2019.1.1～2019.12.31

With you CellSeed Vol.12

CellSeed
Regenerate the Future

CellSeed Inc.

Securities Code: 7776

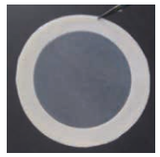
HISTORY

In 2001, CellSeed set the goal of commercializing regenerative medicine based on the cell sheet engineering advocated by Honorary Professor Teruo Okano of Tokyo Women's Medical University. At the beginning, the focus was on research and development, then in 2007 CellSeed launched in Japan sales of its UpCell® temperature-responsive cell cultureware, which is essential to produce cell sheets. In 2010, CellSeed was listed on the JASDAQ Growth section of the Tokyo Stock Exchange. Today, we are striving to contribute to global health care, for instance by establishing the joint venture in Taiwan with MetaTech, which has business alliances with us since 2017.

2005 2010 2015 2020

May 2001
Establishment of CellSeed Inc.

Established to conduct R&D based on cell sheet engineering



Cell sheet

January 2004
Sales of temperature-responsive cell cultureware launch

Sales of RepCell™ and HydroCell™ launched

RepCell™

HydroCell™

September 2007
Start of temperature-responsive cell cultureware for cell sheet collection

Sales for UpCell® launched

UpCell®

February 2008
Overseas sales launch temperature-responsive cell cultureware

March 2010
Listing on JASDAQ

Listed on the JASDAQ Growth section

May 2015
Establishment of CellSeed Sweden AB in Stockholm

January 2016
Head office relocation to the Telecom Center Building

August 2016
Start of Clinical trials of cell sheets for esophageal regeneration

Clinical trials begin in Japan

November 2016
Establishment of Cell Processing Facility

March 2017
Acquisition of the permission to manufacture specified cell products

April 2017
Conclusion of the contract for business alliance with MetaTech (AP) Inc.

Business alliance concluded with Taiwanese company

January 2020
Establishment of joint venture in Taiwan

Up Cell Biomedical Co. established with MetaTech (AP) Inc. and other investors

November 2018
Acquisition of the permission to manufacture regenerative medicine products and start of regenerative medicine contract services

Management Philosophy

Mission

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

Vision

We establish a cell sheet business platform and provide excellent regenerative medicine products around the world.

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Medium-Term Business Plan Fiscal Year 2020 to Fiscal Year 2022

Epithelial Cell Sheets for Esophageal Regeneration

Discussions are moving forward with Japan's Pharmaceuticals and Medical Devices Agency (PMDA) on an additional clinical trial. Seek for early manufacturing and sales approval.

Chondrocyte Sheet (Autologous Cells)

Proceed the contract manufacturing of cell sheets for advanced medical technology from Tokai University.

Chondrocyte Sheet (Allogeneic Cells)

Acceleration of building of cell stock and automation of cell sheet manufacturing for early start of crinical trials.

Third Line of Products

Discussions for further study of periodontal ligament cell sheets with Tokyo Medical and Dental University.

Business Alliances

We are actively pursuing business alliances to promote the global development of made-in-Japan cell sheet engineering.

An Earnings Opportunity in Taiwan

With a focus on expanding investment in regenerative medicine in Taiwan, cooperative efforts are being strengthened with MetaTech (AP) Inc. and the joint venture.

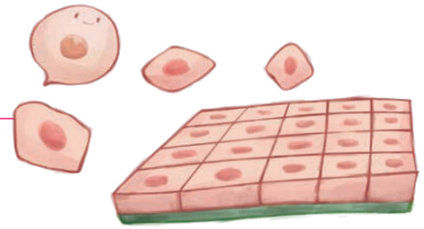
Cultureware Business

To develop new products and expand production capacity to meet increasing demand for further earning expansion.

