

CellSeed Inc.

Fiscal 2020 Earnings Results

Presentation



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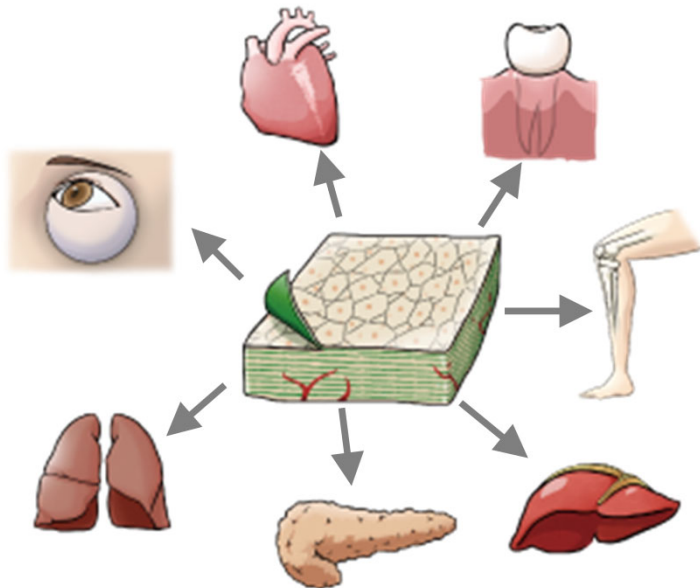
- Company Profile
- Financial summary FY 12/2020
- Mid-term Business Plan Fiscal Year 2021 to Fiscal Year
2023

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

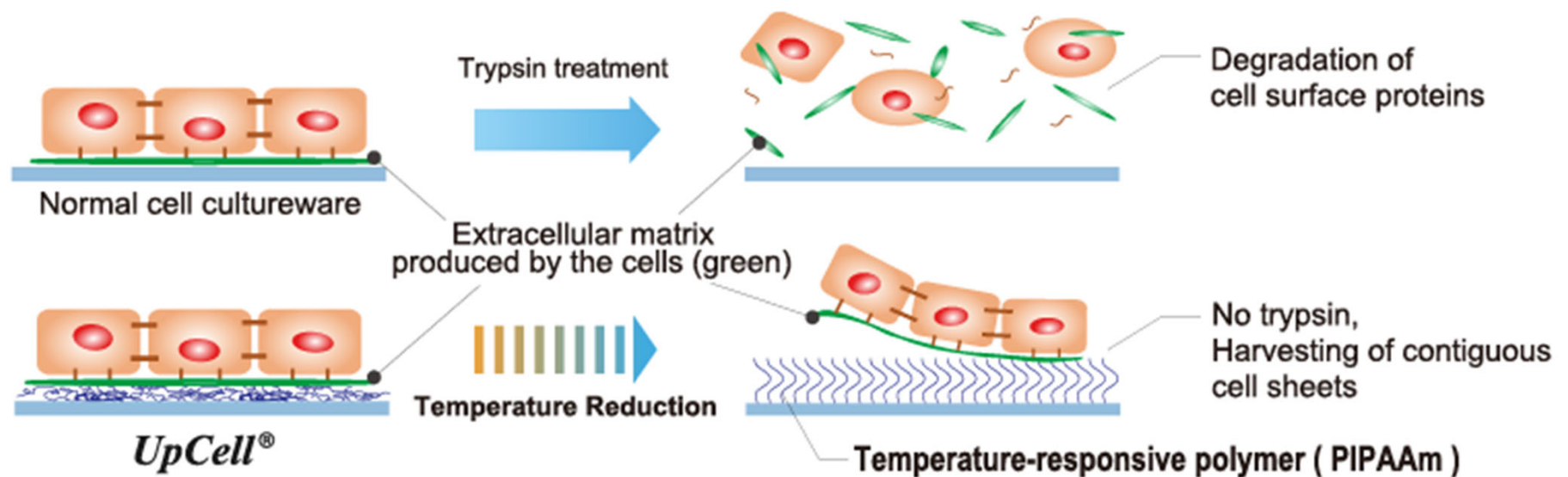


CPC

“Cell Sheet Engineering”

