



Setsuko Hashimoto, President &CEO

CellSeed Inc. (7776)



Company Information

Market	JASDAQ
Industry	Precision Instrument (Manufacturing)
President	Setsuko Hashimoto, Ph.D.
HQ Address	Telecom Center Building, Aomi 2-5-10, Koto-ku, Tokyo
Year-end	December
Homepage	https://www.cellseed.com/en/

Stock Information

Share Price	Number of shares issued (End of the Term)		Total market cap	ROE Act.	Trading Unit
¥238	17,529,219shares		¥4,171million	-	100shares
DPS Est.	Dividend yield Est.	EPS Est.	PER Est,	BPS Act.	PBR Act.
¥0.00	-	¥-59.95	-	¥78.41	3.0x

*Stock price as of closing on September 2, 2021. Numbers of shares issued, DPS, EPS, and BPS are from the financial results for the second quarter of Fiscal Year ending December 2021. ROE is from the financial results for the previous term.

Earnings Trend

Fiscal Year	Sales	Operating Profit	Current Profit	Net Profit	EPS	DPS
December 2017	85	-956	-964	-966	-93.29	0.00
December 2018	1,026	140	140	129	11.35	0.00
December 2019	275	-780	-786	-782	-66.60	0.00
December 2020	199	-719	-744	-783	-55.31	0.00
December 2021 Est.	213	-976	-998	-998	-59.95	0.00

* The estimates were provided by the company. Units: million yen and yen. Net profit is the profit attributable to owners of parent.

This Bridge Report presents CellSeed Inc.'s earnings results for the second quarter of Fiscal Year ending December 2021, etc.

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Key Points

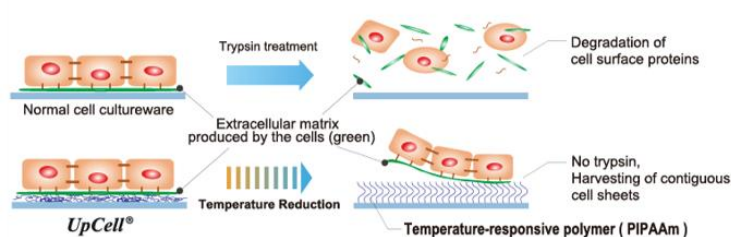
- In the second quarter of the term ending December 2021, sales were 81 million yen, up 39.9% year on year. Especially, overseas sales grew, hitting a record high, as the company cemented cooperation with Key distributors for promoting the sales of devices and conducted sales promotion actively. In addition, Tokai University entrusted the company with the manufacturing of autologous cartilage cell sheets as last year, and the sales from two cases were posted. There was an operating loss of 466 million yen (a loss of 340 million yen in the same period of the previous year). For the epithelial cell sheets for esophageal regeneration, the company carried out active investment in R&D, including additional clinical trials for applying for the approval for production and sale in 2025.
- Both sales and profit exceeded the initial forecasts. Regarding sales, the overseas sales of devices, mainly temperature-responsive cell culture ware, exceeded the initial forecast, despite the delay in some commissioned projects for producing cell sheets in the regenerative medicine supporting business. Regarding profit, the expenses for outsourcing development fell below the initial forecast, and through cost reduction efforts, the costs for R&D, manufacturing, and SG&A decreased.
- There is no revision to the earnings forecasts. For the term ending December 2021, sales are projected to be 210 million yen, up 7.0% year on year, and operating loss is forecasted to be 970 million yen (710 million yen in the previous term). The sales of the regenerative medicine supporting business are expected to be 173 million yen, hitting a record high this term, once again. The company will make continuous efforts to increase especially overseas sales of devices. In addition, the company will proceed with the commissioned manufacturing of regenerative medicine products and others for comprehensively supporting the R&D and commercialization of regenerative medicine. The sales of the cell sheet regenerative medicine business are expected to be 40 million yen. The company will continue investment in R&D, and mainly develop epithelial cell sheets for esophageal regeneration and epithelial cell sheets for cartilage regeneration.
- The company started the operation of facilities for developing and manufacturing flasks for enhancing the sale of devices, which is a priority measure, and responding to the growth of sales volume outside Japan, in September earlier than scheduled. The company is developing the operation systems in preparation for a great leap in the term ending December 2022. We also would like to pay attention to the progress of the application for approval for production and sale of the epithelial cell sheets for esophageal regeneration (by 2025) and the seizure of earning opportunities by re-fostering cooperation with MetaTech and the Taiwanese joint venture company.

1. Company Overview

Regenerative medicine is a new kind of medicine for regenerating and curing lost, damaged or deteriorated tissues.

CellSeed uses the fundamental technologies of “cell sheet engineering” developed in Japan by Professor Okano of the Tokyo Women’s Medical University in its “cell sheet regenerative medicine” that employs “cell sheets” for the cell regenerative medicine business, and the regenerative medicine support business, where temperature responsive cell cultureware used to fabricate cell sheets are developed and sold and the regenerative medicine consignment services, which support for research and development and commercialization of regenerative medicine, is provided.

“Cell sheet engineering” – Basic Technologies for Regenerative Medicine



(From the company material)

“Cell sheet engineering” is the world’s first platform technology developed in Japan by Professor Emeritus Mitsuo Okano of Tokyo Women’s Medical University. Cells are cultured in cell cultureware whose surface is processed with the temperature responsive polymer that changes the molecular structure according to temperatures. The surface of the cell cultureware becomes moderately hydrophobic (waterproof) at 37 degrees Celsius to allow cells to adhere to it and hydrophilic (containing water) at a temperature of 20 degrees Celsius to prohibit cells from attaching to it. Thus, an organically combined cell sheet can be obtained from the cultureware just by changing temperatures while the extracellular matrix (adhesive proteins) is maintained.

