



Setsuko Hashimoto, President

CellSeed Inc. (7776)



Company Information

Market	JASDAQ
Industry	Precision Instrument (Manufacturing)
President	Setsuko Hashimoto
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
¥130	17,759,419shares		¥2,308million	-	100shares
DPS Est.	Dividend yield Est.	EPS Est.	PER Est,	BPS Act.	PBR Act.
¥0.00	-	¥47.19	-	¥56.44	2.3x

*Stock price as of closing on March 15, 2022. Each number is taken from the financial results of Fiscal Year ended December 2021.

Consolidated Earnings Trend

Fiscal Year	Sales	Operating Profit	Current Profit	Net Profit	EPS	DPS
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	161	-864	-887	-914	-53.18	0.00
December 2022 Est.	209	-834	-834	-838	-47.19	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 of Fiscal Year ended December 2021, etc.

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Key Points

- In the term ended December 2021, sales were 161 million yen, down 18.9% year on year. The sales of the regenerative medicine support business were unchanged from the previous term, but the sales of cell culture equipment hit a record high, thanks to the growth of overseas demand from last year. In addition, the company undertook the production of autologous cartilage cell sheets for 5 cases entrusted by Tokai University following last year. The sales of the cell sheet regenerative medicine business declined. The company posted an operating loss of 864 million yen (719 million yen in the previous term). Regarding epithelial cell sheets for esophageal regeneration, the company actively invested in R&D, for example, by conducting additional clinical trials for applying for an approval for production and sale in 2025.
- For the term ending December 2022, sales are expected to increase 47 million yen to 209 million yen, while operating loss is projected to shrink 53 million yen to 834 million yen. In the regenerative medicine support business, the company will continue to expand sales of its equipment, especially overseas. The company plans to release its new product UpCell® Flask. In addition, the company will promote contract manufacturing for regenerative medicine to support R&D and commercialization of regenerative medicine through comprehensive support for regenerative medicine. Through these efforts, the sales in this segment are expected to reach 209 million yen. The cell sheet regenerative medicine business will continue to mainly promote the development of epithelial cell sheets for esophageal regeneration and allogeneic cartilage cell sheets. In addition, it will actively negotiate with potential new business partners in Europe and the United States other than Asia for the introduction of pipeline technologies.
- The balance of cash on hand (cash and deposits) as of the end of the term ended December 2021 was 930 million yen, and the financial base has been stable. On the business side, however, the company has not yet been able to show the path to the early commercialization of its first cell sheet regenerative medicine product, which is a significant issue in the cell sheet regenerative medicine business. As of the end of December 2021, the company considered that the current situation raises doubts regarding the continuation of operations. In order to resolve this situation, the company will promote the development of epithelial cell sheets for esophageal regeneration and cartilage cell sheets, and aim to realize the early commercialization of the first cell sheet regenerative medicine product and acquire more earning opportunities through business partners.
- Sales of equipment in the regenerative medicine support business in the term ended December 2021 reached a record high due to the continued expansion of overseas demand from last year. Sales in this segment for the current fiscal year are expected to significantly exceed those of the previous fiscal year, due to the start of operations at the new facility for the cell culture equipment business in part. Quarterly trends of the company deserve to be paid attention. On the other hand, in the cell sheet regenerative medicine business, which continues to struggle, it is deserve to be paid attention that how the “early commercialization of the first cell sheet regenerative medicine product” by promoting the development of epithelial cell sheets for esophageal regeneration and cartilage regeneration sheets and the “acquisition of more earning opportunities” by developing business partners will progress in this fiscal year.

