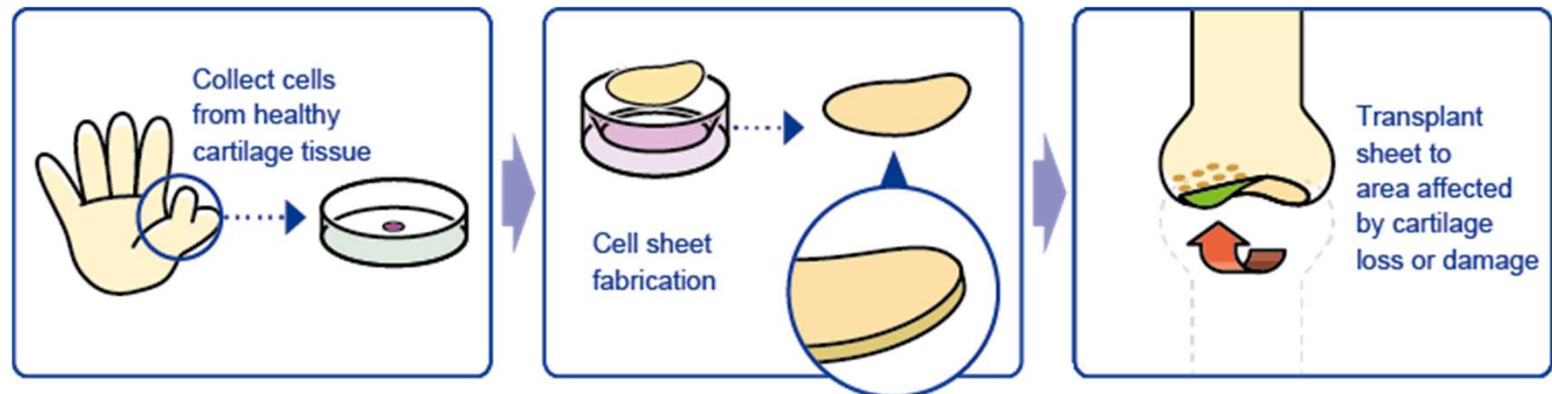
Chondrocyte Sheet

- 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.