In general, cells grow by secreting the extracellular matrix and fixing themselves. In other words, they cannot develop unless they fix themselves somewhere while releasing adhesive proteins, and cells cultured are conventionally harvested by decomposing adhesive proteins using such proteolytic enzymes as trypsin (breaking down adhesive proteins was the only way to obtain cells cultured).

Japan Leads the World in Cell Sheet Engineering.

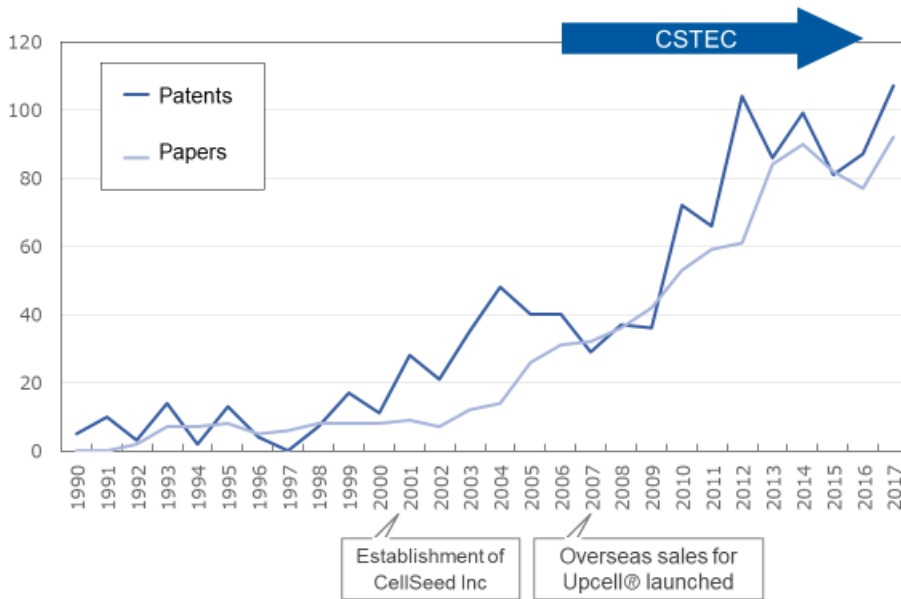
Since a paper regarding “cell sheet engineering” was published about 30 years ago, a lot of papers have been published and applications for many patents have been submitted, and in recent years, over 100 papers and patent applications have been issued every year. Namely, the research in this field has progressed in the past decade.

In addition, most of the papers and patent applications came from Japan. This is one of a few technologies in which Japan leads the world.

BRIDGE REPORT



Expansion of Cell Sheet Engineering

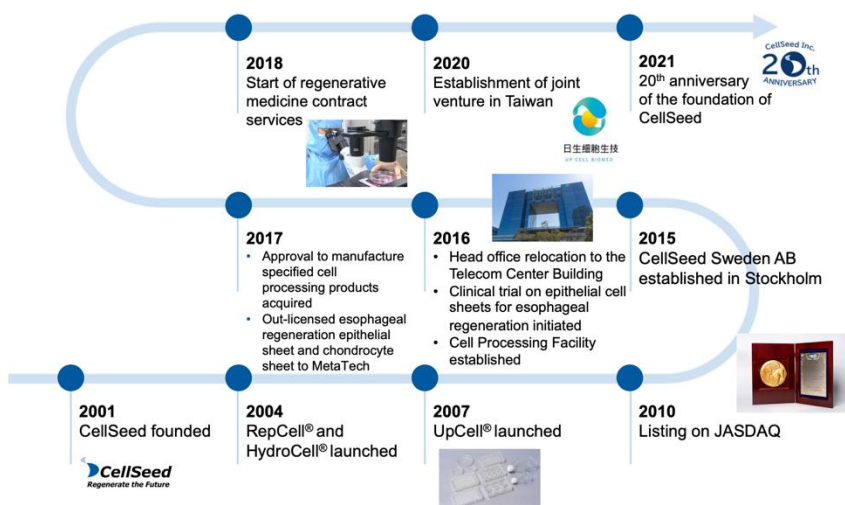


(From the company material)

CellSeed celebrates its 20th anniversary.

In May 2021, the company celebrated its 20th anniversary. While in the past 20 years, researchers in academia have produced many research results applying cell sheet engineering, in April 2016, CellSeed began clinical trials in Japan for epithelial cell sheets for esophageal regeneration in the cell sheet regenerative medicine business. The development of cartilage cell sheets has also been steadily progressing. In the regenerative medicine supporting business, the company established a Cell Processing Facility (CPF) in 2016 and launched a regenerative medicine consignment service in 2018. The company is aiming to capture more profit opportunities in both businesses in the future.

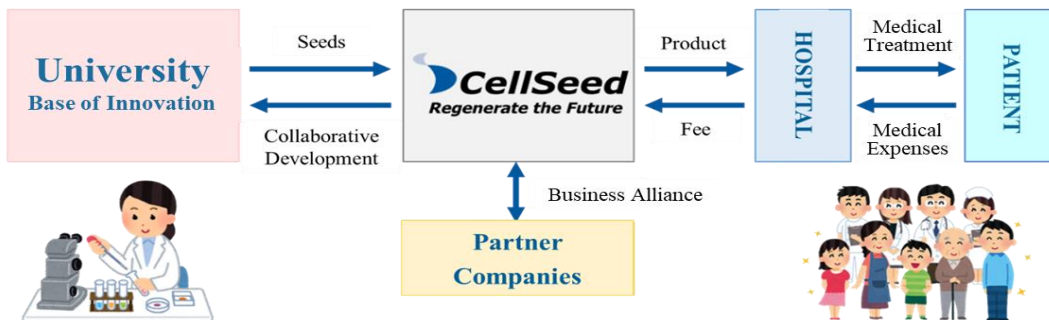
20th anniversary of the foundation of CellSeed



1-1 Business model of CellSeed

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

Using the outcomes of research into cell sheets conducted at universities as seeds, the company performs clinical trials, transforms them into regenerative medicine products, and provides products to patients.