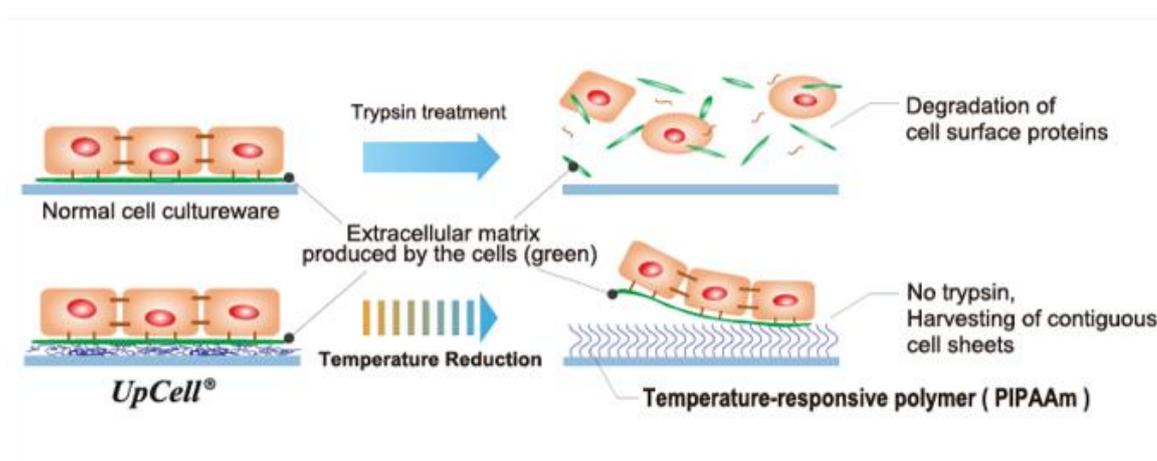
1. Company Overview

[1-1 Regenerative medicine of CellSeed]

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 a platform technology originating in Japan and the first of its kind in the world, which was invented by Mr. Teruo Okano, a professor emeritus of Tokyo Women's Medical University. Cells are cultured in “UpCell®,” a cell culture dish whose surface is processed with a temperature-responsive polymer that changes its molecular structure with temperature. The surface of a cell culture dish becomes moderately hydrophobic (water-repellent) at 37 °C, at which cells can attach, and hydrophilic (water-absorbent) at 20 °C, at which cells cannot attach. Therefore, by simply changing temperature, the organically bound "cell sheet" which retains the extracellular matrix (adhesion protein) can be recovered from the culture dish.

In general, cells secrete an extracellular matrix and grow by fixing themselves. In other words, cells cannot grow unless they are fixed somewhere while secreting adhesion proteins. However, in the conventional culture method, adhesion proteins are decomposed and recovered from cultured cells using proteolytic enzymes such as trypsin (there was no method for recovering cultured cells other than by decomposing adhesion proteins).

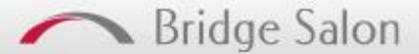
Huge Regenerative Medicine Market

The market size of regenerative medicine is expected to reach 2.5 trillion yen in Japan and 38 trillion yen worldwide in 2050, and a significant economic effect is expected.

	再生医療 (国内)	周辺産業 (国内)	再生医療 (グローバル)	周辺産業 (グローバル)
2020	950	950	10,000	11,000
2030	10,000	5,500	120,000	52,000
2050	25,000	13,000	380,000	150,000

(From the company material, Unit: hundred million yen)

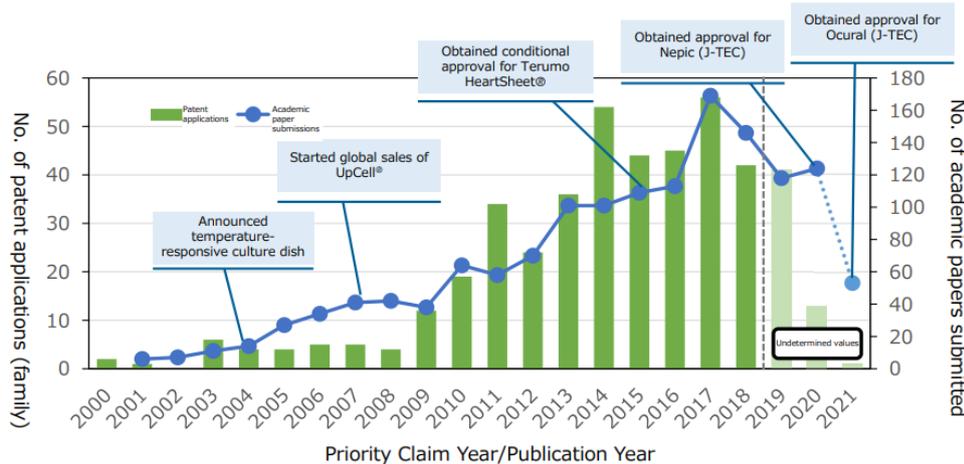
BRIDGE REPORT



Japan Leads the World in Cell Sheet Engineering.