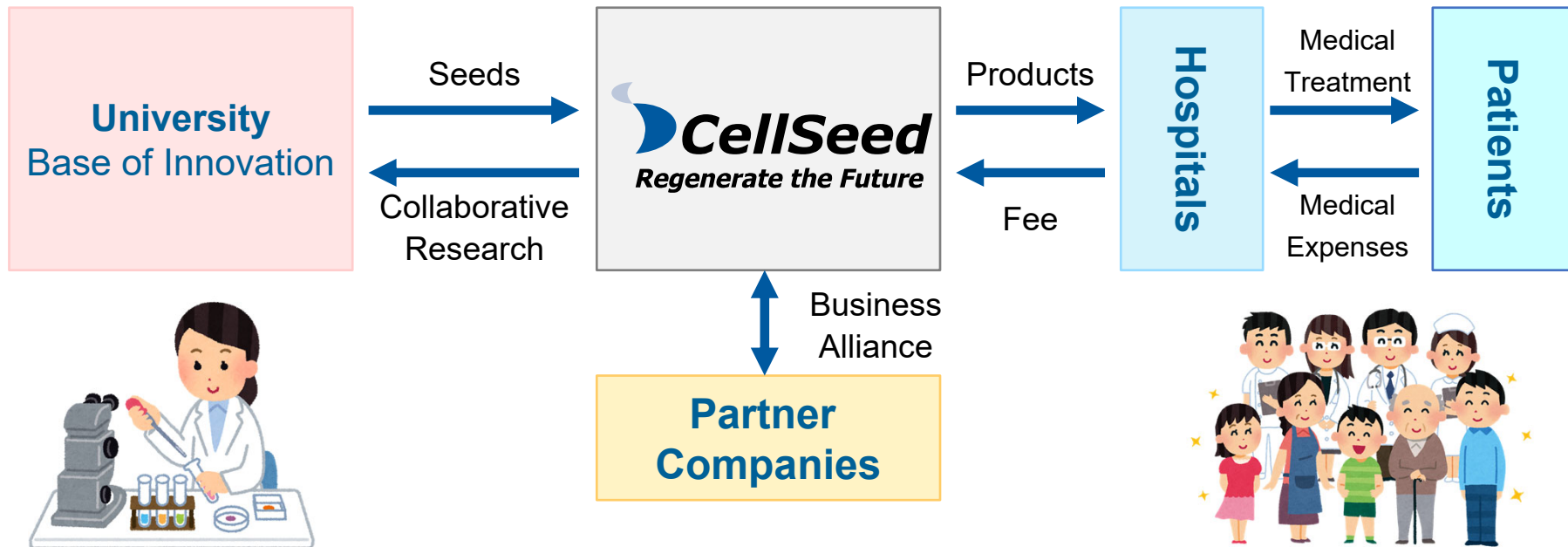
Platform Technology of Regenerative Medicine