(From the company material)

1-2 Business Description

(1) Cell sheet regenerative medicine business

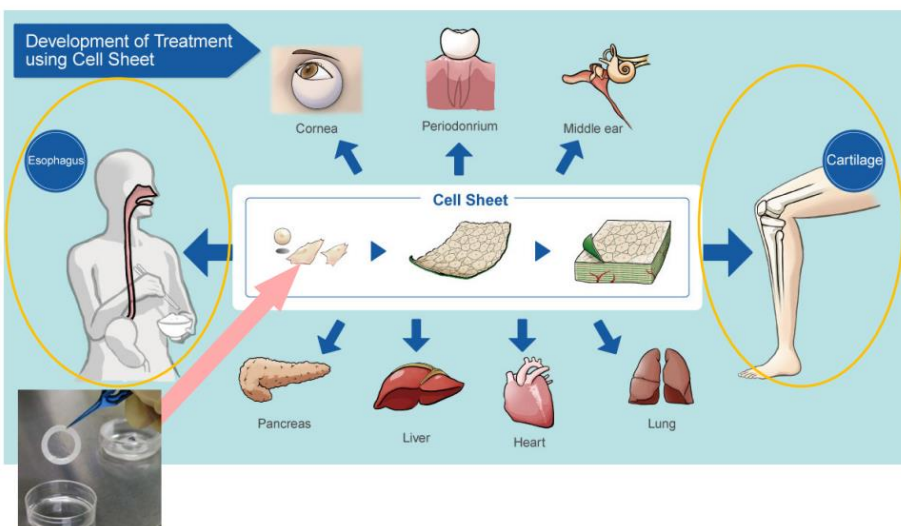
The treatment methods based on “cell sheet engineering” are targeted at various body parts, but the company currently focuses on “epithelial cell sheets for esophageal regeneration” and “cartilage cell sheets” for knee cartilage.

In April 2016, the company started clinical trials for “epithelial cell sheets for esophageal regeneration” in Japan, but failed to obtain sufficient data regarding their effectiveness. For this reason, an additional clinical trial notification was submitted in October 2020, and the first case was registered in February 2021. As for business in overseas nations, CellSeed entered into a business alliance with MetaTech (AP) Inc. (hereinafter referred to as MetaTech) in Taiwan in April of fiscal 2017 and the company submitted a clinical trial notification at the end of December 2018.

In January 2019, the advanced medical treatment for cartilage cell sheets, for which Tokai University Hospital had applied, was approved, and treatment for Regenerative Medicine B began in 2020.

Furthermore, CellSeed has licensed out the product to MetaTech and efforts are put forth to commercialize autologous cartilage sheets in accordance with the Taiwanese law (which is equivalent to those governing Japan’s Advanced Medical Care B Program).

Development of treatment methods using “cell sheet engineering”



(From the company material)

“Epithelial Cell Sheet for Esophageal Regeneration”

22,000 patients within Japan are diagnosed with esophageal cancer every year with 11,500 patients dying every year. The rate of occurrence and death related to esophageal cancer in male patients is five times that of female patients. In addition, 90% of the esophageal cancer cases diagnosed within Japan are squamous cell carcinoma and five years survival rates for males and females, which is said to be 41% and 46%, respectively, are under 50%. The endoscopic resection surgery (ESD) was posted in the drug price list from 2008 and is on the rise, but its side effect of esophageal stricture after surgery has been recognized as a problem.

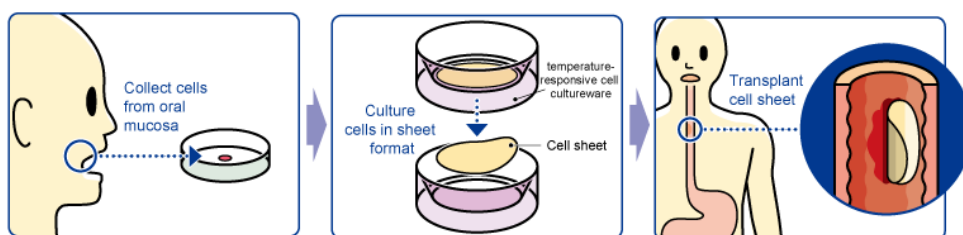
However, introduction of epithelial cell sheets for esophageal regeneration will allow esophageal strictures to develop less frequently, which is expected to improve the quality of life of patients.

The treatment with “the epithelial cell sheet for esophageal regeneration” was developed by Tokyo Women's Medical University, in order to solve the problem with the regenerative medical treatment against esophageal cancer (treatment of esophageal tear and prevention of stenosis). Cells taken from the oral mucosa of a patient are cultured for about 2 weeks using the temperature-responsive cell cultureware to produce cell sheets. In conjunction with the process of culturing cell sheets, an endoscopic surgery for esophageal cancer excision is performed and the cell sheets are transplanted to the part of an esophageal tumor in the patient. Clinical studies were conducted at universities between 2008 and 2014: 10 cases at Tokyo Women's Medical University, 10 cases at Tokyo Women's Medical University and Nagasaki University (long-distance transport validation: cells collected at Nagasaki University were cultured at Tokyo Women's Medical University and transplanted at Nagasaki University), 10 cases at Karolinska University Hospital (Sweden), for a total of 30. The company signed a basic development agreement with Tokyo Women's Medical University and took over the university's research results for commercialization.