A paper on "cell sheet engineering" was published about 30 years ago, and since then many papers have been published and patent applications have been filed. It is one of the few technologies in which Japan has taken the lead in patent applications and research papers in the life science field. Since the global launch of "UpCell®," both patent applications and published papers have been increasing.

Annual changes in the number of patent applications and submitted academic papers related to cell sheet engineering



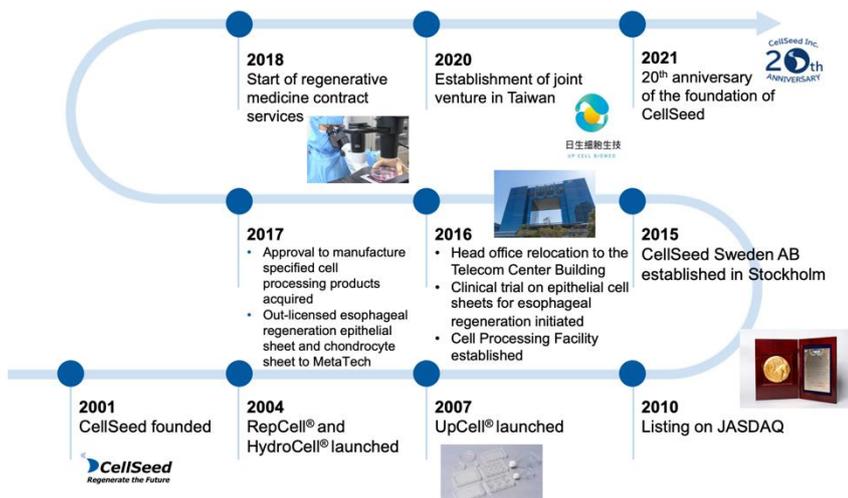
- For this graph, we analyzed patent applications by the priority claim year
- Since there is a maximum grace period of one year from the priority claim to application and a maximum time difference of 1.5 years from application to publication, applications are treated as undetermined for 2.5 years from the time of that screening is implemented.

(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 (CPC) 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.

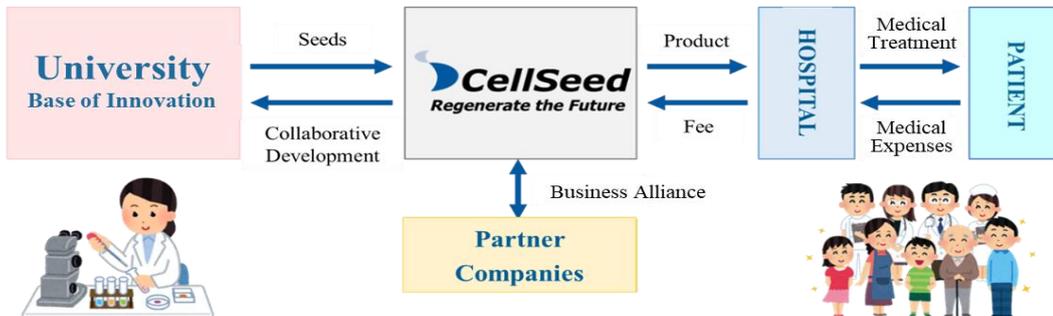
20th anniversary of the foundation of CellSeed



[1-2 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)

[1-3 Business Description]

