CellSeed
Regenerate the Future

CellSeed Inc.

Fiscal 2024 Earnings

Results Presentation

Tokyo Stock Exchange Growth Code:7776

Contents

CellSeed
Regenerate the Future

Head office・CPC・development and manufacturing facility

CellSeed
Regenerate the Future

Established	May, 2001
Core competence	Cell Sheet Engineering based on Temperature Responsive Polymers
Listed	Tokyo Stock Exchange Growth（7776）

Head Office

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

Cell Processing Center

Telecom Center Building 6F
Total Floor Area 763 ㎡
(Facility Number:FA3160008)
(The Permission to Manufacture Products for Regenerative Medicine)

Aomi Cell Cultureware Innovation Center

Time 24 Building, 4-32,
Aomi 2-chome, Koto-ku, Tokyo
(ISO9001 certification acquired)

Telecom Center

Time 24

CellSeed Inc. Corporate Information

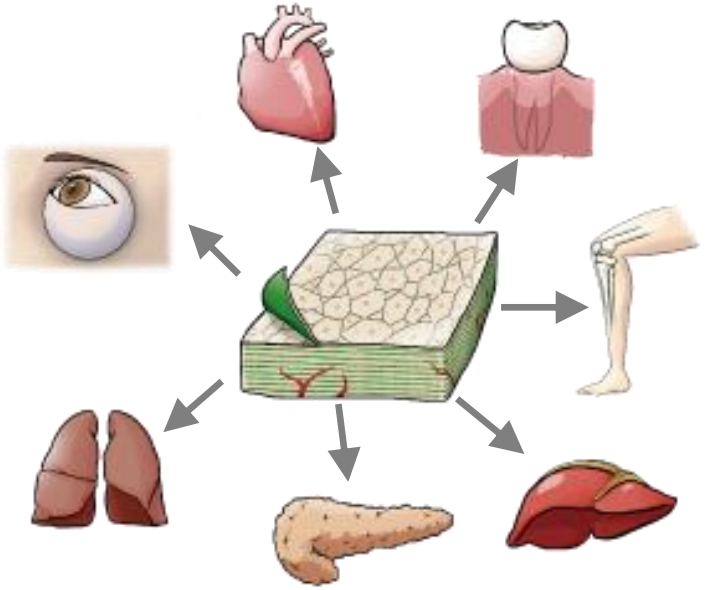
CellSeed
Regenerate the Future

Mission

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

Regenerative Medical Products Business

- Commercialization of Cell Sheet Therapies

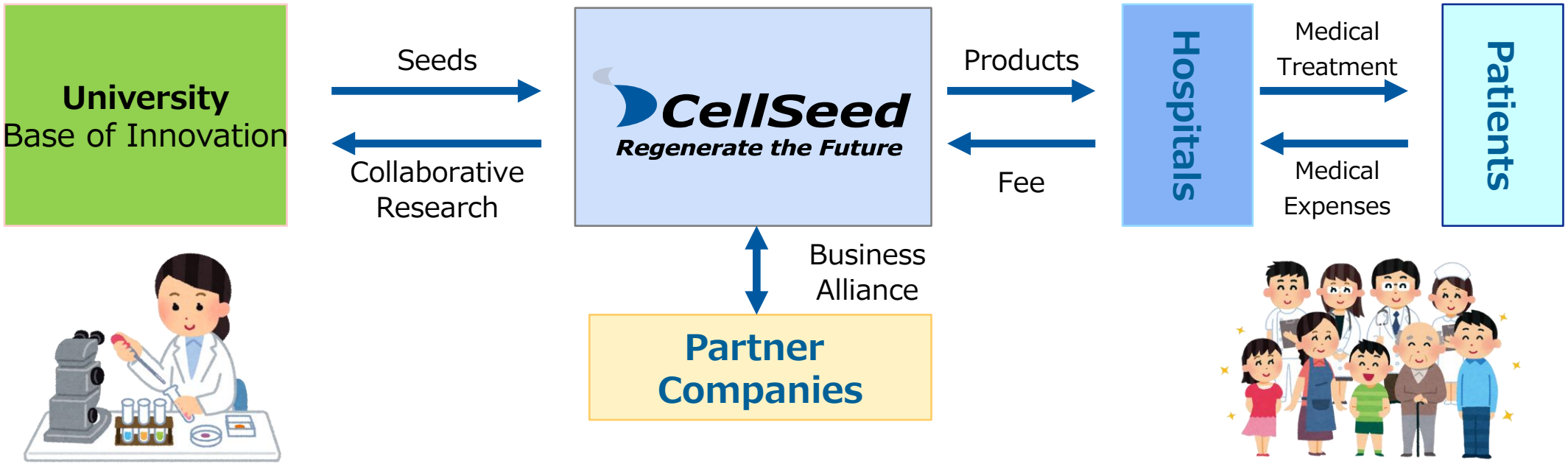


Regenerative Medicine Supporting Business

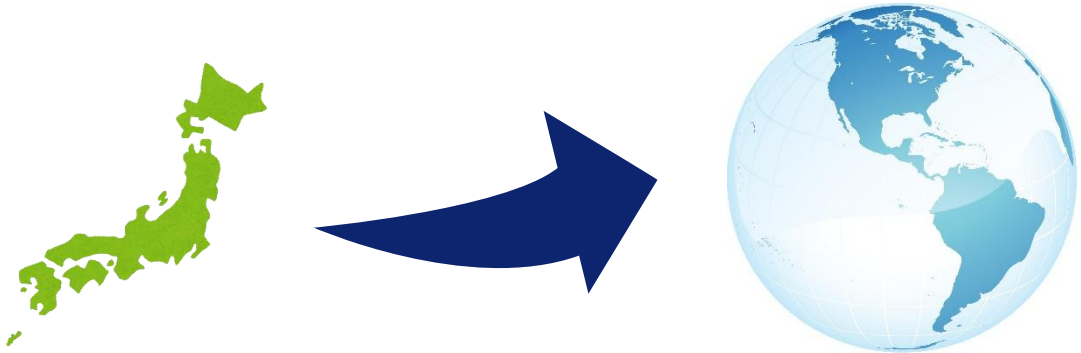
- Intelligent Culture Ware as Research Tools

- Regenerative Medicine Contract Manufacturing Services

Our Business Model



Delivering the technology developed at a university and developed at a venture to patients as soon as possible.