The company submitted a plan for clinical trials in April 2016 and finished the trials in March 2019, but failed to prove statistical superiority, and additional clinical trials became necessary. After consulting with PMDA about additional clinical trials, the company submitted a plan for additional clinical trials in October 2020, and the first case was registered in February 2021.

Outside Japan, the company licensed MetaTech in Taiwan, with which it formed an alliance in April 2017, to use the sheet. In 2018, MetaTech submitted a plan for clinical trials.

Meanwhile, the company was proceeding with development in Europe, based on a subsidiary in Sweden, but it decided to stop the development in 2020, because endoscopic therapy had not been diffused in Europe as expected and the company had to concentrate on the acquisition of approval for production and sale in Japan.



(From the company material)

“Regenerated Cell Sheet”

The company researched the “regenerated cell sheet” with Professor Masato Sato of Department of Orthopedics, Tokai University. Its indications are cartilage defects and osteoarthritis caused by sport injury and aging.

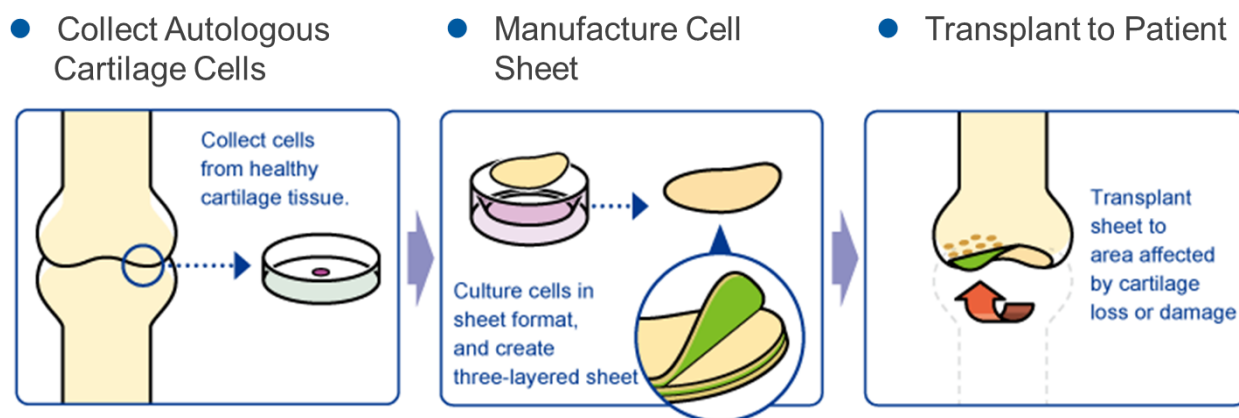
Knee osteoarthritis is refractory articular cartilage degeneration that progresses slowly. The number of potential patients in Japan is estimated to be about 30 million, of which about 10 million patients are thought to have subjective symptoms. Furthermore, population aging in Japan is expected to raise the number of patients diagnosed with the illness, making it a disease that needs to be dealt with immediately from the perspective of citizens' healthy life expectancy and costs of long-term care and medical services. As of now, there are no methods to cure the injury completely, but the collaborative research with Professor Masato Sato is aimed at regenerating the cartilage surface radically. The cartilage of the knee is called hyaline cartilage, which is hard and excellent in cushioning and abrasion resistance properties, differing from the cartilages of the ear, nose, etc., and it is difficult to regenerate. However, it was confirmed in clinical research that the “regenerated cartilage sheet,” which is being researched collaboratively with the professor, can regenerate the cartilage of the knee as hyaline cartilage.

Professor Masato Sato started clinical research into autologous cartilage sheets in 2010 and has completed the study of 8 cases. In January 2019, “the cartilage regeneration treatment with autologous cell sheets” proposed by Tokai University Hospital was approved as Advanced Medicine B at “the 71st advanced medical care meeting” hosted by the Ministry of Health, Labor and Welfare.

CellSeed will manufacture regenerative cartilage sheets on consignment for treating patients by regenerating cartilage using autologous cell sheets as an advanced medical care program, and a surgery of the first patient under the category of Advanced Medical Care B Program was completed in August 2020.

The licensee MetaTech in Taiwan started the commercialization of autologous cartilage sheets in accordance with the Taiwanese law (complying with Advanced Medicine B in Japan), and performed transplantation for 10 patients. Then, CellSeed received a milestone revenue of 50 million yen.

In addition, in November of 2019, CellSeed and Tokai University jointly applied for a patent of “Cell Culture Sheet and Manufacturing Method and Use Thereof,” one of the outcomes of the joint research with Professor Masato Sato of the university, in the U.S. and the patent application was approved. This ensures that the intellectual property right of the product is now protected in Japan, the United States of America, and Europe.



(Source: the company)

The company is also proceeding with the R&D of treatments with allogeneic cartilage sheets, which are derived from cells of people other than patients.