(1) Cell sheet regenerative medicine business

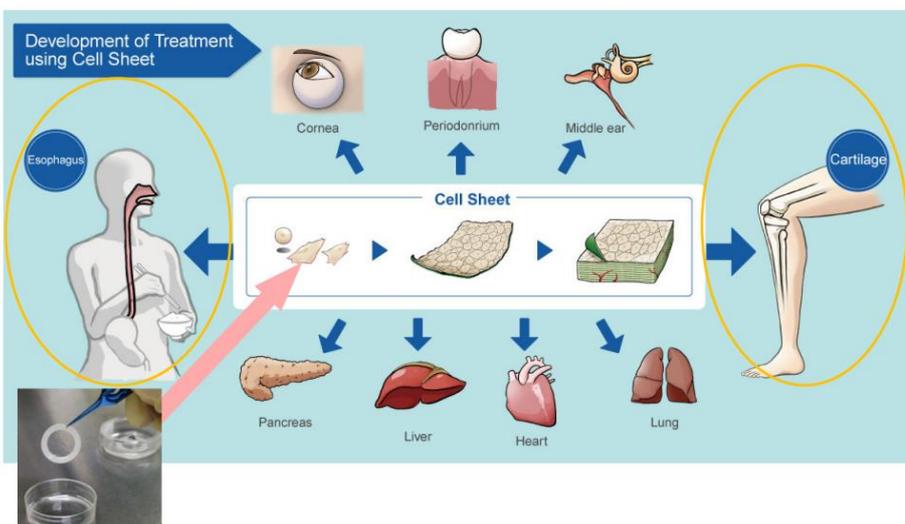
The treatment methods based on “cell sheet engineering” are targeted at various body parts, but the company currently focuses on “epithelial cell sheets for esophageal regeneration” and “cartilage cell sheets” for knee cartilage.

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”

About 26,300 patients within Japan are diagnosed with esophageal cancer every year with about 11,100 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 comparative 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.

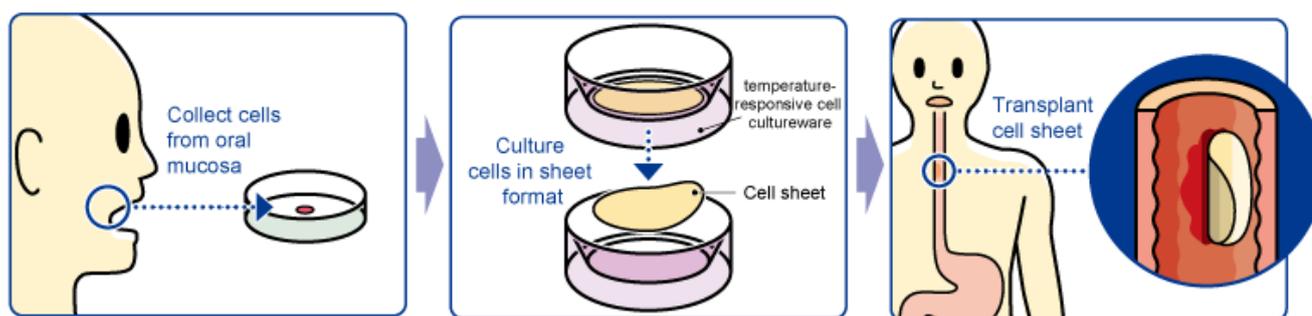
The treatment with “the epithelial cell sheet for esophageal regeneration” was developed by Tokyo Women's Medical University, in order to solve the problem with the regenerative medical treatment against esophageal cancer (treatment of esophageal tear and prevention of stenosis). Cells taken from the 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.

In February 2017, it received a designation under the “Sakigake Designation Scheme” for regenerative medicine products from the Ministry of Health, Labour and Welfare. The company plans to apply for an approval for manufacturing and sale in 2025.

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.

