

2018.1.1~2018.12.31

 **CellSeed**
Regenerate the Future

CellSeed Inc.

JASDAQ Growth (7776)

With you CellSeed Vol.11





Regenerative Medicine Technology to Support the Medical Care of the Future



What Is Cell Sheet Engineering?

Cell sheet engineering is a technique for culturing 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 methods. In addition, this technique can also be used to prepare cell sheets from cells of a number of biological tissues and organs, and we are making progress on research into stacking multiple cell sheets and bonding them to produce tissues and organs of the needed thickness.

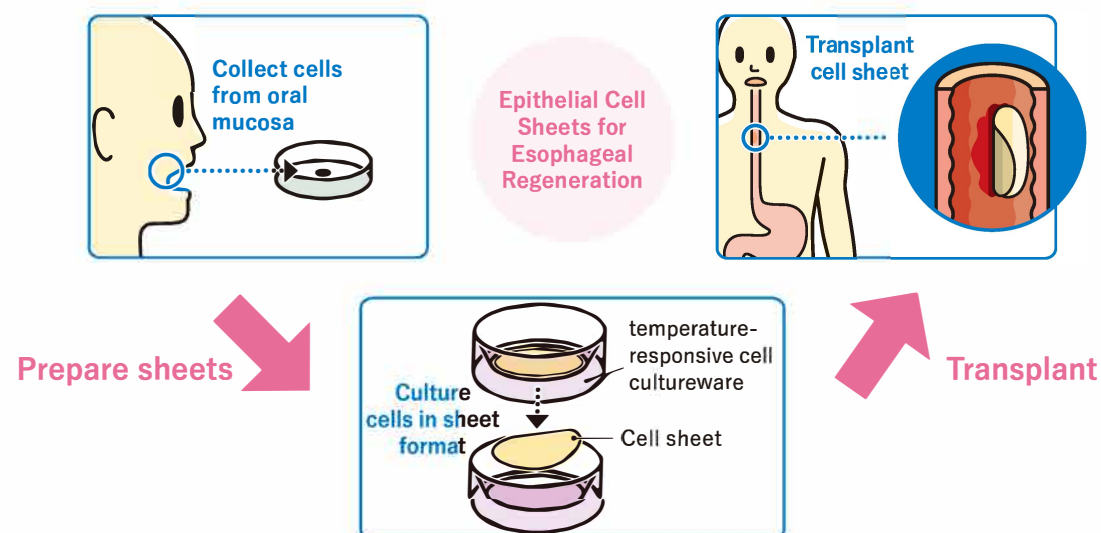
*Cell cultureware that allows for the collection of cells cultured in sheet form by altering the temperature and without the use of enzymes.