- **Autologous chondrocyte sheets**

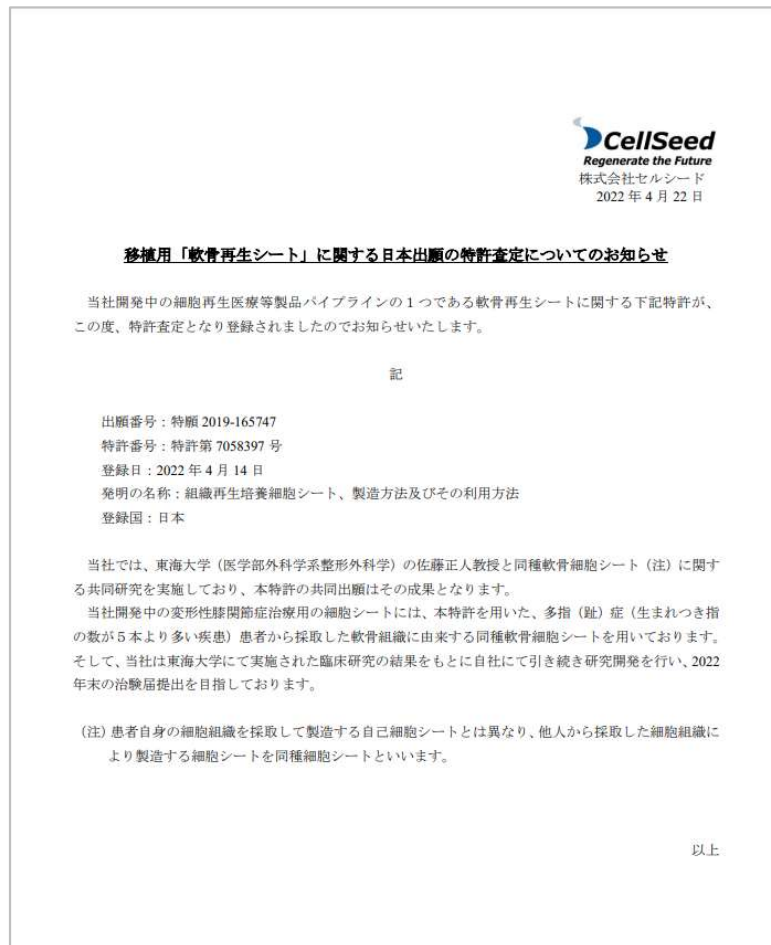


- **Allogeneic chondrocyte sheets**



Acquisition of a patent regarding allogeneic cartilage cell sheets

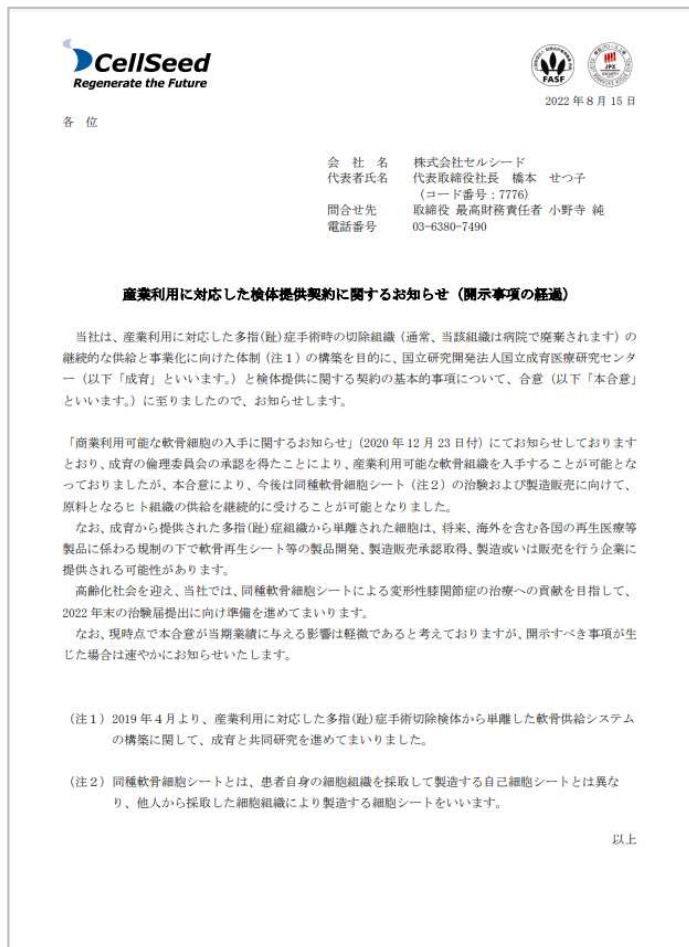
In April 2022, we acquired a patent on allogeneic cartilage cell sheets we are currently developing. We had jointly applied for this patent with Professor Sato of Tokai University.



- Application No. 2019-165747
- Patent No. 7058397
- Registration date: April 14, 2022
- Invention title: Cultured cell sheets for tissue regeneration, and methods for manufacturing and using them
- Country where it was registered: Japan

National Center for Child Health and Development agrees to sign a contract for supplying specimens

We are now able to continuously receive cartilage cells, which are required for producing and selling allogeneic cartilage cell sheets, from National Center for Child Health and Development.