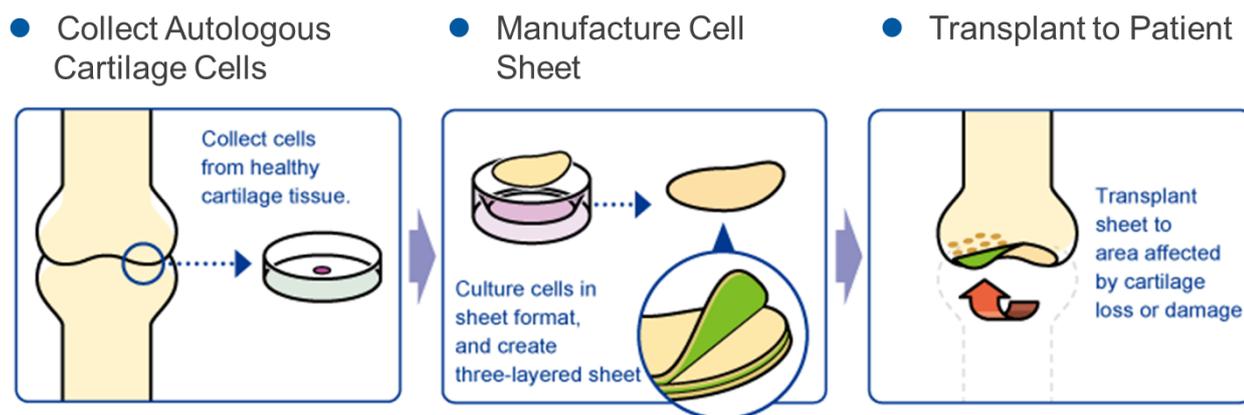
Knee osteoarthritis is slowly progressing, intractable degeneration of articular cartilage with no fundamental treatment. The number of potential patients in Japan is estimated to be about 30 million, of which about 10 million patients are thought to have subjective symptoms. Furthermore, population 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 cartilage cell 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.

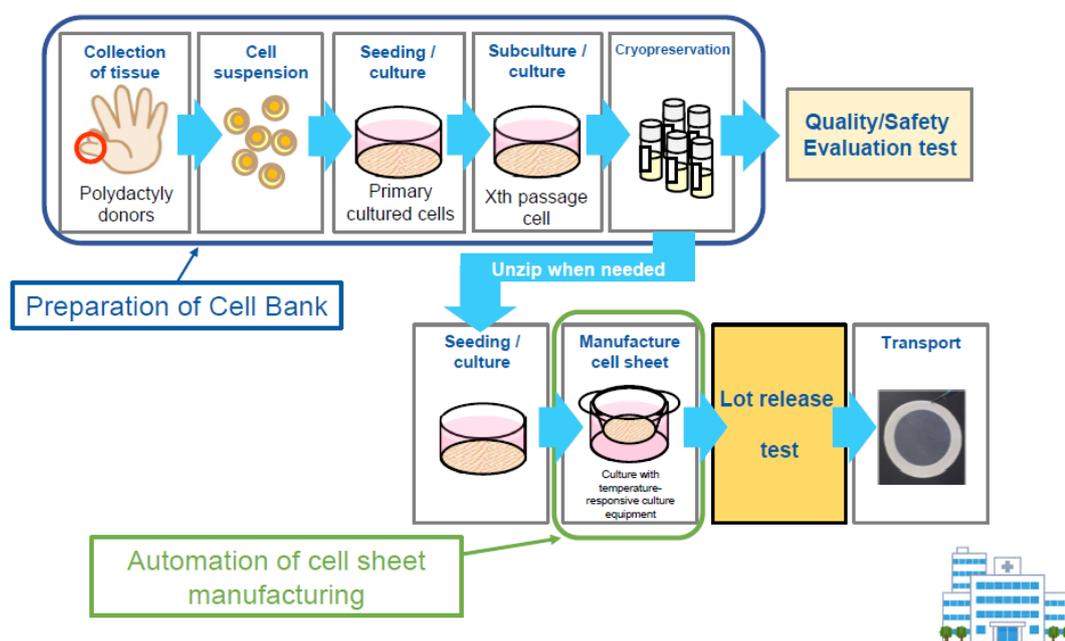
In parallel with clinical research, a cell bank will be established and manufacturing of cell sheets will be automated. The treatment with allogeneic cartilage sheets has been adopted in the project for developing evaluation methods, etc. for the industrialization of regenerative medicine (support for 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.

The company plans to submit a clinical trial plan at the end of 2022.

<Allogeneic cells> Development of cartilage cell sheets



(From the company material)

In November 2020, the company entered into a technology transfer agreement with KanonCure Inc., a venture company originating from Tottori University, for the manufacturing of clinical trial cell sheets for treating liver diseases using mesenchymal stem cells, which KanonCure Inc. is developing as a regenerative medicine product. However, in response to a change in the development policy of KanonCure Inc., the company was notified of its intention to discontinue the technology transfer to CellSeed. After careful discussions between the two companies, the company agreed to terminate the agreement in December 2021.