37°C Hydrophobic ⇔ 20°C Hydrophilic

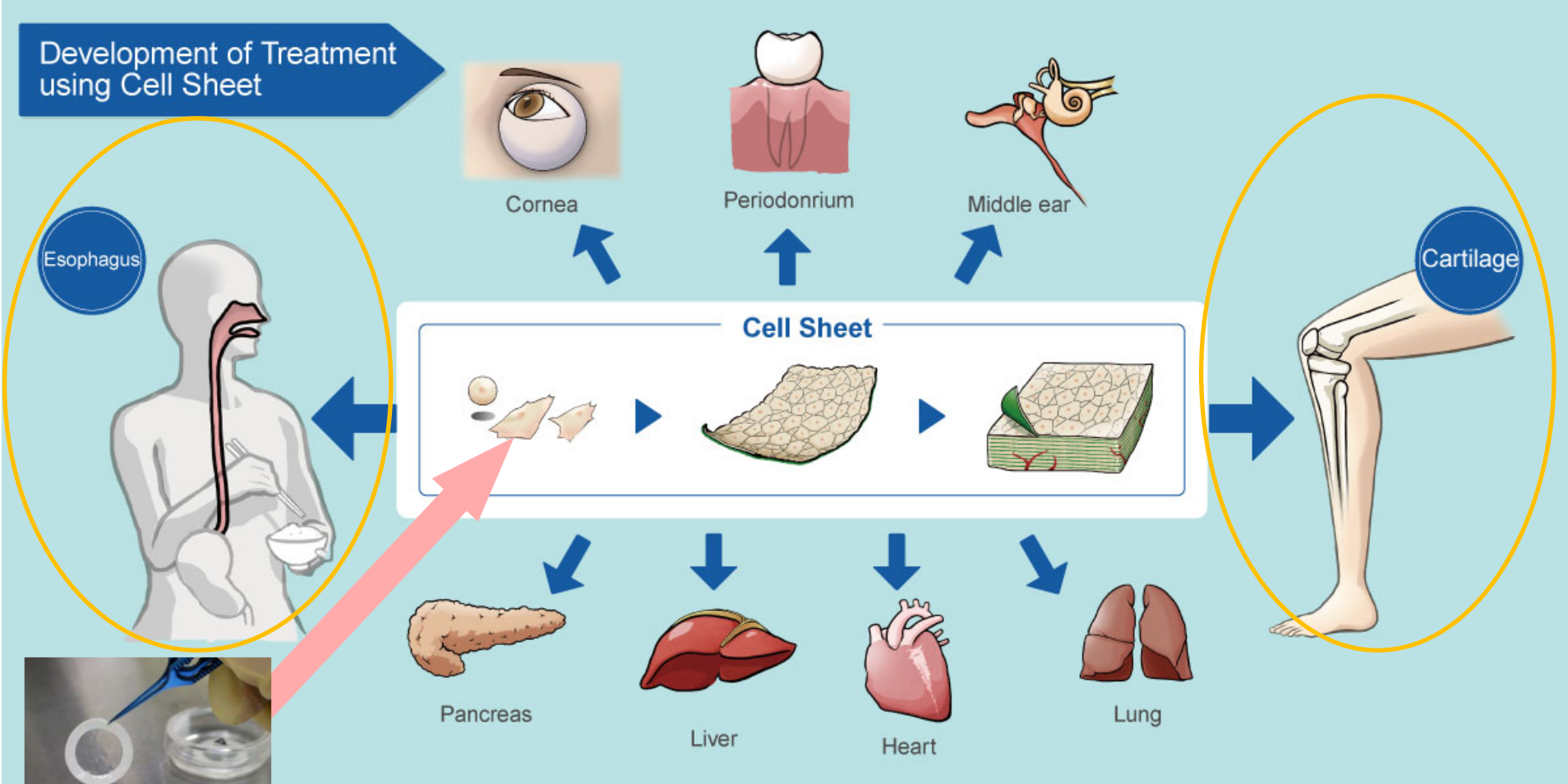


Our Business Model

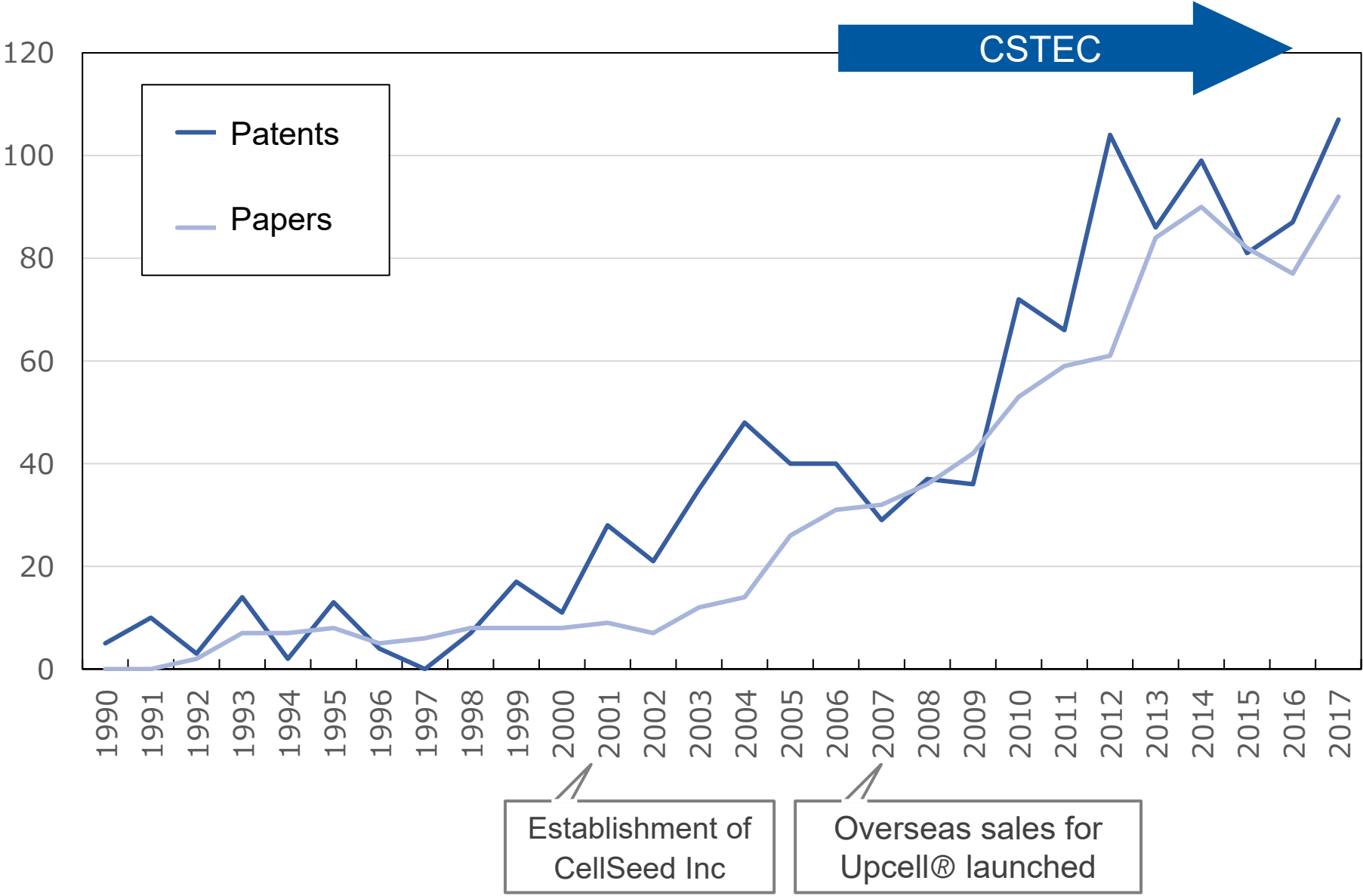
Mission
We take the initiative of contributing to global health care in the valuable and innovative field of regenerative medicine.