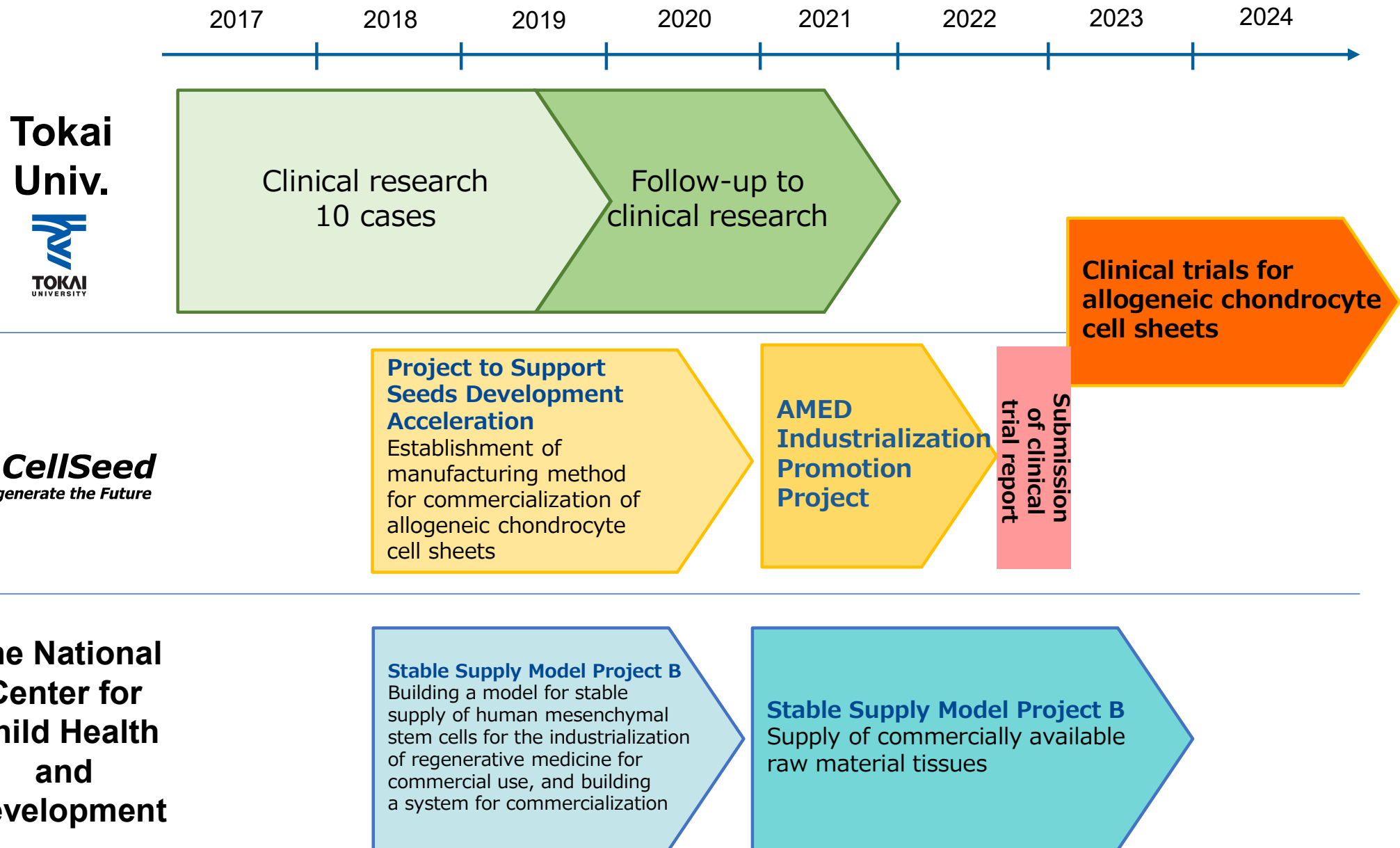
Dec. 23, 2020

After obtaining the approval of the ethical committee of National Center for Child Health and Development, we were allowed to receive cartilage cells for industrial application.