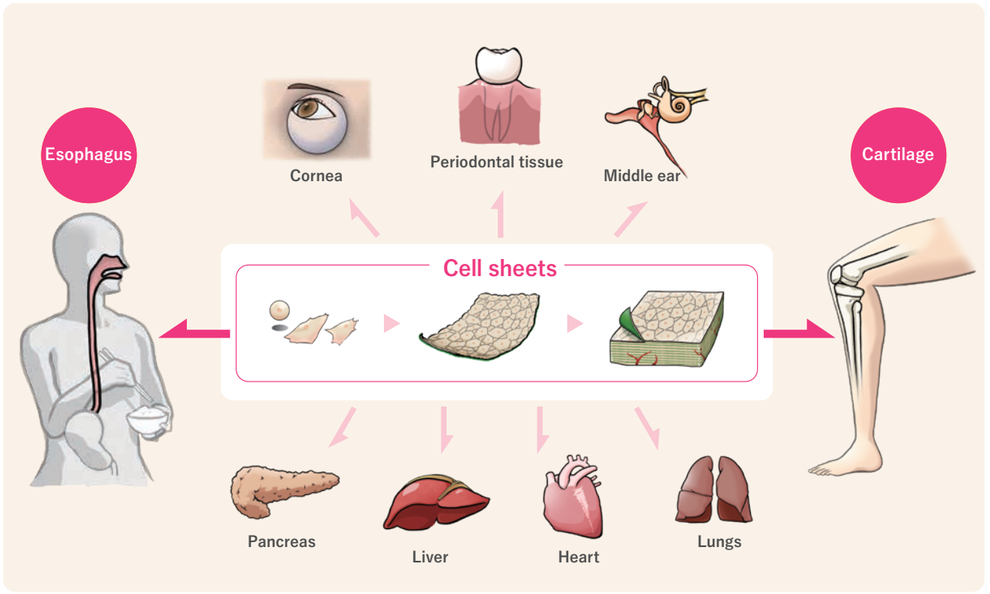
Contract Manufacturing

To accelerate contract manufacturing and consulting business for further earnings gain.

01 What Is Cell Sheet Engineering?



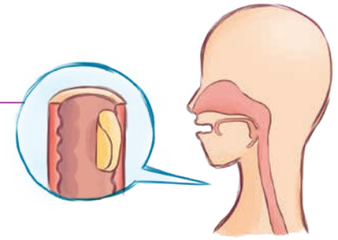
Cell sheet engineering is a technique for recovering cells in sheets using temperature-responsive cell cultureware.* These cell sheets are expected to effectively treat diseases that have proved difficult to address with conventional therapies. This technique can also be used to prepare cell sheets from the cells of a number of biological tissues and organs. We are making progress on research into stacking multiple cell sheets to produce tissues and organs of the needed thickness.

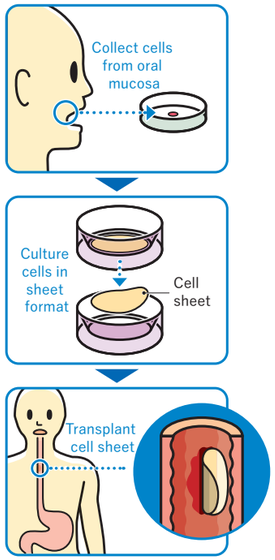


*Cell cultureware that allows for the collection of cells cultured in sheet form by altering the temperature and without the use of enzymes.

CellSeed is building up its development pipeline with the goal of early commercialization of epithelial cell sheets for esophageal regeneration and chondrocyte sheets.
Also, to develop a third line of products, we have decided to begin discussions to further study practical development of periodontal ligament cell sheets with Tokyo Medical and Dental University.
We are moving ahead with development of regenerative medicine products using cell sheets to commercialize "cell-sheet engineering" originated from Japan to the world.