Cell Sheet Regenerative Medicine Business

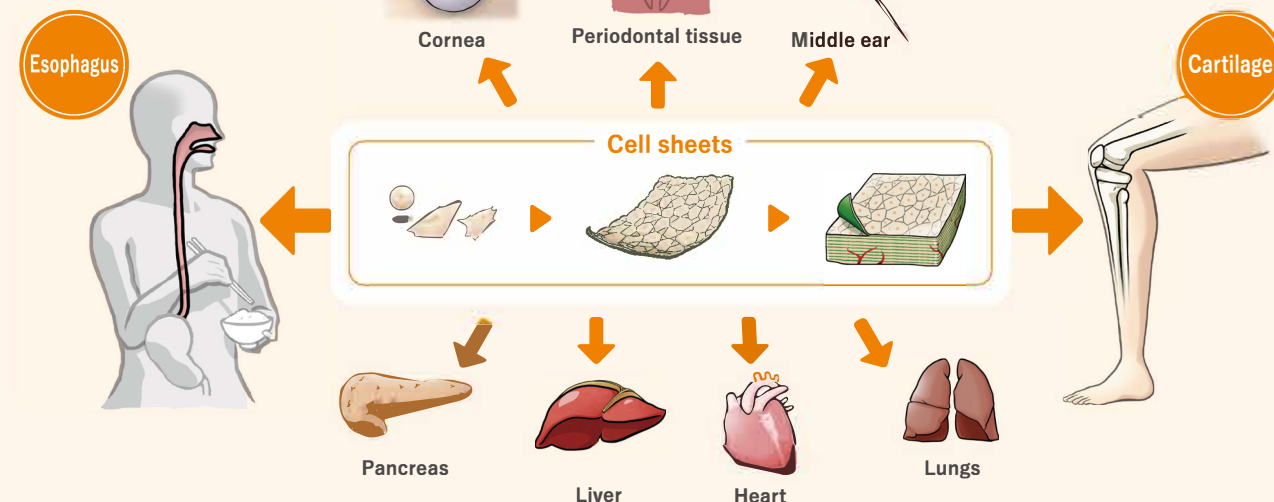


Epithelial Cell Sheets for Esophageal Regeneration

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 due to 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.

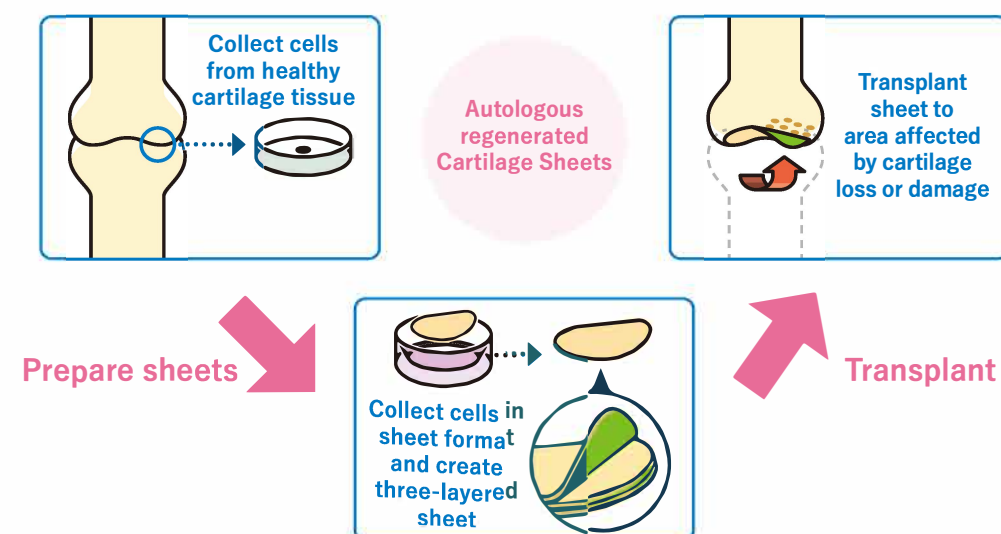


Cell sheet applications



Regenerated Cartilage Sheets

The regeneration of hyaline cartilage has been confirmed with autologous cartilage cell sheets using the patient's own knee joint cartilage, manufactured in the temperature-responsive cell cultureware, then transplanted into knee joints affected by cartilage loss or damage. This autologous cartilage cell sheet has been approved for the Advanced Medical Care B program at Tokai University Hospital. Going forward, we will contract manufacture of cell sheets used in Advanced Medical Care for a fee. We are also currently exploring the development of other types of allogeneic regenerated cartilage sheets using allogeneic cartilage cells.



Regenerative Medicine Support Businesses 1

Regenerative Medicine Contract Services



At our Cell Processing Facility, we engage in contracted business related to the manufacture of cell sheets, the operation of facilities, and the preparation of application documents. With a manufacturing and quality control system that conforms to Good Gene, Cellular, and Tissue-Based Products Manufacturing Practices (GCTP) in compliance with Japan's Act on the Safety of Regenerative Medicine, we provide safe and high quality products and services through our experienced staff. In November 2018, we won an order for allogenic periodontal ligament-derived mesenchymal stromal cell sheets from the Institute of Advanced BioMedical Engineering and Science, Tokyo Women's Medical University in our first contracted project.