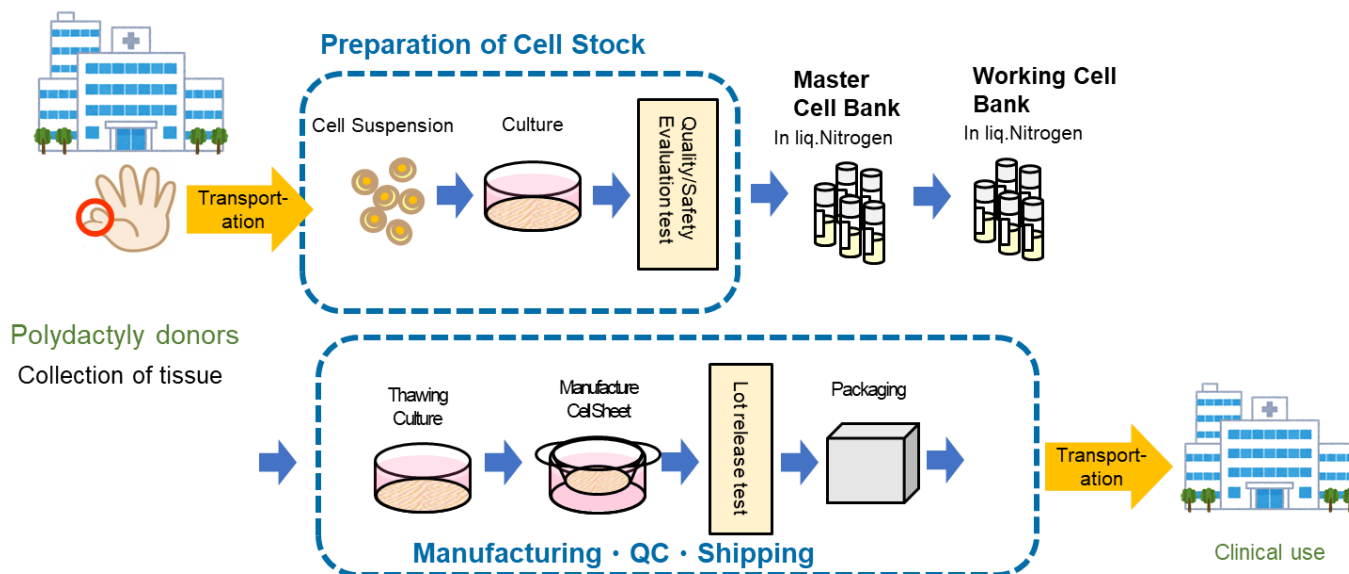
The professor Masato Sato started clinical research regarding the transplantation of allogeneic cartilage cell sheets in February 2017, and performed transplantation for 10 patients in 3 years. In December 2019, the 10th transplantation was finished.

In parallel with clinical research, a cell bank will be established and manufacturing of cell sheets will be automated. The treatment with allogeneic cartilage sheets has been adopted in the project for developing evaluation methods, etc. for the industrialization of regenerative medicine (support for acceleration of development of regenerative medicine seeds) of AMED (project period: Oct. 2018 to Mar. 2021(plan)).

For developing cartilage cell sheets with allogeneic cells, the discarded tissue of patients with polydactyly who have six fingers, so it is necessary to solve ethical issues, but in December 2020, the company obtained approval for the provision of cartilage tissue collected from patients with polydactyly from National Center for Child Health and Development. Accordingly, the company is now able to obtain the tissue of cartilage cells in a stable manner. This will accelerate R&D for receiving approval for clinical trials, manufacturing, and sale.

In addition, in July 2021, CellSeed's R&D proposal was selected by the Japan Agency for Medical Research and Development (AMED) as a subsidized project for the development of basic technologies for the industrialization of regenerative medicine and gene therapy (project to promote the industrialization of regenerative medicine, cell therapy, and gene therapy) in 2021.

<Allogeneic cells> Development of cartilage cell sheets



(From the company material)

The company is also implementing measures for expanding its business in new fields.

In November 2020, the company signed a contract for technological transfer with KanonCure Inc., which is a venture company from Tottori University, for the manufacturing of products for clinical trials of cell sheets for treatment of liver disease using mesenchymal stem cells, which are being developed by KanonCure, as products for regenerative medicine, etc.

It is said that about 53,000 people suffer from liver disease and about 2,200 patients need liver transplantation every year, but the number of patients who can undergo liver plantation is only about 500 per year. Based on the accumulated know-how for commissioned manufacturing of cell sheets and the technological information from KanonCure, CellSeed will discuss necessary technologies for manufacturing hepatic cell sheets and related technologies, transfer manufacturing methods, and prepare for concluding a contract with KanonCure for entrustment of manufacturing of products for clinical trials.

(2) Regenerative Medicine Consignment Services

The company provides regenerative medicine services on consignment in relation to temperature responsive cell cultureware, etc., including development, manufacture, and sales and cell sheet products, including development of manufacturing methods and contract manufacturing, facility management and application support, and training and education in cell culturing technology.

In the commissioned manufacturing of cell sheet products, the company develops and manufactures mainly cell sheets on consignment for pharmaceutical companies and research institutions. The company has a number of staff members with extensive knowledge and experience with cell culturing practices, such as clinical cultivatists certified by the Japanese Society for Regenerative Medicine, and they do those services at the facility with permission for manufacturing and processing specified cell products.

The company's main commissioned projects for regenerative medicine contract service include the development of autologous cartilage cell sheets, cell sheets for treatment of liver disease, and periodontal ligament cell sheets.

For autologous cartilage regeneration sheets, Tokai University's application for advanced medical treatment B was approved in January 2019, and the commissioned manufacturing of autologous cartilage cell sheets began in 2020.

In November 2020, the company signed a technology transfer agreement with KanonCure for the manufacturing of clinical trial products of cell sheets for treatment of liver diseases.

The periodontal ligament cell sheet is the first project for commissioned manufacturing of cell sheets for use in physician-led clinical trials.

In recent years, there has been a great deal of interest in the use of cells cultured in large quantities to produce biopharmaceuticals, conduct immunotherapy using the cells themselves, and even solve food and environmental problems.

When using proteolytic enzymes as a common cell retrieval technique, the cells are retrieved in a damaged state, making it difficult to fully maintain their original functions and components. In contrast, with the company's products, cells can be retrieved intact, and all the functions and components of the cells can be used while retaining their original properties, which is expected to greatly improve the efficiency and effectiveness of the industry in new markets.

Cell Culture Center

The cell sheets used for advanced medicine are cultivated at the cell culture center of CellSeed on commission.