Development of Treatment Using Cell Sheet Engineering

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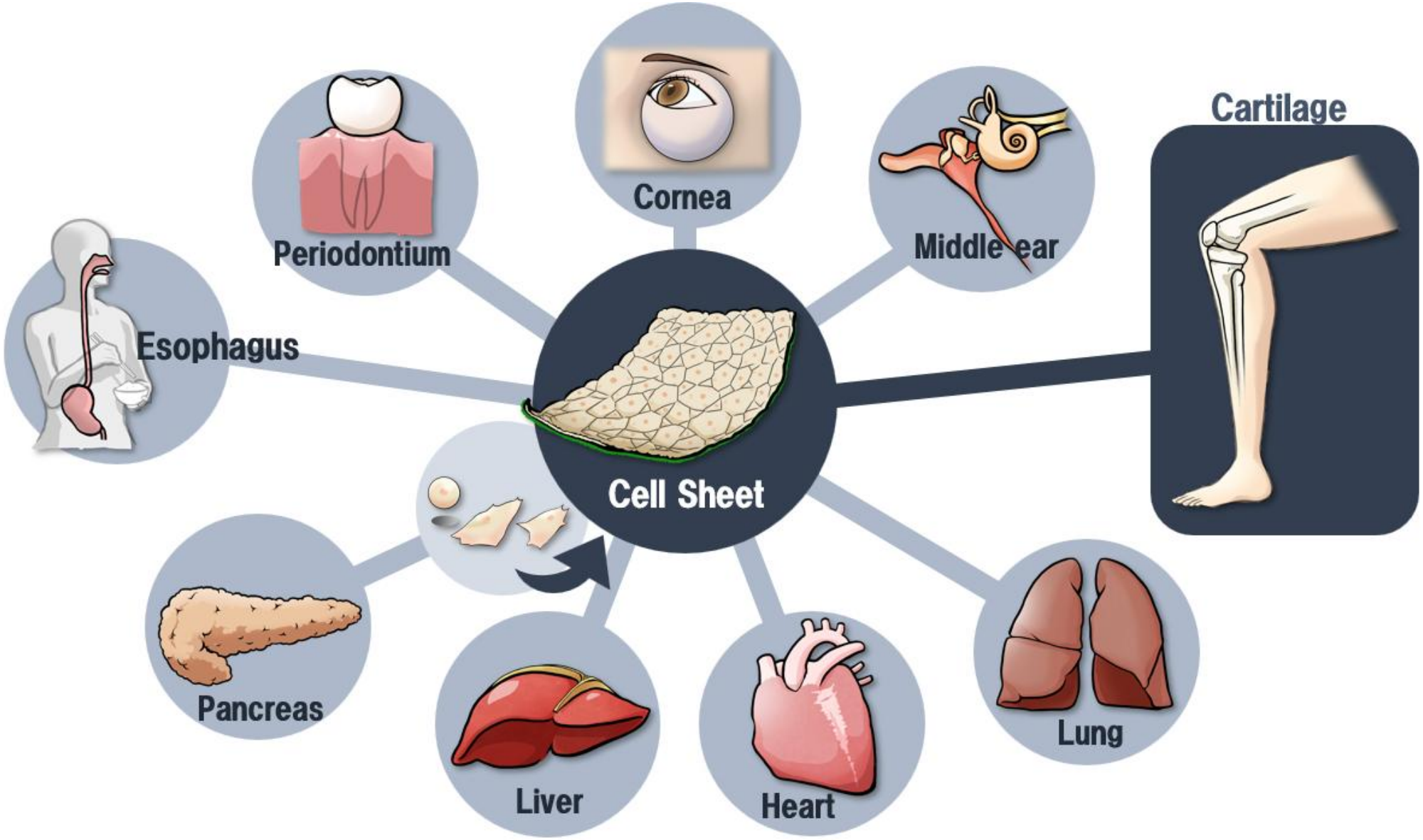

New law related to regenerative medicine, enforced in 2014

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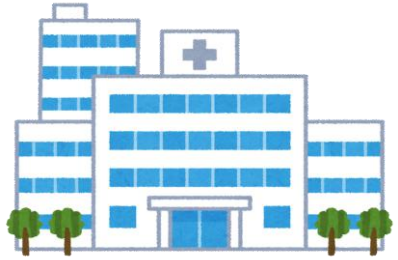
Act on the Safety of Regenerative Medicine

Law for regulating regenerative medicine, etc. performed **on the responsibility of a medical doctor**



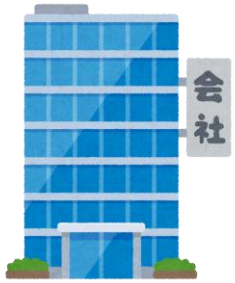
Classified into Classes 1 to 3, according to risk.
Medical institutions submit plans for regenerative medicine.
Evaluation by the certified committee for regenerative medicine, etc.

- Self-funded medical treatment
- Clinical research
- Advanced medical care

Over 5,000 plans for regenerative medicine

Act on Pharmaceuticals and Medical Devices

Law for regulating products for regenerative medicine, etc. manufactured and sold by **enterprises**



Clinical trials conducted by enterprises
Clinical trials led by medical doctors

↓

Approved as products
Covered by health insurance

Nineteen products have been approved so far.