(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 such as 「UpCell®」 「RepCell®」 「HydroCell®」.

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.

In addition, support is provided for the preparation of regulatory approval applications, obtaining manufacturing and marketing business licenses as well as training of engineers, for each stage from product development to manufacturing and sale.

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, periodontal ligament cell sheets and pediatric autologous epithelial cell sheet etc. Autologous cartilage cell sheets were approved in January 2019 as Advanced Medical Care B under the Act on the Safety of Regenerative Medicine, following which Tokai University started Advanced Medical Care B in 2020. The commissioned manufacturing of the autologous cartilage cell sheets by the CellSeed started. The contract was continued in 2021.

As described above, in November 2020, the company concluded a technology transfer agreement with KanonCure Inc., a venture company originating from Tottori University, for the manufacturing of clinical trial products for cell sheets for the treatment of liver diseases. However, following KanonCure Inc.'s notification of its intention to discontinue the technology transfer to CellSeed due to a change in its development policy, the two companies carefully discussed and agreed to terminate the agreement in December 2021.

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

Pediatric autologous epithelial cell sheets are for children after surgery for congenital esophageal atresia.

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.

In addition, in order to provide consistent quality and services, the company maintains its ISO9001 and ISO13485 certifications, and has obtained a manufacturing license for specified cell products and a manufacturing license for regenerative medicine products.

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)

Aomi Cell Culture Innovation Center

The full-scale operation started in September 2021. The company develops and manufactures cell culture equipment, including laboratory flask products.

[1-4 Growth Strategy]

The company's two main growth strategies are “Business expansion of cell culture equipment” and “Promotion of business cooperation for global development.”

(1) Business expansion of cell culture equipment

In 1989, Professor Okano of Tokyo Women's Medical University invented temperature-responsive cell culture equipment that can exfoliate cells simply by lowering temperature as described above, making it possible to recover intact cell sheets for the first time, leading to the advancement of research and development of treatment methods using the cell sheet by many researchers.

In 2020, the company's equipment business exceeded 100 million yen in sales for the first time. In September 2021, the company established a new development and manufacturing facility exclusively for cell culture equipment products, and also agreed to extend the sales contract with Thermo Fisher Scientific of the United States, an alliance partner for expanding sales of equipment products overseas, until 2025.

In recent years, many efforts have been made to manufacture biopharmaceuticals using cells cultured in large quantities, perform immunotherapy using the cells themselves, and solve food and environmental problems.

However, with proteolytic enzymes, that is, a commonly used cell recovery technique, cells are recovered in a damaged state, and it is difficult to completely maintain the original functions and components of the cells. On the other hand, by adopting this product, it is possible to recover cells without damage, and it is expected to greatly contribute to improvement of industrial efficiency and effectiveness in the new market, because all functions and components of cells are maintained.

In line with the steady expansion of product sales for the R&D phase for application to regenerative medicine, sales of products for new applications for mass culture of research cells are expanding rapidly, particularly overseas.

For this reason, the company is focusing on the development of products to provide solutions that meet the needs of new markets, such as the development of new cell culture equipment and the establishment of new manufacturing facilities, in addition to the conventional development of products in the regenerative medicine market.

The company is strengthening its sales structure to further expand its overseas sales channels. As mentioned above, the company extended its sales contract with Thermo Fisher Scientific, the company's alliance partner for expanding sales of equipment products overseas, and further strengthened their cooperation. In addition, the company established a quality management system to provide consistent quality and services and further enhance customer satisfaction. In January 2020, the company acquired ISO9001:2015 certification, an international standard.

(2) Promotion of business cooperation for global development

Aiming for global expansion, the company has been promoting business alliances by participating in exhibitions held not only in Japan but also in other Asian countries and Europe, such as an alliance with MetaTech in Taiwan in April 2017, establishment of Up Cell Biomedical Inc. in January 2020, and a presentation at “Translate! 2021 – Metrics and Milestones of Success” held in Berlin in January 2021. The company aims to find business partners by participating in exhibitions held in various regions.