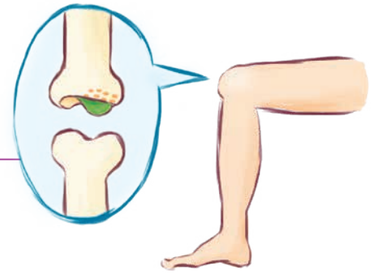
02 Epithelial Cell Sheet for Esophageal Regeneration



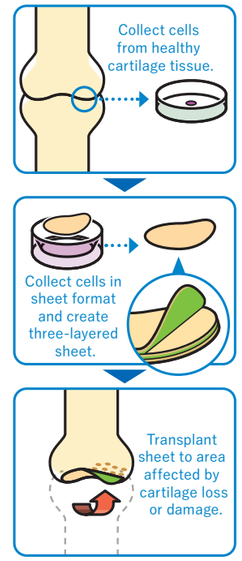


This cell sheet is under development as a medical treatment to promote the healing of wounds and prevent esophageal stricture after resection of the esophagus cancer by Endoscopic Submucosal Dissection (ESD). Cells collected from the oral mucosa are used to create cell sheets (epithelial cell sheets for esophageal regeneration) on temperature-responsive cell cultureware, which are transplanted back into the patient following resection of the esophagus cancer.
Clinical trials began in 2016 and concluded in the 1st quarter of 2019.
Safety was verified, but Japan's PMDA requires submission of additional data to confirm efficacy.
Meanwhile, steroids are noted as the most common treatment method for preventing stenosis in the Guidelines for Diagnosis and Treatment of Carcinoma of the Esophagus 2017.
In further clinical testing, the necessity has emerged to include patients who have a risk for steroid medication, and we are moving forward with discussions with the PMDA regarding subjects and the number of cases.

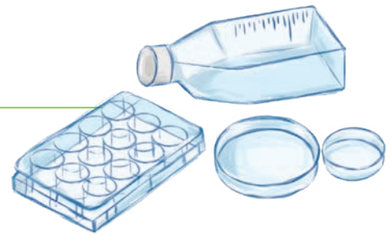
03 Chondrocyte Sheet



The regeneration of hyaline cartilage has been confirmed with chondrocyte sheets using the patient's own knee joint cartilage (autologous chondrocyte sheets), manufactured in the temperature-responsive cell cultureware, then transplanted into knee joints affected by cartilage loss or damage.
This autologous chondrocyte sheets was approved for implementation as Advanced Medical Care B at Tokai University Hospital.
Furthermore, a patent application was jointly submitted in the United States for "Cultured cell sheet, production method thereof, and application method thereof," which is one of the joint research outcomes achieved with Prof. Masato Sato of Tokai University. The patent was granted in November 2019, providing intellectual property protection of our chondrocyte sheets in Japan, the United States, and Europe, in addition to the patents that have already been registered in Japan and Europe.
Clinical research on allogeneic cells (donor cells) by Tokai University concluded with transplantation in 10 patients by December 2019. However, since the framework for providing human tissue for the purpose of commercial use is undeveloped, our company's procurement of tissue was delayed and the start of the clinical trial was pushed back.



04 Cell Cultureware



CellSeed provides cell researchers with a powerful tool for recovering intact cells.
These products are already used by many researchers around the world for various applications such as regenerative medicine, cell biology, and molecular biology.
The product lineup includes the world's first cell cultureware UpCell® that can produce intact cell-sheets without using some proteases or cell scraper, RepCell™ recovers intact cells, and HydroCell™ enables three-dimensional culture of cancer cells, ES cells, iPS cells, etc.