Sources of cells used for regenerative medicine

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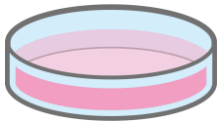
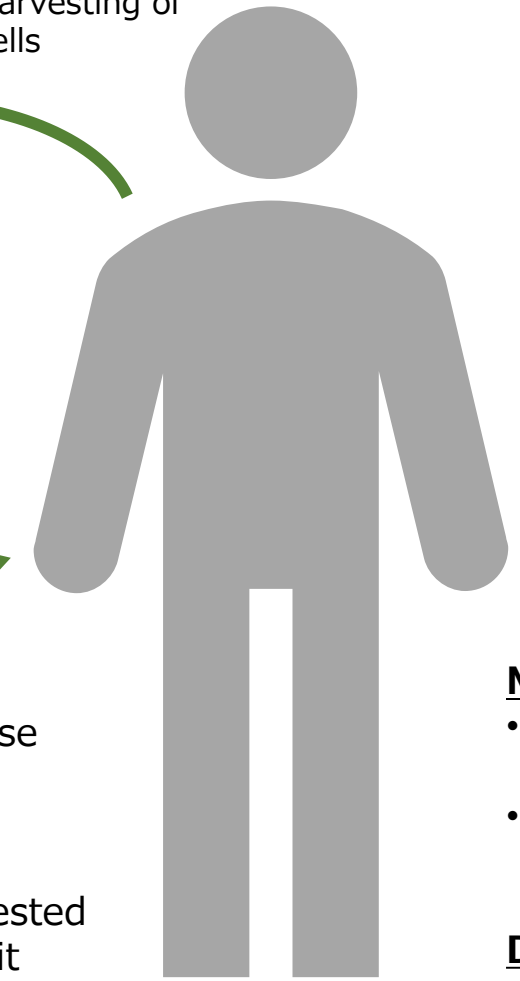
Autologous

Cells of patients
- Somatic cells
- Mesenchymal stem cells
- iPS cells



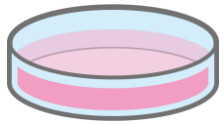
Harvesting of cells

Administration

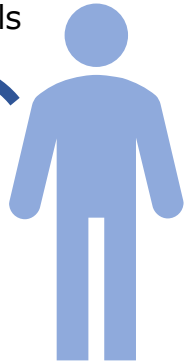


Allogeneic

Cells of others
- Somatic cells
- Mesenchymal stem cells
- iPS cells



Harvesting of cells



Donor

Administration

Merits
- Free from rejection response

Demerits
- Only after a treatment is determined, cells are harvested and cultured. Accordingly, it takes time to start administration.

Merits
- It is unnecessary to harvest cells from patients.
- It is possible to stock cells and store cultured cells.

Demerits
- Rejection response may occur.

Methods for administering products for regenerative medicine, etc.

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- To directly administer or implant a product to a target area for regeneration by surgery or with an endoscope

- To administer a product to the entire body via blood vessels by injection or intravenous drip

Contents

- Company Profile
- Financial Summary of Fiscal Year Ending

  Year December 31, 2024
- Progress of each business

Year financial summary FY 12/2024

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	First Half of the FY2024 (January 2024 - Dec 2024)			First Half of the FY2023 (January 2023 - Dec 2023)
	Amount (Millions of yen)	Change from Previous Period (Millions of yen)	Change from Previous Period (%)	Amount (Millions of yen)
Sales	193	3	1.7	190
Operating profit	△846	△148	–	△697
Ordinary profit	△847	△137	–	△710
Net profit	△859	△13	–	△846

Full-year results in FY 2024

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[million yen]	Initial forecast (A)	Full-year result (B)	Difference between the forecast and the result (B – A)
Sales	170	193	**23**
Operating income	△920	△846	**74**
Ordinary income	△920	△847	**73**
Net income	△940	△859	**81**

Both sales and profit exceeded the forecasts.

Sales
- The sales of cell cultureware in the overseas market grew significantly from the previous year.

Profit
- We reduced the costs for outsourcing development, operating cell culture facilities, etc.
- The start of a clinical trial for allogeneic chondrocyte sheets was delayed.

Topics (FY 12/2024)

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- Cell cultureware business
  - The sales in the overseas market increased considerably year on year.
  - The sales of the cell cultureware business grew from the previous fiscal year, hitting a record high.

- Commissioned regenerative medicine business
  - We undertook the manufacturing of several kinds of cell sheets.
    - Manufacturing of autologous chondrocyte sheets (advanced medical care B) for two cases, entrusted by Tokai University
    - Manufacturing of esophageal cell sheets for children (clinical research) for 1 case, entrusted by National Center for Child Health and Development

- Cell sheet regenerative medicine business
  - Established a system for enabling surgery at each clinical trial facility.
  - Continued negotiations about the remuneration for each milestone in joint development with Tokai University.

Contents

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Cell Cultureware Business

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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.