2. Fiscal Year ended December 2021 Earnings Results

[2-1 Consolidated Earnings]

	FY12/20	Ratio to sales	FY12/21	Ratio to sales	YoY	Initial Forecast	Revised Forecasts
Sales	199	100.0%	161	100.0%	-18.9%	213	160
Gross Income	138	69.3%	84	52.0%	-39.2%	-	-
SG&A	857	430.0%	948	586.8%	+10.6%	-	-
R&D	438	220.0%	541	335.1%	+23.5%	-	-
Operating Profit	-719	-	-864	-	-	-976	-847
Ordinary Profit	-744	-	-887	-	-	-998	-869
Net Income attributable to owners of parent	-783	-	-914	-	-	-998	-900

* Unit: million yen. Net profit is the profit attributable to owners of parent.

Sales decreased, operating loss expansion

In the term ended December 2021, sales were 161 million yen, down 18.9% year on year. The sales of the regenerative medicine support business were unchanged from the previous term, but the sales of equipment hit a record high, thanks to the growth of overseas demand from last year. In addition, the company undertook the production of autologous cartilage cell sheets for 5 cases entrusted by Tokai University from last year. The sales of the cell sheet regenerative medicine business declined.

The company posted an operating loss of 864 million yen (719 million yen in the previous term). Regarding epithelial cell sheets for esophageal regeneration, the company actively invested in R&D, for example, by conducting additional clinical trials for applying for an approval for production and sale in 2025.

[2-2 Segment trends]

	FY12/20	Ratio to sales	FY12/21	Ratio to sales	Increase/decrease
Regenerative medicine supporting business	147	73.9%	147	91.4%	+0
Cell sheet regenerative medicine business	52	26.1%	13	8.6%	-38
Consolidated sales	199	100.0%	161	100.0%	-37
Regenerative medicine supporting business	-38	-	-76	-	-38
Cell sheet regenerative medicine business	-390	-	-537	-	-146
Adjustments	-290	-	-250	-	-
Consolidated operating Income	-719	-	-864	-	-145

*Unit: million yen

Regenerative medicine supporting business

Sales were 147 million yen (up 0.0% year on year), and operating loss was 76 million yen (38 million yen in the previous term).

A development and manufacturing facility for cell culture equipment was newly established, and the full-scale operation was started in September 2021. The full-scale operation of the facility will enable the company to not only sell cell culture equipment in the regenerative medicine market, but also to sell cell culture equipment products for new applications for mass culture of research cells, especially in response to strong demand overseas.

In addition, in the commissioned regenerative medicine business which supports regenerative medicine by utilizing the Cell Culture Center, the manufacturing of autologous cartilage cell sheets for advanced medical treatment was entrusted by Tokai University, which is a joint research partner, and the sales for 5 cases were recorded in this fiscal year.

Cell sheet regenerative medicine business

Sales were 13 million yen (down 38 million yen year on year), and operating loss was 537 million yen (390 million yen in the previous term).

In the pipeline of epithelial cell sheets for esophageal regeneration, additional clinical trials have been ongoing since October 20, 2020, when the clinical trial plan was submitted, and the time of submission of the manufacturing and marketing approval application is scheduled for 2025.

Although overseas expansion has been delayed due to the spread of COVID-19, the company will continue to provide support to MetaTech for businesses of the epithelial cell sheets for esophageal regeneration and cartilage cell sheets. It will also actively negotiate with potential new business partners outside Taiwan.

[2-3 Financial Condition and Cash Flows (CF)]

Summary of BS

	December 20	December 21	Increase/ decrease		December 20	December 21	Increase/ decrease
Current Assets	1,622	1,094	-527	Current Liabilities	120	172	+52
Cash	1,460	930	-529	Accounts payable	41	82	+40
Receivables	45	28	-17	Advance payment	28	34	+6
Inventories	42	41	-1	Fixed Liabilities	160	192	+32
Fixed assets	184	297	+113	Net Liabilities	280	365	+84
Total Assets	1,806	1,392	-414	Net Assets	1,526	1,027	-499
				Total Liabilities and Net Assets	1,806	1,392	-414

* Unit: million yen

Total assets stood at 1,392 million yen due to the decrease of cash and deposit, down 414 million yen from the end of the previous term. Net assets stood at 1,027 million yen, down 499 million yen from the end of the previous term.