Products

UpCell®

Collected as a cell-sheet only by changing the temperature

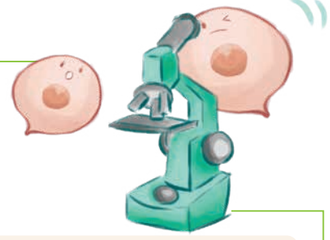
RepCell™

Recover intact cells without using a protease

HydroCell™

Completely suppresses cell adhesion and promotes the formation of spheroid

05 Regenerative Medicine Contract Services



At our Cell Processing Facility, cell sheet manufacturing, facility management, and contract business related to preparing applications and other documents. With the highly experienced staff, the Cell Processing Facility provides safe, high-quality products and services. Our manufacturing and quality control system conforms to Good Gene, Cellular, and Tissue-Based Products Manufacturing Practices (GCTP) in compliance with Japan's Act on the Safety of Regenerative Medicine. In addition to contract manufacturing of cell sheets, we also: provide clients with the support needed to address and respond to authorities at each stage from product development and manufacturing through marketing; prepare applications for product approval; acquire approvals for manufacturing business and manufacturing/marketing business; and train technicians. We are promoting the development of regenerative medicine products to obtain approval for the manufacture and sale of cell sheets.

1 Development of Manufacturing Methods and Contract Manufacturing for Cell Sheet Products

- Development of cell sheet manufacturing methods
- Contract manufacturing of cell sheet products
- Quality testing of cell sheets, etc.

2 Facility Management and Application Support

- Support for preparing and submitting applications
- Support for document creation/ consulting
- Support for operation and maintenance of facilities equipment/ management system, etc.

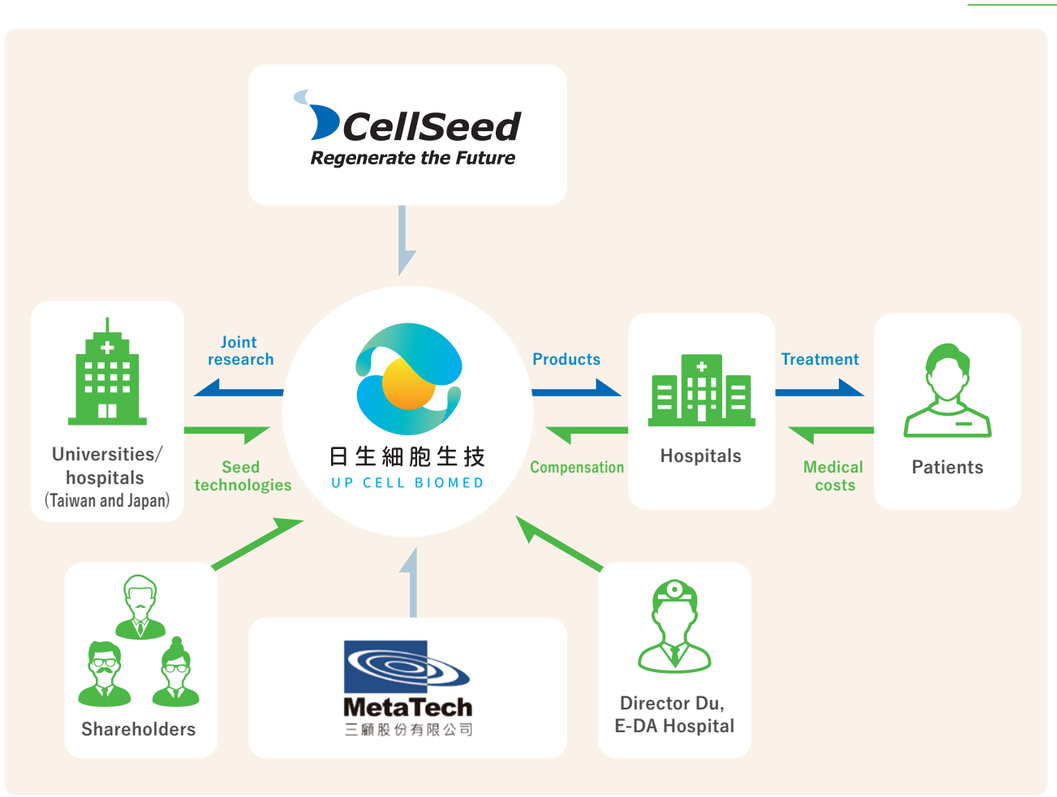
3 Training of Cell Culturing Technicians

- Cell sheet culturing training
- Cell sheet harvesting training, etc.