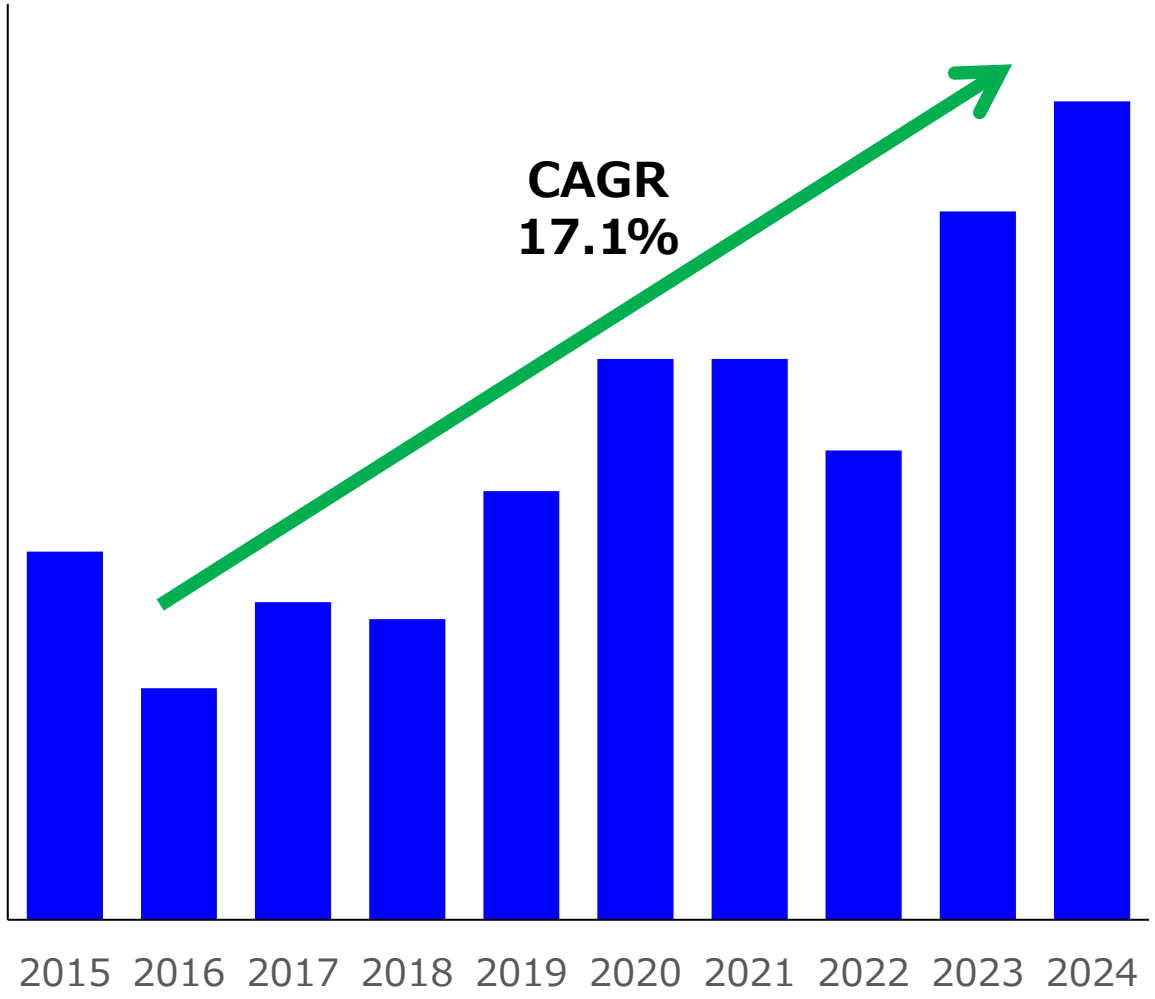
HydroCell®

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.

Variation in sales of the cell cultureware business



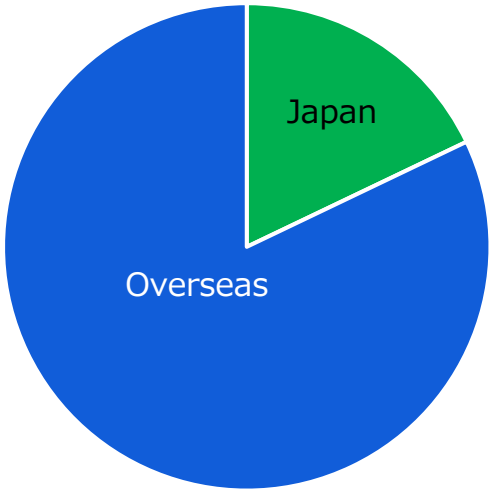
- Sales have grown 3.5 times over the past eight years.
- Continued significant increase in overseas sales from last fiscal year**.**
- In FY 12/2024, **sales hit a record high.**

<u>In the first half of FY 12/2024</u>
We received a healthy number of orders from an overseas distributor (Thermo Fisher).

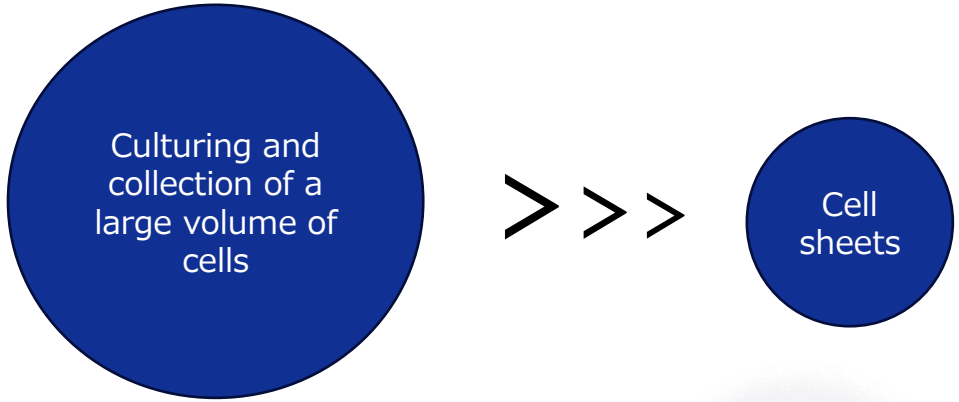
Sales increased from the previous year.

Overseas needs for cell cultureware

- Overseas sales account for about 80%.



- Overseas regenerative medicine
  - There are an increasing number of cases of cellular therapy against cancer, allergies, and immunity disorder and stem cell treatment.