With a floor space of about 763 square meters, the Cell Culture Center is equipped with an automated monitoring system that controls the cleanliness, room pressure, temperature and humidity, and operational status of equipment (such as incubators and reagent stockers), and a surveillance camera system throughout the entire facility. Besides, the facility is only twenty-minute drive from Haneda International Airport, making it possible and easy to transport products by air. In March 2017, a license to manufacture and process specified cell products as per the provisions set forth in Paragraph 1, Article 35 of the Act on Safety of Regenerative Medicine was granted by the Ministry of Health, Labour and Welfare. Consequently, CellSeed is able to process specified cell products on consignment.



(From the company material)

2. Second Quarter of Fiscal Year ending December 2021 Earnings Results

2-1 Consolidated Earnings

	FY 12/ 20 2Q	Share	FY 12/ 21 2Q	Share	YoY Change	Initial Forecast
Sales	58	100.0%	81	100.0%	+39.9%	50
Gross Income	40	69.2%	43	52.8%	+6.7%	-
SG&A	381	653.4%	509	624.1%	+33.6%	-
R&D	181	310.5%	319	392.0%	+76.6%	-
Operating Income	-340	-	-466	-	-	-587
Ordinary Income	-341	-	-477	-	-	-601
Net Income attributable to owners of parent	-340	-	-486	-	-	-601

* unit: million yen

Sales increased, and sales and profit exceeded the forecasts

In the second quarter of the term ending December 2021, sales were 81 million yen, up 39.9% year on year. Especially, overseas sales grew, hitting a record high, as the company cemented cooperation with Key distributors for promoting the sales of devices and conducted sales promotion actively. In addition, Tokai University entrusted the company with the manufacturing of autologous cartilage cell sheets as last year, and the sales from two cases were posted. There was an operating loss of 466 million yen (a loss of 340 million yen in the same period of the previous year). For the epithelial cell sheets for esophageal regeneration, the company carried out active investment in R&D, including additional clinical trials for applying for the approval for production and sale in 2025.

Both sales and profit exceeded the initial forecasts. Regarding sales, the overseas sales of devices, mainly temperature-responsive cell culture ware, exceeded the initial forecast, despite the delay in some commissioned projects for producing cell sheets in the regenerative medicine supporting business. Regarding profit, the expenses for outsourcing development fell below the initial forecast, and through cost reduction efforts, the costs for R&D, manufacturing, and SG&A decreased.

	FY 12/ 20 2Q	Share	FY 12/ 21 2Q	Share	YoY Change
Regenerative medicine supporting business	56	96.9%	76	93.8%	+35.3%
Cell sheet regenerative medicine business	1	3.1%	5	6.2%	+182.8%
Sales, Total	58	100.0%	81	100.0%	+39.9%
Regenerative medicine supporting business	-6	-	-19	-	-
Cell sheet regenerative medicine business	-183	-	-319	-	-
Adjustments	-150	-	-127	-	-
Operating Income, Total	-340	-	-466	-	-

* Unit: million yen

Regenerative medicine supporting business

Sales were 76 million yen (up 35.3% year on year), and operating loss was 19 million yen (a loss of 6 million yen in the same period last year).

As a result of further strengthening cooperation with existing distributors and aggressive sales promotion activities to expand sales of devices and overseas sales were particularly strong, achieving a record high. As for the company's commissioned regenerative medicine business, which supports regenerative medicine using the company's Cell Processing Facility (CPF), the company was entrusted by Tokai University, which is a joint research partner, with the manufacturing of autologous cartilage cell sheets for advanced medical treatment as they contracted in 2020, and recorded sales from two cases.

To respond to the new products' research and development, strong demand from customers, and increased demand due to the expansion of overseas sales, the company established new development and manufacturing facilities for cell culture ware, which started operation in September 2021.

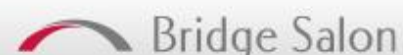
Cell sheet regenerative medicine business

Sales were 5 million yen (up 182.8% year on year), and operating loss was 319 million yen (a loss of 183 million yen in the same period last year).

Regarding the esophageal regeneration sheets pipeline, additional clinical trials were continued in preparation for filing for the approval for production and sale in 2025. In addition, as for the regenerated cartilage sheets pipeline, the company's R&D proposal (R&D to start corporate trials, including the establishment of a cell bank for the commercialization of allogeneic cartilage cell sheets (CLS2901C)) was selected by the Japan Agency for Medical Research and Development (AMED) as a 2021 subsidized project for the development of basic technologies for the industrialization of regenerative medicine and gene therapy (project to promote the industrialization of regenerative medicine, cell therapy, and gene therapy) in July 2021.

Furthermore, the company plans to develop, manufacture, and sell pipeline products other than esophagus and cartilage through a Taiwanese joint venture company established in January 2020 with investment from the company and MetaTech in Taiwan.

BRIDGE REPORT



2-2 Financial Condition and Cash Flows (CF)

Summary of BS

	December 20	June 21	YoY		December 20	June 21	YoY
Current Assets	1,622	1,556	-65	Current Liabilities	120	192	+72
Cash	1,460	1,416	-44	Accounts payable	41	85	+44
Receivables	45	29	-15	Advance payment	28	57	+28
Inventories	42	51	+8	Fixed Liabilities	160	160	+0
Fixed assets	184	200	+16	Net Liabilities	280	352	+72
Total Assets	1,806	1,756	-49	Net Assets	1,526	1,403	-122
				Total Liabilities and Net Assets	1,806	1,756	-49

* Unit: million yen

Total assets stood at 1,756 million yen, down 49 million yen from the end of the previous term. Net assets stood at 1,403 million yen, down 122 million yen from the end of the previous term. The capital adequacy ratio declined 5.0 percentage points from the end of the previous fiscal year to 78.2%.