Development of Treatment Using Cell Sheet Engineering



Expansion of Cell Sheet Engineering



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Financial summary FY 12/2020

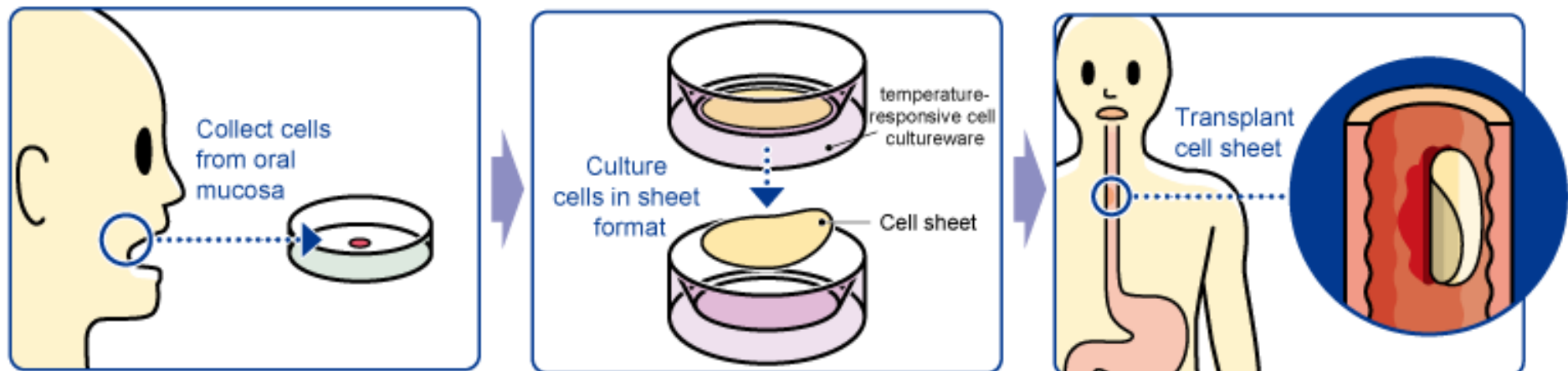
	FY2020 Consolidated (January 2020 - December 2020)			FY2019 Consolidated (January 2019 – December 2019)
	Amount (Millions of Yen)	Change (Millions of Yen)	Change from Previous Period (%)	Amount (Millions of Yen)
Net sales	199	-76	-27.7	275
Operating profit	-719	61	–	-780
Ordinary profit	-744	41	–	-786
Profit attributable to owners of parent	-783	-1	–	-782

- Overseas sales of our cultivation equipment business expanded smoothly and we achieved a record high in sales through the supply of products aimed at the large-scale cultivation of cells for research, and by strengthening collaboration with our agents along with sales promotion activities.
- Advanced Medicine B using cartilage cell sheets was started, but we could not reach the estimated sales, but sales from the 3 cases were posted.
- Cartilage cell sheet treatment was started in Taiwan where we reached a milestone revenue of 50 million yen.