- UpCell Flask: a product suited for large-scale cell recovery
  - Released in Japan in 2022
  - Scheduled to be released outside Japan

Cultivation of new markets for cell cultureware

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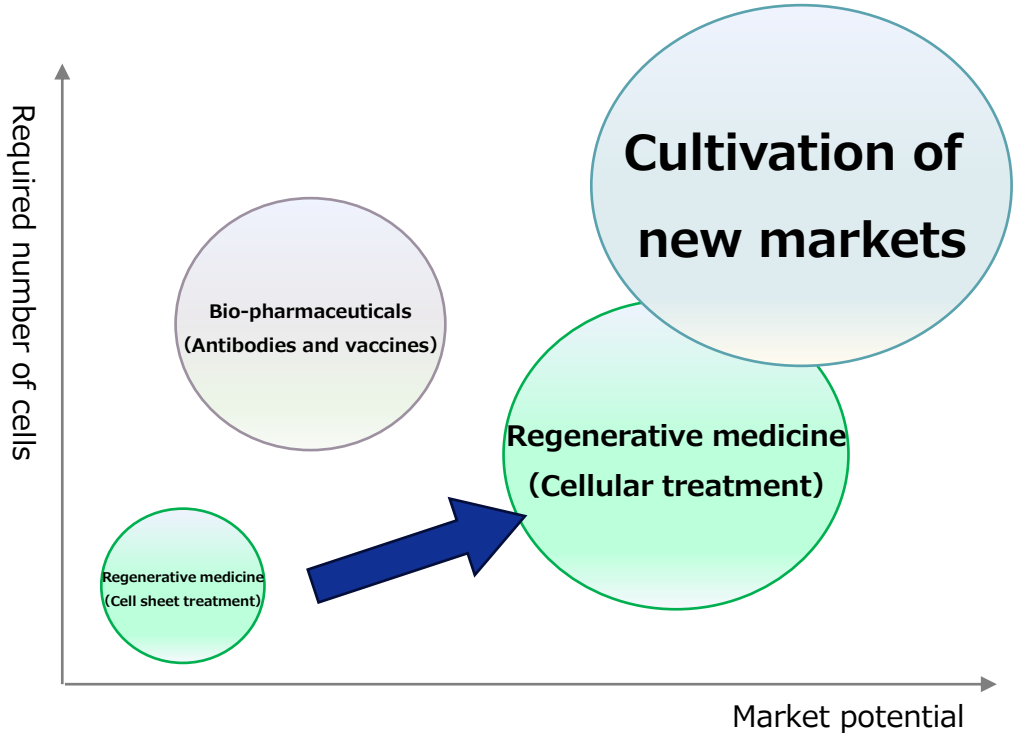
Need for technology to culture cells in large quantities

- Biopharmaceutical manufacturing
- Manufacturing cells for use in immunotherapy
- Development of cellular foods such as cultured meat

Possibility of market expansion



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

Regenerative Medicine Contract Manufacturing Services

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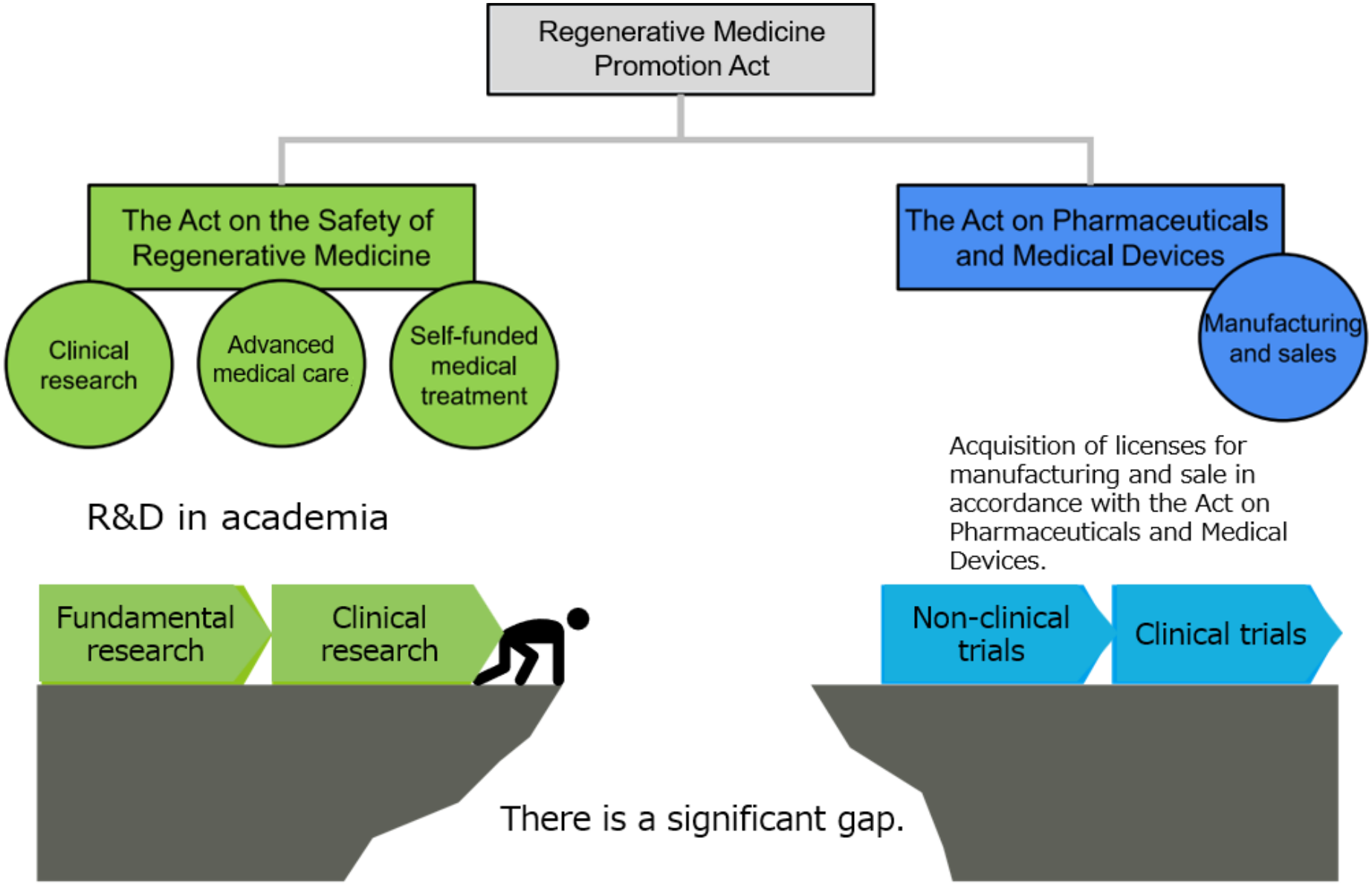