CF

	FY12/20 2Q	FY12/21 2Q	YoY Change
Operating Cash Flow	-260	-360	-99
Investing Cash Flow	-5	-31	-26
Free Cash Flow	-265	-392	-126
Financing Cash Flow	484	344	-139
Cash and Equivalents at the end of term	1,282	1,416	+133

* Unit: million yen

3. Fiscal Year ending December 2021 Earnings Forecasts

3-1 Consolidated earnings forecasts

	FY 12/ 20 Act.	Share	FY 12/ 21 Est.	Share	YoY Change
Sales	199	100.0%	213	100.0%	+13
Operating Income	-719	-	-976	-	-256
Ordinary Income	-744	-	-998	-	-253
Net Income	-783	-	-998	-	-214

* unit: million yen

There is no revision to the earnings forecasts. Sales will be 213 million yen, up 7.0% year on year, and operating loss will be 976 million yen (719 million yen in the previous term).

There is no revision to the earnings forecasts. The sales of the regenerative medicine supporting business is projected to be 173 million yen, hitting a record high this term, again. The company will make continuous efforts to sell mainly devices especially outside Japan. In addition, the company will proceed with the manufacturing of devices for regenerative medicine on consignment for supporting the R&D and commercialization of regenerative medicine, through comprehensive support regarding regenerative medicine.

The sales of the cell sheet regenerative medicine business are forecasted to be 40 million yen. The company will continue the investment in R&D, to develop mainly epithelial cell sheets for esophageal regeneration and for cartilage regeneration. The estimated sales of 40 million yen in this segment will come from the exclusive business alliance contract with MetaTech (AP) Inc.

3-2. Topics

(1) The operation of facilities for developing and manufacturing new cell culture ware began

In September 2021, the company finished the interior work of facilities for developing and manufacturing flasks for meeting the strong demand from clients and responding to the growth of sales volume outside Japan, the installation and relocation of equipment from the headquarters smoothly, and the operation of the facilities was started on September 1, 2021.

According to the news release in June 2021, the operation was scheduled to be started in the fourth quarter of the term ending December 2021, but it was started earlier than scheduled.

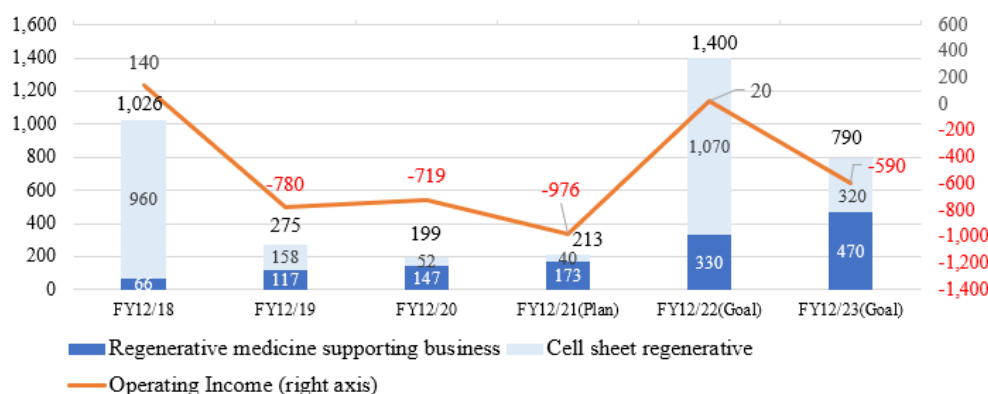
(2) Completion of exercise of the 19th share acquisition rights (with the provision for revising the exercise price)

All of the 19th share acquisition rights issued to Barclays Bank PLC on August 6, 2020 were exercised on July 29, 2021. The total exercise price amounted to about 860 million yen.

4. Conclusions

The company started the operation of facilities for developing and manufacturing flasks for enhancing the sale of devices, which is a priority measure, and responding to the growth of sales volume outside Japan, in September earlier than scheduled. The company is developing systems in preparation for a great leap in the term ending December 2022. We also would like to pay attention to the progress of the application for approval for production and sale of the epithelial cell sheets for esophageal regeneration (by 2025) and the seizure of earning opportunities by re-fostering cooperation with MetaTech and the Taiwanese joint venture company.

Achievement, Plan, and Goal of Sales and Operating Income (unit: million yen)



<Reference1: Mid-term Management Plan>

The company announced the mid-term management plan for the 3 years from the term ending December 2021 to the term ending December 2023.

(1) Activities in each business

Business	Outline
Cell sheet regenerative medicine business	<ul style="list-style-type: none"> *To start additional clinical trials for epithelial cell sheets for esophageal regeneration, and aim to apply for certification for manufacturing and sale in 2025. *To accelerate the acquisition of non-clinical data for submitting a plan for clinical trials for allogeneic cartilage regeneration sheets at the end of 2022 *To redevelop collaborative business with MetaTech and a joint venture in Taiwan, with the aim of increasing earning opportunities *To actively form business alliances for diffusing cell sheet engineering created in Japan, with the aim of increasing revenues
Regenerative medicine supporting business	<ul style="list-style-type: none"> *To cement the cooperation with Thermo Fisher Scientific, Inc. with the aim of increasing overseas sales of devices *To expand business by developing and supplying devices for new markets for mass culture of cells for research *To enrich and expand production systems and capabilities to meet overseas increasing sales and supply of devices to new markets, and aim to increase earning opportunities *To proceed with the businesses of development, commissioned manufacturing, and consulting, with the aim of increasing earning opportunities

(Major points)

*Epithelial cell sheets for esophageal regeneration

The company plans to apply for the certification for manufacturing and sale in 2025. It will have discussions for shortening the period of each clinical trial by increasing facilities for clinical trials, etc.