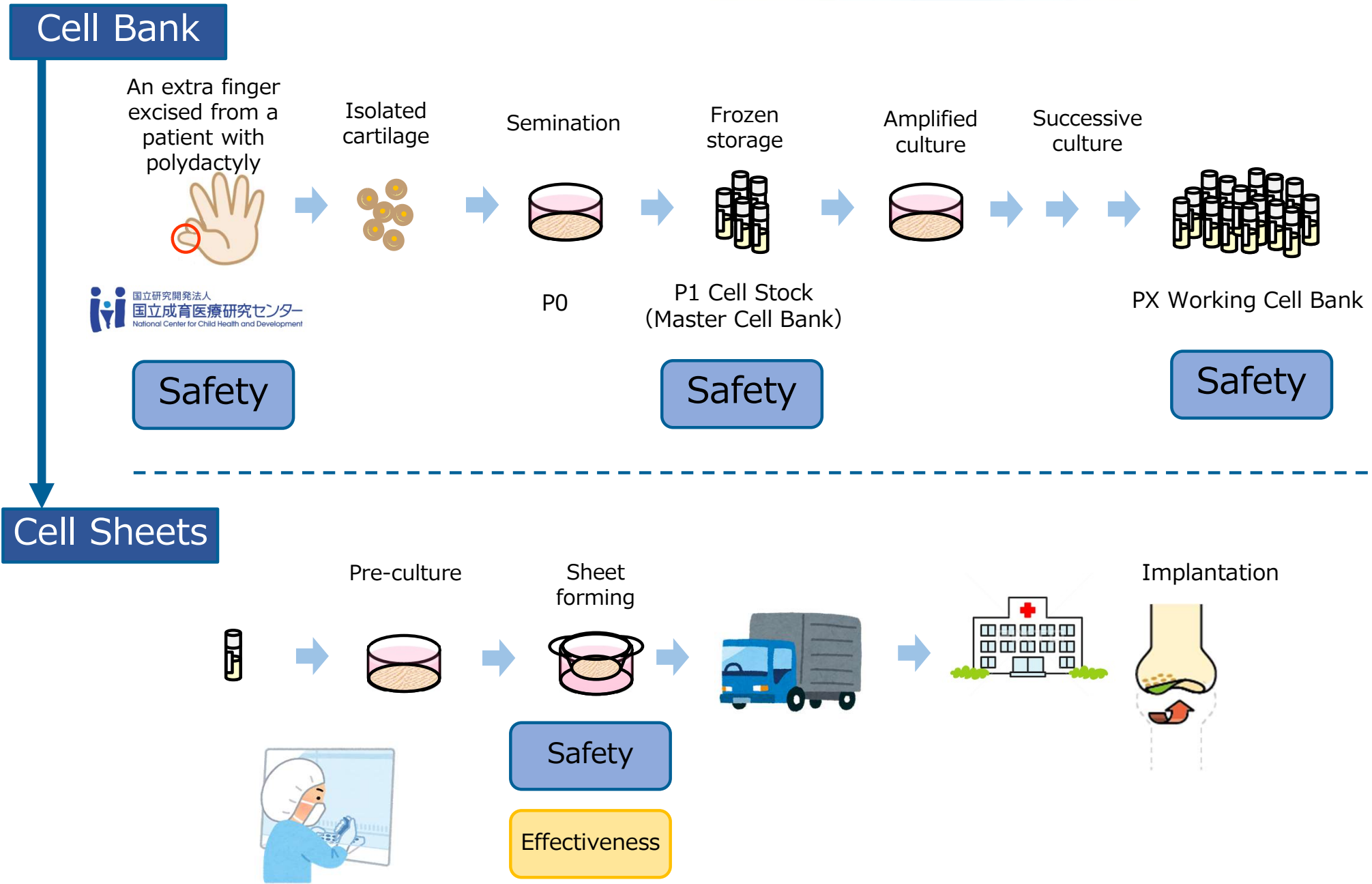
Aug. 15, 2022

We concluded a contract for supplying specimens for a broader range of industrial use with National Center for Child Health and Development.