Regenerative Medicine Contract Manufacturing Services

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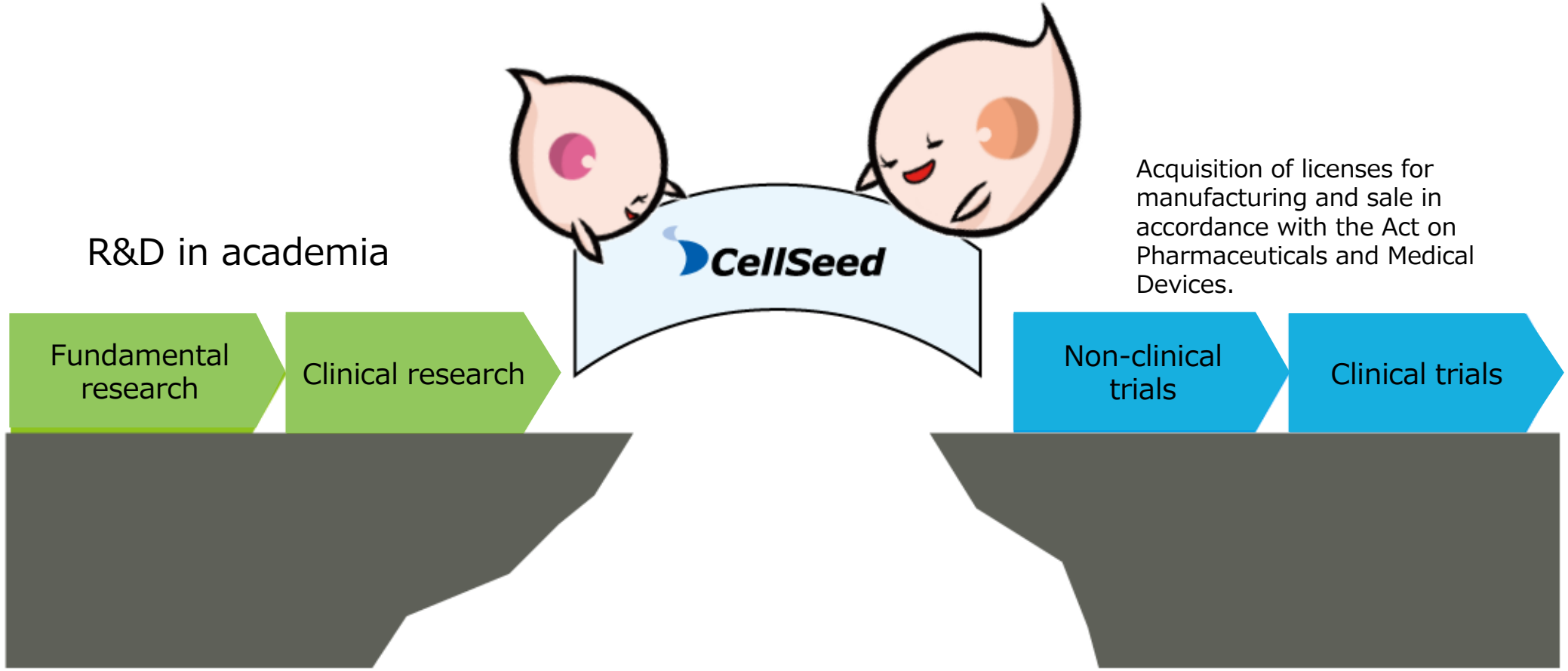
Serving as a bridge to deliver regenerative medicine to patients by solving problems with academia and closing the gap



CellSeed aims to contribute to the provision of regenerative medicine to patients by offering the service of undertaking regenerative medicine projects.

Regenerative Medicine Contract Manufacturing Services

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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.