*Our Cell Processing Facility was licensed in March 2017 to manufacture and process specified cell products (license number: FA3160008).

06 Establishing Up Cell Biomedical Co.

In November 2019, CellSeed pooled funds with its business partner, MetaTech (AP), and the two established a joint venture in January 2020. The aim is to conduct research and development in order to commercialize cell sheet regenerative medicine based on seed technologies from universities and other entities in Taiwan and Japan.



Name	Up Cell Biomedical Co.
Address	14F.-2, No. 75, Sec. 1, Xintai 5th Rd., Xizhi Dist., New Taipei City 221, Taiwan (R.O.C.)
Representative	President Andrew H.-J. Wang
Capital	NT$130,000,000 (at establishment; approx. 500,000,000 yen)

Board Members

- President / Andrew H.-J. Wang
- Vice President / Ho Hung-Neng
- Director / Setsuko Hashimoto

Scientific Advisory Board

- Chen Yaochang
- Huang Yen-Hua
- Masayo Takahashi

Creating New Medical Treatments for Patients

Setsuko Hashimoto
Representative Board Director and President/CEO CellSeed Inc.

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Masayo Takahashi
Representative Board Director and President/CEO Vision Care Inc.

■ Pioneer's Perspectives on Regenerative Medicine

Hashimoto: Dr.Takahashi, you are an extremely brave physician, the first in the world to carry out regenerative medicine using iPS cells. You regard the perspective of clinicians as important, and there is so much to learn from your remarks. I'm impressed with your intent to create the new medical treatment of regenerative medicine and your perspective of always considering what is best for the patients.
Moreover, you made the extraordinary and courageous transformation from being a researcher to being a company president to achieve your own dream. Would you please tell us a little about your company?
Takahashi: I have been involved with regenerative medicine using iPS cells for a long time, since I was at the Institute of Physical and Chemical Research (RIKEN). Regenerative medicine is one method of many, but I established Kobe Eye Center based on the principle of improving the lives of people with visual impairments using every possible method.
The establishment of my company brought together four types of organizations: the Kobe Eye Center Research Institute, hospitals, patient care departments and Vision Care.
In the last two years, departments outside Vision Care have been steadily arriving, so we are still putting the finishing touches on this corporation. Right now, we have eight employees, but in the future the RIKEN Takahashi lab will join, so there will be 40–50 employees.

■ Kobe, Home to a Biomedical Innovation Cluster

Takahashi: Thirteen years ago, I moved from Kyoto University Hospital to RIKEN in Kobe, a city that is home to a Biomedical Innovation Cluster. It very intentionally attracts health-care-related companies.
Hashimoto: As a reconstruction measure after the Great Hanshin-Awaji Earthquake, Kobe has attracted numerous companies with its policy of bringing together everything from basic research on regenerative medicine to hospitals.
Takahashi: That's true. Today, there are about 360 companies. At first, there were many empty lots, but after more than 100 companies came it seemed to gain momentum. Basic research, industry, and hospitals are very close, so interactions are unfettered and extremely efficient. Given that I was at RIKEN in Kobe, I also was inclined to create a company in the city.
Hashimoto: It's good to have a cluster with a concentration of various functions. How do you feel about it now?
Takahashi: From the beginning, I felt it was necessity to have a corporate organization as part of the Kobe Eye Center, so I established it as a corporation. I left RIKEN, took the plunge, and transitioned to business management when it came time for full-fledged commercialization of regenerative medicine. The truth is, I think I might be more suited to company management (laughs).

■ Aims of Regenerative Medicine

Hashimoto: Thank you. Could you tell us about the regenerative medicine you envision?
Takahashi: This kind of new treatment method tends to be expensive if it uses conventional culturing processes, and that makes it difficult for many people to use. I want to create treatments that are extremely fast, safe, and inexpensive.
I believe there is an opportunity to do this in the Japanese system, and our company is aiming to create a patient-oriented treatment system.