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.

Primary Services

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

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



2 Facility Management and Application Support

- Support for preparing and submitting applications for obtaining a business license to manufacture specified cell products
- Preparation of SOPs, standards, and other documentation; consulting; etc.



3 Training Cell Culturing Technicians

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



Cell Processing Facility

Completed in 2016, our Cell Processing Facility was licensed in March 2017 to manufacture and process specified cell products (license number: FA3160008). In October 2018, the facility gained manufacturing business accreditation for regenerative medicine products, and we are now promoting development aimed at acquiring manufacturing and marketing approval for cell sheets as a regenerative medicine product.

Features

Control System

24-hour automatic monitoring system

Monitors cleanliness, room pressure, temperature, humidity, operational status of instruments and equipment, etc

Human resources

Staffed by a good number of clinical cultivators accredited by The Japanese Society for Regenerative Medicine and other experts in cell culturing

Access

Approx. 20 minutes by car from Haneda Airport

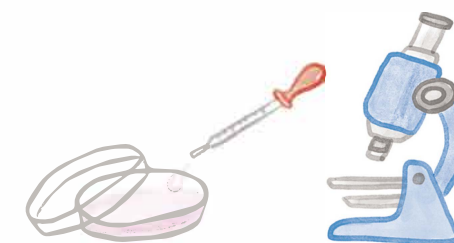
Track record

- Contracted manufacturing of products for clinical trials (Tokyo Women's Medical University)
- Technology transfer
- Process Validation
- Contracted cell sheet culturing training, etc.



Regenerative Medicine Support Businesses 2

Products that Support Regenerative Medicine



We deliver unique and super tools to support researchers working on regenerative medicine, as well as basic medical researchers who work with cells. Our lineup includes such cultureware as UpCell® proprietary cell cultureware capable of producing cell sheets, RepCell™ for intact cell recovery, and HydroCell™ capable of 3D culture of cancer cells, ES cells, and iPS cells.



cell cultureware

UpCell®

Temperature-responsive cell cultureware for cell sheet collection

Collected as a cell sheet only by altering the temperature

cell sheet
Image of collection

37°C → 20°C



Collected using CellShifter™ as cell sheet support medium

HydroCell™

The ultimate low cell binding cultureware

Completely suppresses cell binding to make 3D cultivation possible



RepCell™

Temperature-responsive cell cultureware for cell collection

Collects intact cells without use of proteolytic enzymes

Regenerative Medicine Support Labware



cellZscope+ / cellZscope2

Real-time monitoring system for tight cellular junctions

- Monitors formation of and changes to intercellular adhesion in real time
- Ideal for in vitro pharmacology evaluation of lead compounds



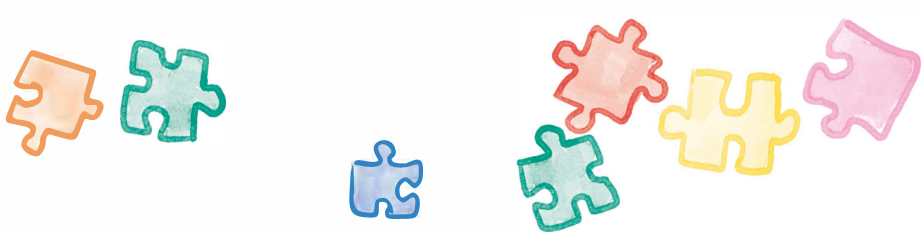
cellZscopeE

Real-time monitoring system for tight cellular junctions

- Available in a more compact size
- Upgrade to cellZscope+ also available



The World's First Cell Sheet Engineering from Japan to the World



Setsuko Hashimoto

President and CEO
CellSeed Inc.