The capital adequacy ratio declined 11.1 percentage points from the end of the previous fiscal year to 72.0%.

CF

	FY12/20	FY12/21	Increase/decrease
Operating Cash Flow	-700	-817	-116
Investing Cash Flow	-12	-110	-97
Free Cash Flow	-713	-927	-214
Financing Cash Flow	1,102	396	-706
Cash and Equivalents at the end of term	1,460	930	-529

* Unit: million yen

Cash positions decline.

3. Fiscal Year ending December 2022 Earnings Forecasts

[3-1 Consolidated earnings forecasts]

	FY12/21 Act	FY12/22 Est.	YoY
Sales	161	209	+47
Operating Income	-864	-834	+30
Ordinary Income	-887	-834	+53
Net Income	-914	-838	+76

* Unit: million yen

Increase in sales, narrowing of loss

For the term ending December 2022, sales are expected to increase 47 million yen to 209 million yen, while operating loss is projected to decrease 30 million yen to 834 million yen.

In the regenerative medicine support business, the company will continue to expand sales of its equipment, especially overseas. The company plans to release its new product UpCell® Flask. In addition, the company will promote contract manufacturing for regenerative medicine to support R&D and commercialization of regenerative medicine through comprehensive support for regenerative medicine. Through these efforts, the sales in this segment are expected to reach 209 million yen.

The cell sheet regenerative medicine business will continue to mainly promote the development of epithelial cell sheets for esophageal regeneration and allogeneic cartilage cell sheets. In addition, it will actively negotiate with potential new business partners in Europe and the United States other than Asia for the introduction of pipeline technologies.

[3 -2 Significant Events Related to Going Concern]

The balance of cash on hand (cash and deposits) as of the end of the term ended December 2021 was 930 million yen, and the financial base has been stable.

On the business side, however, the company has not yet been able to show the path to the early commercialization of its first cell sheet regenerative medicine product, which is a significant issue in the cell sheet regenerative medicine business. As of the end of December 2021, the company considered that the current situation raises doubts regarding the continuation of operations.

In order to resolve this situation, the company will promote the development of epithelial cell sheets for esophageal regeneration and cartilage cell sheets, and aim to realize the early commercialization of the first cell sheet regenerative medicine product and acquire more earning opportunities through business partners.

4. Conclusions

Sales of cell culture equipment in the regenerative medicine support business in the term ended December 2021 reached a record high due to the continued expansion of overseas demand from last year. Sales in this segment for the current fiscal year are expected to significantly exceed those of the previous fiscal year, due to the start of operations at the new facility only for the cell culture equipment business in part. Quarterly trends of the company deserve to be paid attention.

On the other hand, in the cell sheet regenerative medicine business, which continues to struggle, it is deserve to be paid attention that how the “early commercialization of the first cell sheet regenerative medicine product” by promoting the development of epithelial cell sheets for esophageal regeneration and cartilage regeneration sheets and the “acquisition of more earning opportunities” by developing business partners will progress in this fiscal year.

<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 cell 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 demand of devices to new markets, and aim to increase earning opportunities *To proceed with the businesses of development, contract 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 cell 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 2021, 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**

In established joint venture, 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.

(2) Numerical goals

As mentioned above, the company had disclosed its target value for the term ending December 2022 as "1.4 billion yen in sales, 20 million yen in operating profit, 19 million yen in ordinary profit, and 10 million yen in net profit." However, due to the impact of COVID-19 and changes in management strategies in terms of technological licenses of the company's pipeline with overseas business partner candidates, it will be difficult for the company to achieve a net profit of 10 million yen, and a net loss is expected for the term ending December 2022.

The company has withdrawn its performance targets for the term ending December 2023 as it expects to continue to be affected to a certain extent by changes in the business environment. The company plans to make an announcement as soon as it becomes possible to calculate its earnings forecast.

<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, including 3 external ones

◎Corporate Governance Report(Latest Update:March 29, 2022)

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."

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