■ Impressions of CellSeed Products

Hashimoto: You're using our company's cell cultureware, UpCell®, and we have also asked you to evaluate new UpCell® products. What do you think of them?
Takahashi: I have very high expectations of UpCell®. Using it enables the creation of cells in sheet form, which is extremely important in retina transplants. This made-in-Japan technology of cells in sheet form instead of disconnected cells supports this medical treatment.
Normally, artificial membranes are used when creating sheets, but when they are artificial, there are inevitably unfavorable effects such as inflammation that occur in transplants. I really like that UpCell® uses a basement membrane made of only live cells.
Hashimoto: Cell sheet engineering from Japan, which enables to create cell sheets without any artificial materials, is contributing to regenerative medicine. I'm very pleased that you're interested in it.
Takahashi: I've really been a fan of this cell sheet technology and treatment method for the esophagus, and have always wanted it to succeed since it can truly benefit patients. Talking about it with you, it's great to see that your thoughts about the clinical setting are very similar to mine. CellSeed is a company, but it's earnestly considering how to create treatments beneficial to patients, and there is much that I agree with. I'd appreciate if you would teach me a few things about creating a company (laughs).
Hashimoto: I'm encouraged and reassured by you; every time we meet you ask me how the esophageal clinical trials are going and wish me luck. I believe these clinical trials will help improve the quality of life of patients.

■ Regulations in the PMD Act and Regenerative Medicine

Hashimoto: However, under Japan's current Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (PMD Act), I feel frustration that the advantages of this product cannot find a place within the regulatory agency's approach and current rules.
Takahashi: I feel that way, too. It's ridiculous not to recognize a treatment believed to be truly good for patients, but I think right now an opportunity exists in Japan, so we must make treatments that are good for patients that can acquire approval and generate profits.
Hashimoto: You're hitting the nail on the head. You clearly understood what I was saying about the inconsistencies and shortcomings we are facing implementing the clinical trial. I agree with your view of how things stand.
Takahashi: When conducting surgery in ophthalmology, there is a sense that it is natural for all examples of pathological changes to be different, so the fact we are told to conduct clinical trials according to a single rule is extremely unfortunate. I serve as the director for the Japanese Society for Regenerative Medicine. In Japan, there is a very special environment in which the Ministry of Health, Labour and Welfare, the PMDA, and academic societies cooperate to create rules, and I feel there is likely a way forward unique to Japan.

■ Future Developments in Regenerative Medicine

Hashimoto: CellSeed established a joint venture with a Taiwanese company, and you're a member of that company's Scientific Advisory Board. I'm really looking forward to the opportunities to work together in various areas for the advancement of regenerative medicine, including in Taiwan.
Takahashi: It seems we can gain understanding from Taiwan and various other countries in Asia on the approach to methods of creating treatments. I readily accepted when asked to be an advisor and am very much looking forward to talking with researchers from Taiwan.
Hashimoto: To wrap up, please tell us about the future of development in regenerative medicine.
Takahashi: We're already moving ahead with six regenerative medicine projects using iPS cells in the clinical setting, including heart and cornea. We plan to take up the even greater challenge of photoreceptor cells. I think that is five years ahead of the rest of the world, so there are even more expectations of support from CellSeed in the future.
Hashimoto: Thank you so much for sharing this valuable information with us today.

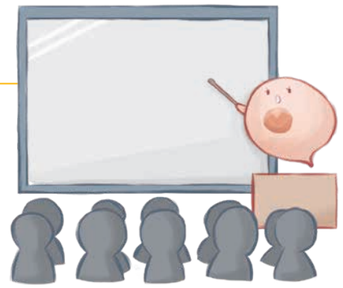
Masayo Takahashi

In 1986, she graduated from the Faculty of Medicine at Kyoto University. In 1992, she concluded the doctorate program at the Graduate School of Medicine at Kyoto University (visual pathology). After working as an assistant at the Graduate School of Medicine at Kyoto University, in 1995 she became a researcher at the Salk Institute for Biological Studies and discovered the possibility of using stem cells in retina treatments. She served as an assistant professor in the Development Dept. of Kyoto University Hospital Translational Research Center, and moved to the Institute of Physical and Chemical Research in 2006. She has been the Representative Board Director and President/CEO of Vision Care Inc. since August 2019.