Hung-Te Tang

General Manager
MetaTech (AP) Inc.

Signing a Business Alliance with Taiwanese Company Drives Progress toward Commercialization

Introduction to Corporate Profile

Hashimoto: Thank you attending this interview in Japan today. We signed an agreement with MetaTech in April 2017. I would like to ask you about MetaTech this time. First of all, could you please introduce the company's profile?

General Manager Tang: We, MetaTech(AP) Inc., were established in 1998. We achieved outstanding results in the distributor of products specializing in electronic components and were listed as the Taiwan over-the-counter company in June 2004.

For the past two decades, we have been operating as a distributor for Samtec, E-switch, and other major electronic components companies. Our customers are now spread worldwide, and they include Inventec, Quanta, Delta, Foxconn, and Lite-On. Our headquarters are located in New Taipei City, Taiwan, with subsidiaries in Hong Kong, Shenzhen, and Singapore, and branches and offices in Thailand, the Philippines, and India.

We also invited a team of biomedical experts from Taipei Medical University in August 2013 to enter the biomedical field. In addition, in April 2017, we partnered with CellSeed in Japan and signed a formal contract to introduce cell sheet technology to Taiwan. We have also forged alliances with a number of medical institutions to develop related fields.

At present, Hung-Neng, superintendent of National Taiwan University Hospital, Jui-Chieh Chen,

superintendent of Taipei Medical University Hospital, Chih-Hui Yang, vice president of E-da E-da Hospital, comprise the Board of Directors. In addition, the President of the "Taiwania Capital" Dr.Jung-I Wu individually act as the independent director of MetaTech. The Taiwania Capital is one of the companies that the Taiwanese government actively supports. The National Development Fund of the Government of Taiwan, one of Taiwan's government-led funds, holds 4.79% of our shares. Therefore, we can say that we are a company supported by the Taiwanese government.

Incentives to Enter the Regenerative Medicine Industry

Hashimoto: What do you believe is the reason you have moved from the

field of electronic components to the field of life science and then to the field of regenerative medicine?

General Manager Tang: I believe this is because companies in Japan, such as Hitachi and Panasonic, have already begun development projects related to regenerative medicine, and Taiwan also undertakes similar activities. Regenerative medicine has attracted attention as a field of growth in Taiwan, and the Taiwanese government is actively supporting this field.

Although Taiwan has a high standard of medical care, regenerative medicine is still in the research and development (R&D) stage, and its practical application has not yet progressed. By introducing world-class regenerative medicine technology, we hope to make significant progress in new devices and technologies that support regenerative medicine, by pioneering new avenues and empowering patients.

Current Status of Medical Care in Taiwan

Hashimoto: What expectations do Taiwanese people have of regenerative medicine?

General Manager Tang: Owing to advances in therapeutic technologies in Taiwan, including in the field of pharmaceuticals and surgery, many diseases can be treated. However, even today, some diseases remain difficult to treat.

There have been many clinics operating in the gray zone, as no clear rules have yet been set on regenerative medicine in Taiwan. These clinics offer what is called "cell therapy" and claim expensive treatment costs for magical treatment effects.

However, the efficacy and safety of these treatments have not been proven, and although patients have paid high treatment costs, they do not respond as expected.

In September 2018, Taiwan's Ministry

of Health and Welfare (equivalent to the Japanese Ministry of Health, Labour and Welfare), in response to the demands of those in need of such treatment, promulgated the Act on the Application of Specific Diagnostic Techniques and Medical Devices in order to facilitate the early introduction of cell therapy technologies.

This legislation stipulates clear requirements for regenerative medicine, such as "being performed by a qualified physician, in a qualified hospital, or a qualified GTP cell processing center." This will eliminate the gray zone of regenerative medicine in the future. People will be able to receive safe and effective treatments at an affordable cost, enabling them to choose treatments that are different from those that are common.