Epithelial Cell Sheet for Esophageal Regeneration

(CLS2702C/D)

- 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 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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Tokyo Women's Medical University

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

■ Epithelial Cell Sheet for Esophageal Regeneration

- Clinical trials conducted for obtaining approval

April 2016 Clinical trials started

March 2019 Clinical trials completed

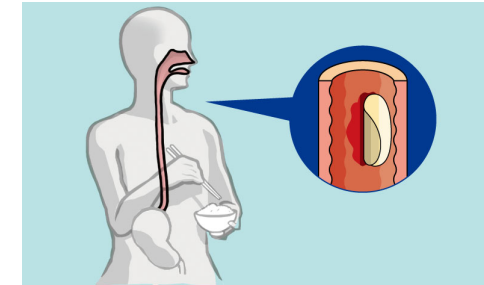
October 2020 Additional clinical trial plan Notification submitted to PMDA

⇒ The application for the approval of manufacture and sales is scheduled for 2025, but measures to shorten the clinical trial period, like the adding more clinical trial facilities, are being considered.

February 2021 First medical case of the additional clinical trial recorded

- Development in Europe using our subsidiary in Sweden as a base

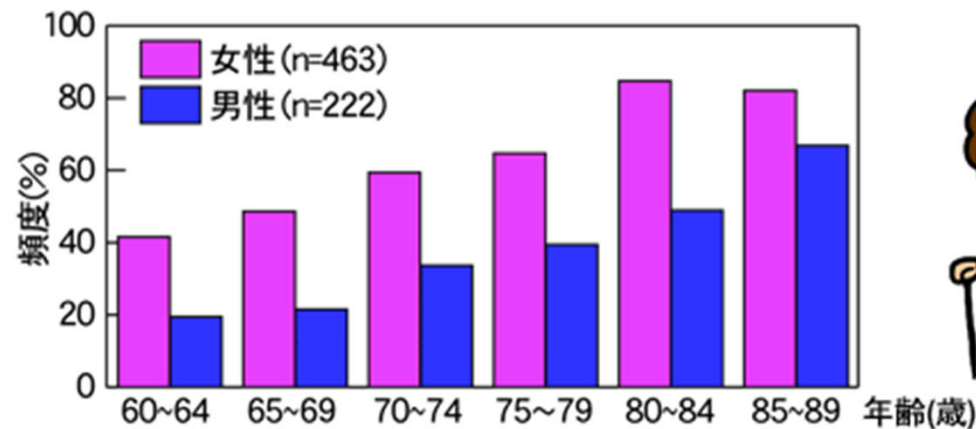
⇒ The plan was cancelled because endoscopy was not diffused in Europe at the initially assumed pace and we will focus on obtaining approval for manufacture and sales in Japan.



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.

変形性ひざ関節症の男女別-年齢別割合 (61~86歳、Grade II 以上)



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

Overview of Chondrocyte Sheet Project

◆ Clinical Research at University

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

Tokai University
School of Medicine



Started medial treatment in Tokai University as Advanced Medicine B

Basic Development Agreement

◆ Development for regulatory approval by companies



Japan



Taiwan

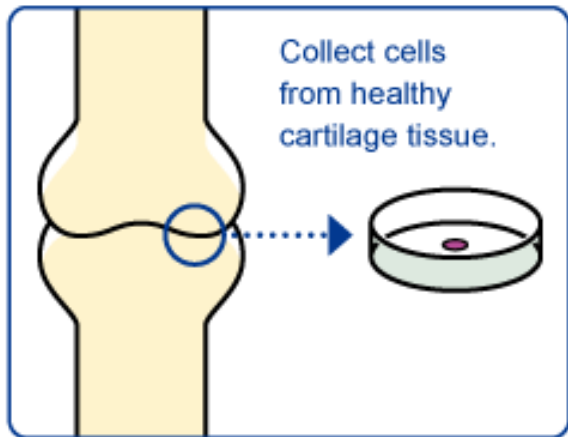
- <Autologous Cartilage Sheets>
Contracted manufacturing of autologous cartilage cell sheets for advanced medicine started
- <Development of Allogeneic Cartilage Sheets>
Acquired cartilage cell for commercial purposes from National Center for Child Health and Development