Setsuko Hashimoto

Joined Hoechst Japan in 1984, Pharmacia BioTech in 1991, and Biacore in 1998 before founding Bio-Business Bridge in 2008. Appointed Senior Investment Advisor at the Embassy of Sweden in Japan in 2009. After serving as Vice President and Executive Director of CellSeed Inc. from March 2014, Hashimoto was appointed Representative Board Director and President/CEO in June of the same year.

08 The first Cell Sheet Engineering Innovation Forum



▲ The 1st Cell Sheet Engineering Innovation Forum held on July 19, 2019

The 1st Cell Sheet Engineering Innovation Forum was held in July 2019 under the theme, “Let’s Talk About the Future of Cell Sheets!” The forum was attended by many people from industry and academia.
This year, the 2nd Cell Sheet Engineering Innovation Forum is planned to be held at Miraikan - The National Museum of Emerging Science and Innovation. The scheduled speakers include Prof. Tatsuya Shimizu of Tokyo Women’s Medical University and Prof. Yuji Miyahara of Tokyo Medical and Dental University. See the CellSeed website for details.

09 Promoting Global Business Alliances

As part of its global business alliance, CellSeed participates in exhibitions held in Japan and abroad. In 2019, we took part in approximately 10 exhibitions in locations such as Taiwan, Shanghai, and the United States. This year, we will continue to participate in exhibitions held at home and overseas with the aim of global development.

Scheduled Participation in Exhibitions in 2020 (Outside Japan)

May	China BIO (Suzhou)
June	BioUS (San Diego)
July	Bio Asia Taiwan (Taipei)
September	BIO Partnering APAC 2020 (Shanghai)
October	BIOEU Fall (Germany)
December	Healthcare EXPO TAIWAN (Taipei)

▲ Bio Asia Taiwan held in July 2019

10 CellSeed Executive Team

Representative Board Director and President/CEO
Setsuko Hashimoto

Board Director and CFO
Jun Onodera

External Board Director
Kenji Oeda

External Board Director
Noriko Taji

Audit & Supervisory Board Member
Masaki Sunaoshi

External Corporate Auditor
Toshio Yamaguchi

External Corporate Auditor
Mariko Hirose

11 Financial Information

Consolidated Income Statement

FY2019 (January 1–December 31, 2019)

Sales	275
Selling, general and administrative expenses	997
Operating income	-780
Yearly profit attributable to owners of parent company	-782

Consolidated Financials

End of FY2019 (Current as of December 31, 2019)

Total assets	1,456
Cash and securities	1,065
Liabilities	110
Net assets	1,345

(Unit: million yen; Note: Fractions smaller than 1 million are rounded off)

Highlights

In the regenerative medicine support business, sales outside Japan in particular increased significantly compared to the previous year, reaching a record high. In November 2018, we launched a business in contract manufacturing of cell sheets at our Cell Processing Facility, and sales were posted for the first time in 2019.