<Allogeneic cells> Industry-academia collaboration in cartilage cell sheets

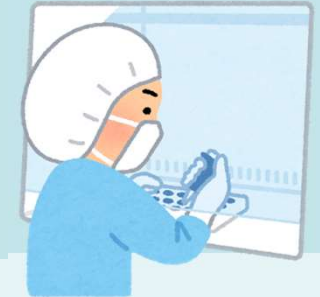


Process of producing allogeneic cartilage cell sheets (CLS2901C)



Safety

- Establishment of a stable system for supplying tissue for a cell bank
- Check of safety of tissue provided by donors
- Check of safety of a cell bank produced from tissue
 - Safety test of a cell bank
 - Virus test for a cell bank



Effectiveness

- Check of the effectiveness of a cell bank
 - Test of implanting a cell sheet to a rat with cartilage damage and observing cartilage regeneration
 - Difference in cartilage regeneration among donors
 - Difference in cartilage regeneration according to the degree of passage of cells

Quality

- Establishment of a method for managing the quality of cell sheets
- Establishment of a method for transporting cell sheets

- ◆ Face-to-face advice: quality (equivalence of clinical trial products) held on June 17
- ◆ Face-to-face advice: clinical practice/trial plan held on July 22

- We produced cell banks with passage number 1 and with passage number 2 from the tissue obtained from 4 donors. Then, we implanted the cell sheets produced from these cell banks to rats with cartilage damage.
- In the group with cell sheets implanted, cartilage regeneration was observed.
- There was no difference in cartilage regeneration according to passage number of cell sheets.
- Good-quality cartilage regeneration was observed.



- We decided to produce cell sheets for a clinical trial by using one of the cell banks we produced this time.



Allogeneic chondrocyte sheets

2017
|
2019

Clinical Research at Tokai University
Completed in December 2019 transplants of 10 cases

2018
|
2021

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

2020-

Acquired cartilage cell for commercial purposes
from the National Center for Child Health and Development


2021
|
2023

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

End of
2022

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

We have commenced collaborative research with Hokkaido University regarding the new therapy based on our cell sheet engineering and diseases related to the damage to the central nervous system.



2022年6月21日

各位

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代表者氏名	代表取締役社長 橋本 せつ子 (コード番号: 7776)
問合せ先	取締役 最高財務責任者 小野寺 純
電話番号	03-6380-7490

中枢神経損傷関連疾患に対する新規治療についての共同研究開始のお知らせ

この度、当社は、国立大学法人北海道大学大学院医学研究院（北海道札幌市北区北15条西7丁目、研究院長：畠山 鎮次、以下「北海道大学」といいます）との間で、当社の細胞シート工学を用いた中枢神経損傷（注1）関連疾患（以下「本疾患」といいます）の新規治療方法に関する共同研究（以下「本研究」といいます）を開始しましたので、お知らせします。

本研究において、北海道大学は、保有する自家骨髄由来細胞などを提供するとともに、当社の技術協力のもと、本疾患に関する治療の品質、安全性および有効性に係る非臨床試験を実施します。

北海道大学は、間葉系幹細胞をヒト骨髄液から高純度に精製分離・培養する方法を有しており、本研究では、当社が提供する再生医療基盤技術「細胞シート工学」を用いて、同方法により精製した骨髄由来間葉系幹細胞から細胞シートを作製する再生医療（注2）の実用化を目指します。

（注1）中枢神経損傷とは、脊髄などの中枢神経に発生した障害をいいます。

（注2）ヒトの骨髄液から分離・培養して作製した細胞シートを本疾患の患者の外傷部分に移植することにより、当該損傷を修復することを目的としております。これまでは、骨髄損傷をはじめとする中枢神経の損傷には、根本的な治療方法がなかったため、神経機能の回復が困難とされておりました。

以上

The central nervous system includes the brain and the spinal cord. If it is damaged, sensory and motor functions will be disturbed, and paralysis will occur.

Hokkaido University will produce cell sheets from mesenchymal stem cells derived from the spinal cord based on our cell sheet engineering technology. We aim to repair the damage to the central nervous system by implanting this cell sheet.



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