- 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

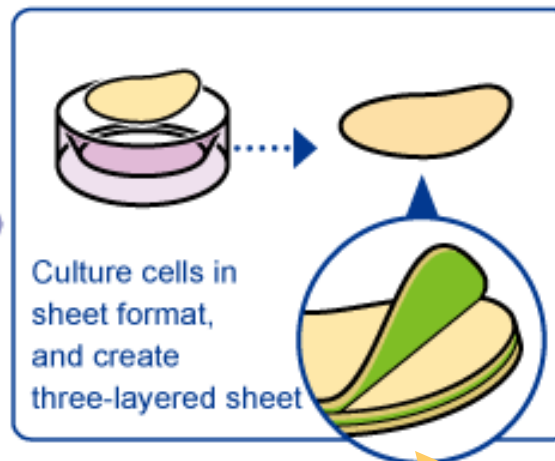
Autologous chondrocyte sheets

Started medial treatment in Tokai University as Advanced Medicine B

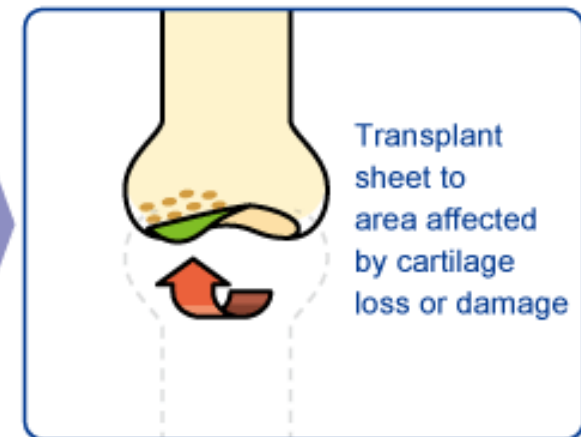
- Collect Autologous Cartilage Cells



- Manufacture Cell Sheet



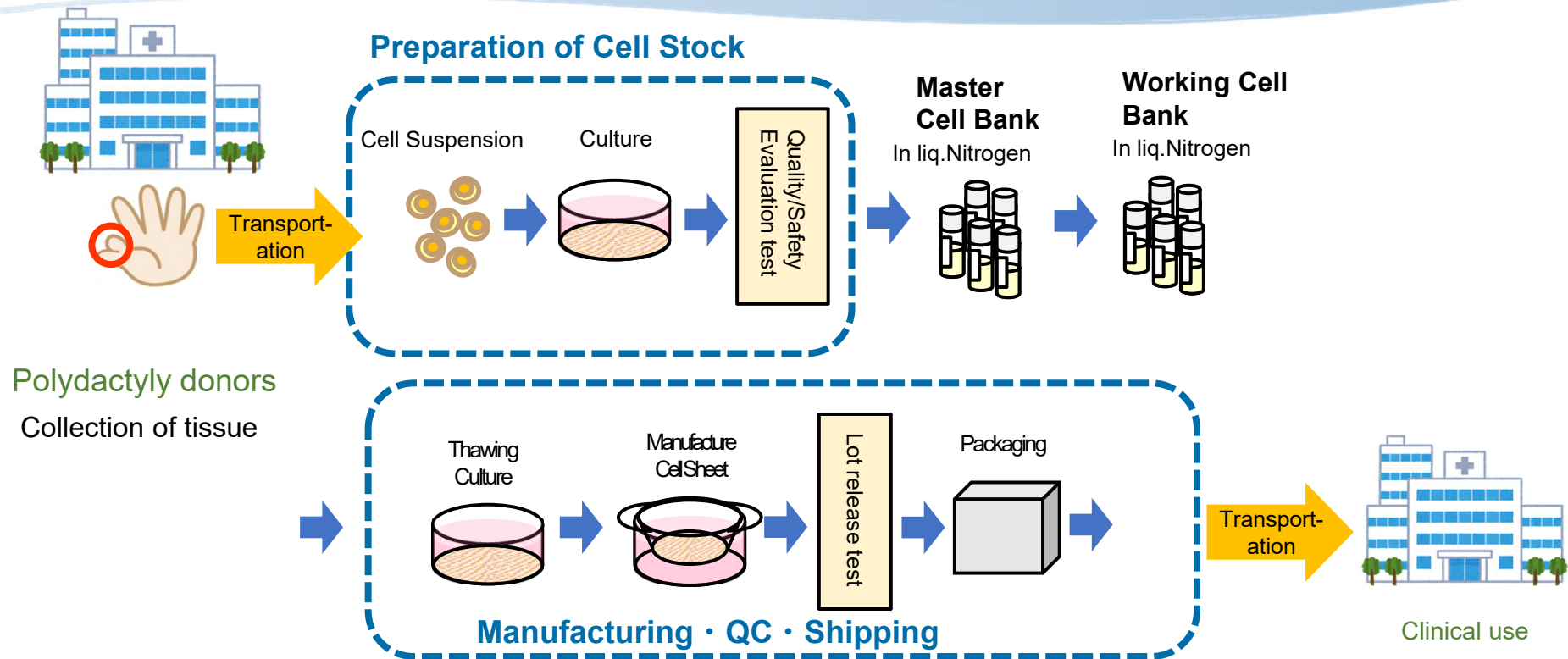
- Transplant to Patient



chondrocyte sheets

Indications : Knee Osteoarthritis

Allogeneic chondrocyte sheets

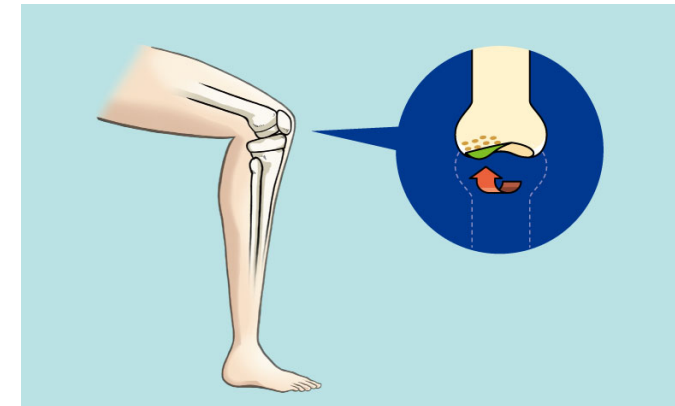


- Clinical Research at Tokai University
 - Completed in December 2019 transplants of 10 cases
 - selected for the 2018 Project Focused on Developing Key Evaluation Technology: Acceleration of Developing Regenerative Medicine Technology Seeds (for 3 years, from October 2018 to March 2021.)
- Started work on the creation of cell bank at CellSeed along with the automation of cell sheet production
- Acquired cartilage cell for commercial purposes from the National Center for Child Health and Development

■ Cartilage Cell Sheets

● Autologous Cartilage Cell Sheets




- August 2020
Contracted manufacturing of autologous cartilage sheets for Advanced Medicine B
- December 2020
Debriefing session on the results of autologous cartilage cell sheet treatment in Taiwan
 - ⇒ Medical treatment was started in 2020, and transplant surgery has been conducted on 10 patients so far.
 - Reached a milestone revenue of 50 million yen.



● Allogeneic Cartilage Sheets

- December 2020
Acquired approval for the provision of cartilage tissue obtained from polydactyl patients from the National Center for Child Health and Development
 - ⇒ Stable acquisition of cartilage tissues became possible, accelerating clinical trials as well as research and development to acquire the approval for manufacture and sales.
- March 2021
A symposium by The Japanese Society for Regenerative Medicine to be announced through poster session.

CellSeed Temperature Sensitive Cell Cultureware Lineup

UpCell® Cell Sheet Recovery (Temperature Sensitive)	RepCell® Cell Recovery (Temperature Sensitive)	HydroCell® Ultra-Low Adhesion Cell Cultureware
<ul style="list-style-type: none">● Temperature-responsive cell cultureware for "Cell Sheet" engineering	<ul style="list-style-type: none">● Temperature-responsive cell cultureware for cell collection	<ul style="list-style-type: none">● Low cell binding cultureware