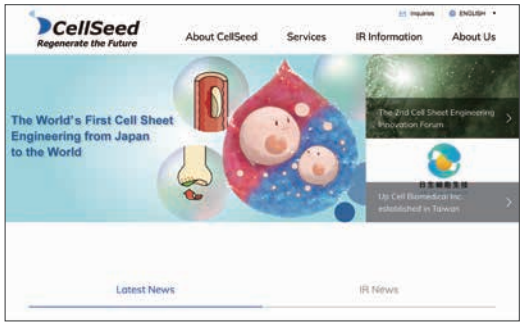
Corporate Overview

Current as of March 27, 2020

Company name	CellSeed Inc.	
Main businesses	Cell sheet regenerative medicine business Regenerative medicine support business	
Head office	Telecom Center Building, East Tower 15F Aomi 2-5-10, Koto-ku, Tokyo 135-0064 Japan	
Date established	May 2001	
Executive Team	Setsuko Hashimoto	Representative Board Director and President/CEO
	Jun Onodera	Board Director and CFO
	Kenji Oeda	External Board Director
	Noriko Taji	External Board Director
	Masaki Sunaoshi	Audit & Supervisory Board Member
	Toshio Yamaguchi	External Corporate Auditor
	Mariko Hirose	External Corporate Auditor
Fiscal year end	December	
Listed market	JASDAQ Growth (7776), Tokyo Stock Exchange	
Subsidiary	CellSeed Sweden AB	

Improved CellSeed Website

The CellSeed website has been updated and improved. Be sure to see not only the information on cell cultureware and contract services, but also the information about our company.



CellSeed Search

https://www.cellseed.com/en/

Stock Information

Current as of December 31, 2019

Total no. of issuable shares ·····35,537,600

Total no. of issued shares ·····12,981,819

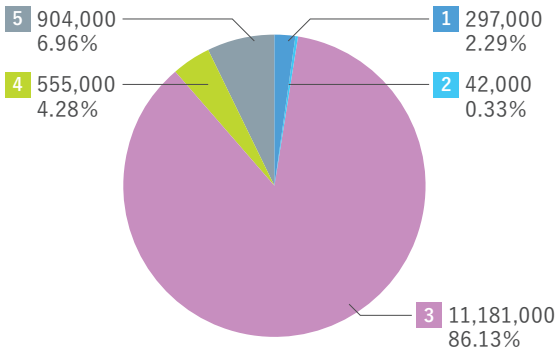
No. of shareholders ···13,853

No. of shares constituting one unit ·····100

Stock Distribution by Owner

1 Foreign corporations, etc. 2 Financial institutions 3 Individuals and others
4 Other corporations 5 Financial instrument brokers

Note: Treasury stock (154 shares) is included in "Individuals and others."



Acquisition of ISO 9001: 2015 Certification

CellSeed offers consistent quality and services in the design of and manufacturing control of cell cultureware. To further improve client satisfaction, we have constructed a quality management system and acquired certification under the international standard, ISO9001: 2015. Aiming to boost client satisfaction, we will comply with this standard and with all relevant laws and regulations as we carry out continuous improvement of quality management.

Date of registration： January 6, 2020

Period of validity： January 6, 2023

Scope of registration： Design and manufacturing control of cell cultureware
Sales of special cell monitoring devices and measuring instruments

Notes for Shareholders

Fiscal year end	December 31
General Shareholders' Meeting	March
Dividend declaration date	December 31 (Interim dividends declared June 30)
Shareholder registry administrator	IR Japan, Inc.
Special account management institution	100-6026 Securities Administration Division, IR Japan, Inc. Kasumigaseki Bldg. 26F Kasumigaseki 3-2-5, Chiyoda-ku, Tokyo Tel: 0120-975-960 (toll-free)

Public notice posted online URL：https://www.cellseed.com

(However, if posting online is not possible due to unavoidable circumstances, public notice will be issued in the *Nihon Keizai Shimbun*.)

Notes:

1. Along with electronic conversion of stock certificates, we comply in principle with petitions for changes of address, purchase requests, and other types of procedures regarding the shareholder made through account management institutions (stock brokerage firms, etc.) where shareholders have established accounts. Please contact the stock brokerage or other institution where the account has been established. Please note that these changes cannot be handled by the shareholder registry administrator (IR Japan, Inc.).
2. With regard to procedures related to shares recorded in special accounts, please contact the special account management institution (IR Japan, Inc.).