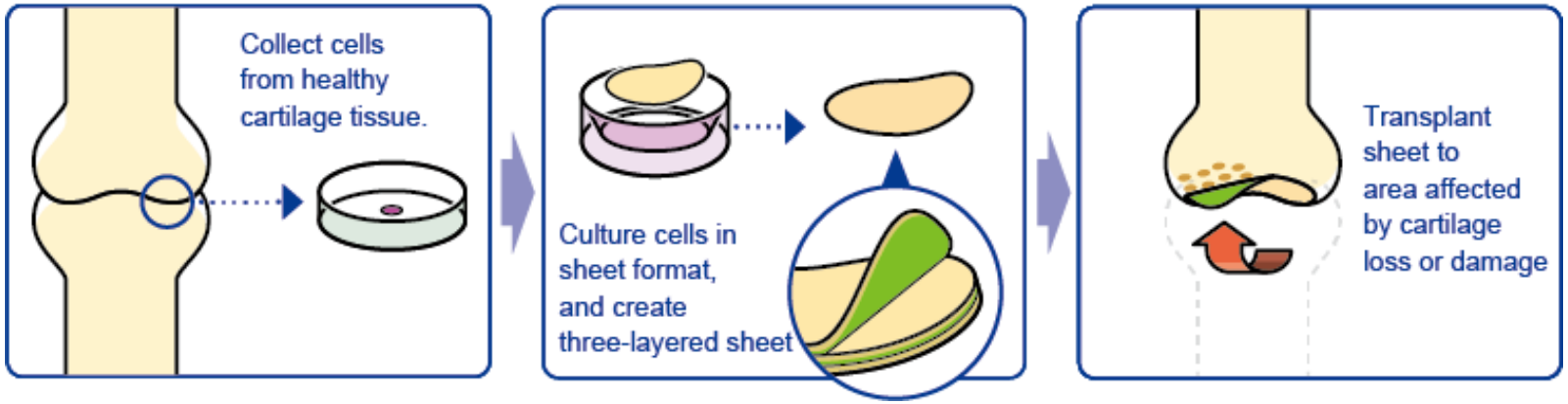
2 Facility Management and Application Support

- 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.

- Cell Processing Center
  - The permission to manufacture specific processed cells (facility No. FA3160008 , March 2017)
  - The permission to manufacture products for regenerative medicine（October 2018 ）
- Examples of Contract Services
  - Autologous chondrocyte sheets
    - Contract manufacturing of autologous chondrocyte sheets for the Advanced Medical Care B program conducted by Tokai University.
    - Support for the self-pay treatment application at Ikegami General Hospital, and the planned contract manufacturing of cell sheets.



  - Pediatric autologous epithelium cell sheet

Background for development of allogeneic chondrocyte sheets (CLS2901C)

- Knee osteoarthritis (OA)
  - Due to the aging of the population, the number of patients is projected to increase.
  - There is no definitive treatment method.

Number of potential patients:
About 30 million
(in Japan)

Number of people with symptoms:
About 10 million
(in Japan)

TOKAI UNIVERSITY

In clinical research, good results were observed in all of 10 cases.

Transfer of technologies

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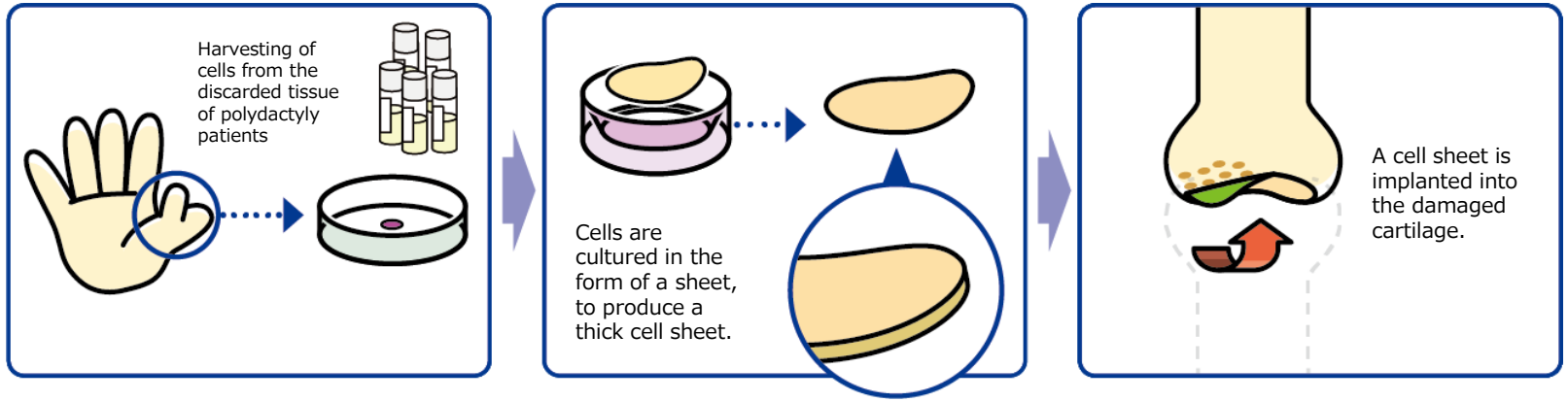
Development as products for regenerative medicine, etc.

- Allogeneic chondrocyte sheets



Manufacturing process of allogeneic chondrocyte sheets (CLS2901C)

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Cell Bank

Fingers removed from polydactyly patients

Safety

Isolated cartilage

Seeding

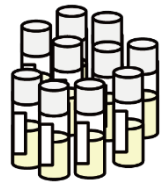
P0

Cryopreservation

P1 Cell Stock
(Master Cell Bank)

Safety

Passage culture



Px Working Cell Bank

Safety

Cell Sheets

Px Working Cell Bank

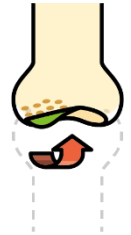
Preculture

Sheet formation

Safety

Efficacy

Transplant



Quality test items for cell banks and cell sheets

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Cell Bank

Tests for cell count, ratio of living cells, aseptic conditions, endotoxin, response to mycoplasma and viruses, etc.

Fingers removed from polydactyly patients → Isolated cartilage → Seeding → P0 → Cryopreservation → P1 Cell Stock (Master Cell Bank) → Passage culture → Px Working Cell Bank

Quality — 4th item to be tested

6th item to be tested — Quality / Safety — 2nd item to be tested

Cell Sheets

Tests for cell forms, sheet properties, protein expression, and response to viruses, check of chromosomal abnormalities, etc.