	 <p>3 x 3 mm Grid Wall</p>	

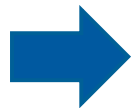
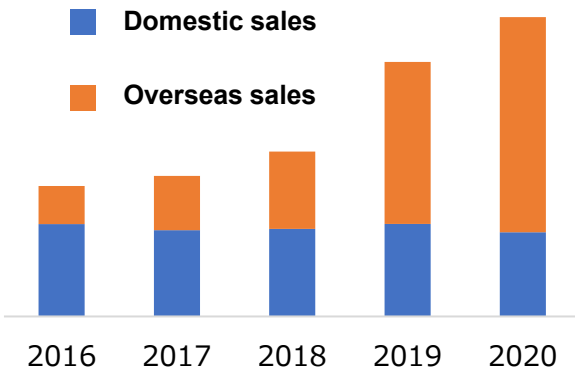
Regenerative Medicine Supporting Business

1. Regenerative Cell Sheet Product Manufacture Method Development, Consigned Manufacture	2. Facility Management, Application Submission Support	3. Cell Culturing Technician Training
<ul style="list-style-type: none">■ Consigned manufacture■ Manufacture method development■ Quality testing <p><Characteristics></p> <ul style="list-style-type: none">• Cell sheet manufacturing using UpCell®• Certified facility for specific cell processing (FA3160008)• Japanese Society for Regenerative Medicine Certified Clinical Culturing Specialist, including large number of staff with bountiful experience and knowledge of culturing technologies	<ul style="list-style-type: none">■ Support for certification application, notification for specific cell processing■ Document creation for procedural manual, standard handbook, others consulting■ Cell processing center facilities, support management structure, maintenance provision■ Application document creation, others	<ul style="list-style-type: none">■ Cell sheet culturing training■ Cell sheet peeling training, others



■ Sales Activities for Equipment

- Initiated the supply of products to new markets to facilitate the mass cultivation of cells for research in order to develop treatments or preventative measures for various infections including the novel coronavirus, as well as cancerous diseases.
- Further strengthening of cooperation with our existing agents with the aim of promoting sales of our equipment, along with the continuation of proactive sales promotion activities



Especially, overseas sales increased favorably, reaching a record high following the previous year

■ Contract Service for Regenerative Medicine

- Entrusted with manufacturing by Tokai University which started the Advanced Medicine B for autologous regenerated cartilage sheets, and sales for 3 cases were posted.
- Signed a technology transfer contract with KanonCure Inc. for the manufacture of clinical trial equipment for cell sheets for the treatment of liver disease.