*Cartilage regeneration sheets

In December 2020, the company obtained the approval of the ethical review committee of National Center for Child Health and Development for the provision of cartilage tissue collected from patients with polydactyly, and became able to stably get cartilage tissue that can be used for commercial purposes. The company will accelerate R&D for obtaining approval for clinical trials, manufacturing, and sale of allogeneic cartilage cell sheets, and plans to submit a plan for clinical trials by the end of 2022.

*Business tie-up

In addition to the milestone income in the previous term, the company is scheduled to receive several-percent royalties according to the sales of autologous cartilage regeneration sheets from MetaTech. The company will make efforts to form new business alliances and find licensees in Asian countries, especially China, but any contracts were not signed in 2020, due to the differences in regulations, etc. The company will keep striving to form business alliances and find licensees with the aim of expanding the cell sheet regenerative medicine business inside and outside Japan while improving its business value by developing pipelines.

*Regenerative medicine supporting business

The company will enhance the development of new devices considering customer needs and emerging demand. For sales, the company will collect and analyze information on sales, etc. provided by major Japanese distributors and conduct marketing cooperatively, for the purpose of promoting the sales of devices, mainly temperature-responsive cell culture devices, and strengthen cooperation for boosting not only domestic sales, but also overseas sales of mainly Thermo Fisher.

The company will strive to enrich and expand its production systems for supplying products to new markets for mass culture of cells for research and expanding overseas sales, while maintaining the stable supply of products.

***Commissioned regenerative medicine business**

The company will operate the consulting business by utilizing a variety of know-how acquired through the manufacturing of cell sheets entrusted by universities, enterprises, etc., commissioned development, and the cell sheet regenerative medicine business, with the aim of increasing earning opportunities.

***Establishment of a joint venture in Taiwan**

Based on the new technologies provided by Japanese or Taiwanese universities and research institutes, the company will conduct R&D of products and methods for regenerative medicine by applying cell sheet engineering, have discussions on indications and optimize manufacturing methods for commercialization. A technology developed by Professor Du Yuan Kun of E-Da Hospital is one of candidates. In the regenerative medicine supporting business, the company plans to offer consulting services for R&D and support the application for approval for manufacturing and sale, and earn sales by receiving fees for technical instructions, etc.

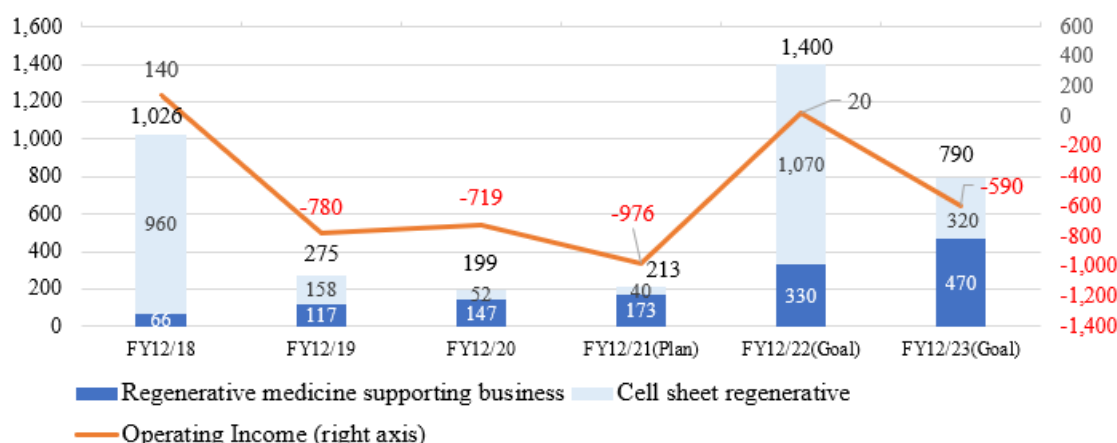
***Epithelial cell sheets for cornea regeneration**

The company will continue discussions with related institutions.

(2) Numerical goals

In the regenerative medicine supporting business, the company will strive to expand overseas sales and grow its business steadily. In the cell sheet regenerative medicine business, the company will seek overseas licensees.

Achievement, Plan, and Goal of Sales and Operating Income (unit: million yen)



<Reference2: Regarding Corporate Governance>

◎Organization type, and the composition of executive directors and auditors

Organization type	Company with audit and supervisory committee
Directors (excluding audit and supervisory committee members)	6 directors, including 4 external ones
Auditors and supervisory committee members	3 committee members, corporate auditors, including 3 external ones

◎Corporate Governance Report(Latest Update:March 29, 2021)

Basic Policy

With the missions to introduce technological innovations, to exert creativity and to contribute to people’s health and welfare by providing high-quality products and services, we are enhancing corporate governance to raise quality in all of our corporate activities. In the future, we will increase our accountability further to improve the transparency of disclosed information and strengthen our checking system even more.

<Reasons for Non-compliance with the Principles of the Corporate Governance Code (Excerpts)>

CellSeed has stated, “Our company implements all the basic principles stipulated in the Corporate Governance Code as a JASDAQ listed company.”

This report is intended solely for information purposes and is not intended as a solicitation to invest in the shares of this company. The information and opinions contained within this report are based on data made publicly available by the company and obtained from sources that we judge to be reliable. However, we cannot guarantee the accuracy or completeness of the data. This report is not a guarantee of the accuracy, completeness or validity of said information or opinions, nor do we bear any responsibility for the same. All rights pertaining to this report belong to Investment Bridge Co., Ltd., which may change the contents thereof at any time without prior notice. All investment decisions are the responsibility of the individual and should be made only after proper consideration.

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