Px Working Cell Bank → Preculture → Sheet formation → Safety — 10th item to be tested

Phase III clinical trials of allogeneic chondrocyte sheets

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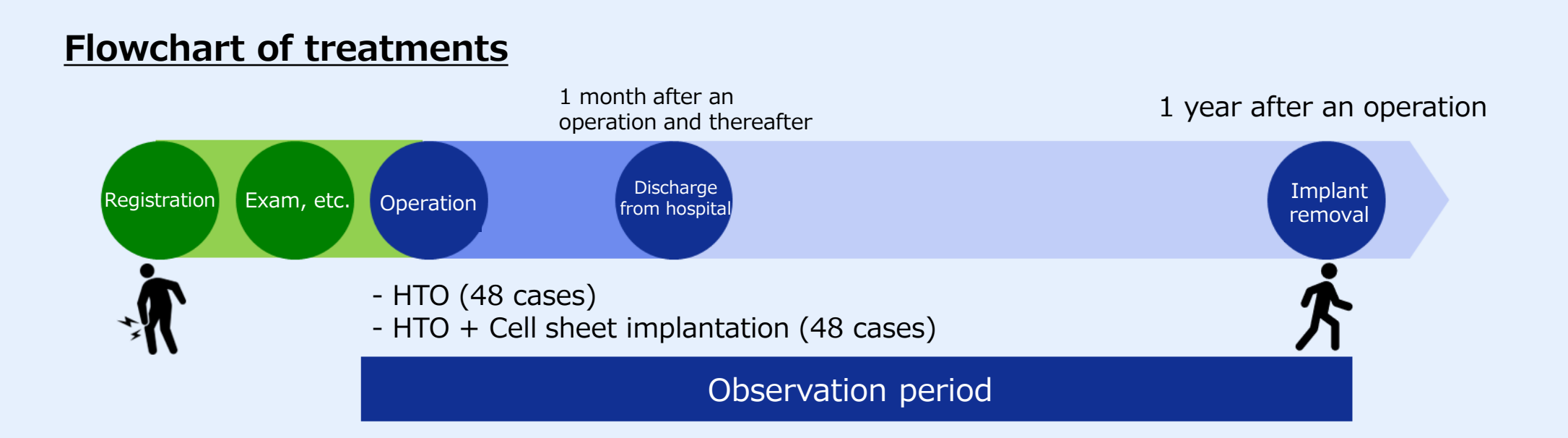
Subjects: patients with knee osteoarthritis who should undergo high tibial osteotomy (HTO)



Five facilities where the test will be conducted: Tokai University Hospital, Yokohama Sekishinkai Hospital, Ebina General Hospital, Juntendo University Hospital, and Yokohama City University Medical Center

Currently, we are developing systems for performing operations at each facility for clinical trials.

U.S. patent related to allogeneic chondrocyte sheets

- In response to the application for the following U.S. patent related to allogeneic chondrocyte sheets, a decision to grant a patent has been made.
  - U.S. patent application No. 17/729,608
  - Title of the invention: a cultured cell sheet for tissue regeneration, and methods for producing and using it
- This is an outcome of research into allogeneic chondrocyte sheets conducted in collaboration with Tokai University.

Exhibitions, research presentations, etc. at academic conferences in 2024

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The Japanese Society for Regenerative Medicine (luncheon, poster, and corporate exhibition; Mar. 21-23, 2024)
The Pharmaceutical Society of Japan (corporate exhibition; Mar. 28-30, 2024)
Japanese Research Group on Knee Osteotomy and Joint Preservation (hosting special lectures and a luncheon seminar; Apr. 19, 2024)
Regenerative Medicine EXPO Tokyo (participation in special lectures and a round-table Talk; Jun. 26-28, 2024)
ISSCR (The International Society for Stem Cell Research) (poster presentation; Jul. 10-13, 2024)
Regenerative Medicine JAPAN (corporate exhibition; Oct. 9-11, 2024)
The Japanese Biochemical Society (poster presentation and corporate exhibition; Nov. 6-8, 2024)
The Molecular Biology Society of Japan (poster presentation and corporate exhibition; Nov. 27-29, 2024)
The Japan Society for Immunology (poster presentation and corporate exhibition; Dec. 3-5, 2024)

We also sponsor academic conferences by posting ads in the collections of abstracts, etc.

Exhibition booth at a conference

Participation in academic conferences, etc.

- Congress of the Japanese Society for Regenerative Medicine

  Date: Thursday, March 21 to Saturday, March 23

  Place: Toki Messe (Niigata)

  - Corporate exhibition
  - Co-hosted academic seminar

Participation in academic conferences, etc.

- Regenerative Medicine EXPO

  Date: Wednesday, June 26, 2024; 14:00 to 15:00

  Place: Tokyo Big Sight

  - Special lecture 2 at Regenerative Medicine EXPO

    Round-table talk: regarding regulations on all phases from clinical trials to after-sales care for products for regenerative medicine, etc.

We will participate in Regenerative Medicine JAPAN

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Dates: Wed., Oct. 9 to Fri., Oct. 11, 2024

Venue: Pacifico Yokohama

再生医療JAPAN
Regenerative Medicine Japan 2024

- Exhibition booth
- Presentations by exhibitors

To hold the 4th Cell Sheet Engineering Innovation Forum

Date: Fri., Nov. 28, 2025

Venue: Miraikan Hall on the 7th floor of Miraikan, etc.

No. of attendees: up to 200 (Pre-registration required; first-come-first-served)

Attendance fee: Free

Lectures by invited professors, et al.

Professor Tatsuya Shimizu

(Director & Professor of Institute of Advanced Biomedical Engineering and Science, Tokyo Women's Medical University)

Dr. Akihiro Umezawa

(Director of National Center for Child Health And Development)

Professor Yasushi Fuchimoto

(Professor [Representative] of Department of Pediatric Surgery, Faculty of Medicine, International University of Health and Welfare)

Other lecturers to be invited

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