A debriefing session on the results of autologous cartilage cell sheet treatment at Taiwan

A debriefing session on the results of autologous cartilage cell sheet treatment was held at Healthcare Expo Taiwan at Taiwan on December 5th, 2020, organized by MetaTech Inc. and E-DA Hospital, E-DA Healthcare Group.



The company participated via the Internet from Japan. The president and CEO Setsuko Hashimoto gave her congratulatory address and the developer of this treatment method, Prof. Masato Sato of Tokai University, greeted the audience with a celebratory message along with an explanation of the features of autologous cartilage cell sheet treatment.

The head of E-DA Hospital, Dr. Du, reported on the results of the treatment over the past year and the transplant surgery conducted so far on 10 patients.

The 2nd Cell Sheet Engineering Innovation Forum

The Second Cell Sheet Engineering and Innovation Forum, which had to be postponed from autumn last year due to the spread of the novel coronavirus, will be held in November 2021.

- Date

Monday, November 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

株式会社セルシート
20th ANNIVERSARY

第2回細胞シート工学イノベーションフォーラム
The 2nd Cell Sheet Engineering Innovation Forum

～細胞シートの未来を語ろう!～

2021年11月1日(月)

開始時間:13時(受付12時)
会場:日本科学未来館 7階
定員:120名(事前登録制、先着順)
参加費:アカデミアの方:無料
企業の方:3,000円

※ 会場は事前確認となります。
※ 日本科学未来館の常設展の入場は別途料金が必要です。

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西田 幸二
大阪大学 医学系研究科 教授

※ 講演者・日程は変更される可能性があります。

CellSeed
Regenerate the Future

ポスター演題募集

テーマ 「細胞シート」、「温度応答性細胞培養器材」及び周辺技術に関する研究

最優秀賞 30万円×1名
優秀賞 5万円×4名
奨励賞 1万円×数名

※ 賞品に差支無効がございます。最優秀賞候補の方には当日発表会(15分)を行います。

旅費支援 関東圏外の方: 交通費全額+宿泊費一律1万円
関東圏内の方: 交通費のみ一律2千円

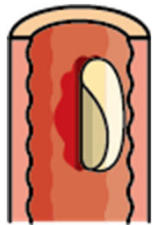
※ 旅費支援はポスター発表に採択された方が対象となります。

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■ Cell Sheet Regenerative Medicine Business

1



Began additional clinical trials for epithelial cell sheet for esophageal regeneration, aiming to apply for approval for manufacture and sales in 2025.

2



Accelerated the acquisition of non-clinical data in order to submit the clinical trial plan notification for allogeneic cartilage regeneration sheet by the end of 2022.

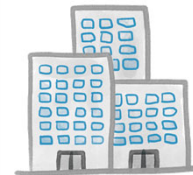
■ Regenerative Medicine Support Business

3



Business expansion through the development and supply of equipment to new markets for the mass cultivation of cells for research.

4



Aiming to acquire more business opportunities through the promotion of development, contracted manufacturing and consulting businesses.

■ Regarding Overseas Businesses

5



Reconstructing the collaboration with MetaTech Inc. and Taiwanese joint ventures for the acquisition of more business opportunities.

6



Proactively promoting business partnerships for the global expansion of Japanese cell sheet engineering with the aim of increasing earnings.

7



Aiming for further increase of overseas sales of equipment by strengthening the cooperation with Thermo Fisher Scientific.

8



The manufacturing system and capacity will be enhanced and expanded in order to keep up with the increase in overseas sales and the supply of equipment to new markets, to further increase business opportunities.

Mid-term Business Plan (2021 – 2023) Financial Targets

(Unit: Million yen; Presented with fractions less than one million yen rounded off)

	Net Sales	Operating Profit	Ordinary Profit	Profit attributable to owners of parent
FY2021 (Estimate)	213	-976	-998	-998
FY2022 (Target)	1,400	20	19	10
FY2023 (Target)	790	-590	-590	-590

*sales composition (Millions of yen)

Regenerative Medical Products Business

FY2021 : 40 FY2022 : 1,070 FY2023 : 320

Regenerative Medicine Supporting Business

FY2021 : 173 FY2022 : 330 FY2023 : 470



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