New Regenerative Medicine-Related Laws in Taiwan

Hashimoto: You mentioned that a new law on regenerative medicine was enacted in Taiwan. Would you like to talk a little more about that law?

General Manager Tang: The laws and regulations for regenerative medicine in Taiwan are similar to Japan, which are subdivided into medical techniques and medical products.

The Act on Specific Diagnostic Techniques and Applications of Medical Devices enables medical institutions to plan treatments in accordance with the designated rules and, after obtaining approval from the Regulatory Affairs of the Ministry of Health and Welfare in Taiwan, provide cell therapy tailored to individual symptoms.

On the other hand, Taiwan's Ministry of Health and Welfare's Food and Drug Administration Department is expected to announce the Regulations for the Management of Regenerative Medicines in 2019. At

the Taiwan Legislative Court, final discussions are currently underway prior to the enactment of the law. This law is intended to establish a licensing system that sets strict conditions for "pre-marketing review and post-marketing surveillance" in accordance with international laws, regulations, and operation trends. The ultimate goal is to reduce the distress of patients with end-stage cancer and other intractable diseases and to improve the quality of life of older people. Taking advantage of Taiwan's superior medical environment, we will work toward becoming the center of cell therapy in Asia in the future.

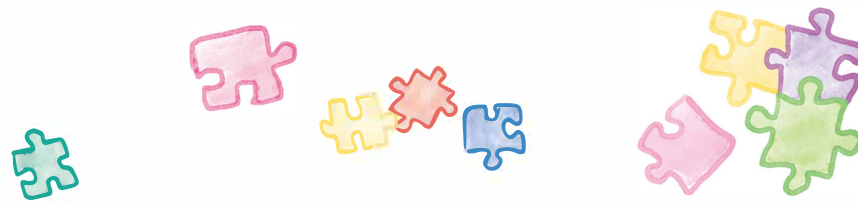
Hashimoto: I think it is very similar to "Act on Securing Quality Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics" revised in 2014.

It is very timely that new legislation will be enforced in Taiwan during the same time MetaTech and CellSeed collaborate.



Hung-Te Tang

Served as Director of Cheer Digiart, Supervisor at Taiyen Biotech, Assistant Manager of the Finance Department at Far Eastern Air Transport, and Manager/ Unit Manager of Jih Sun Bank, before his appointment as Director and General Manager of MetaTech (AP) Inc.



Details of the Alliance and Current Progress

Hashimoto: You have already submitted an application for clinical trials, but would you like to talk a little about what progress is being made?

General Manager Tang: Yes. In December 2018, Taiwan submitted an application for a Phase III clinical trial of Epithelial Cell Sheet for Esophageal Regeneration to the Ministry of Health and Welfare in Taiwan.

We are also discussing collaborating on regenerated cartilage sheets with a well-known hospital in Taiwan. We have already concluded alliances with seven prominent hospitals: the Taiwanese University Hospital, the Tri-Service Hospital, the Taipei Medical University Hospital, the Shin Kong Memorial Hospital, the E-Da Hospital, the Kaohsiung Veterans General Hospital, and the Kaohsiung Medical University Hospital. We expect to collaborate with 12 more prominent hospitals. Currently, we are proceeding with application procedures in accordance with the Regulations Governing the Application of Specific Medical Examination Technique and Medical Device.

Public Response in Taiwan

Hashimoto: We are very pleased to hear that the development is progressing smoothly, about a year and a half since we signed the contract.

How do Taiwanese people view this bilateral alliance?

General Manager Tang: R&D on cell sheets is actively progressing in Japan, with a focus on CellSeed. Once our technology transfer is completed and licensed, we will be able to present this technology to patients as an option. This is why we were able to gather hospitals and

doctors who want to collaborate with us in a short time. Regenerated cartilage sheets are expected to be particularly crucial. In the promotion of cartilage regeneration for both physicians and patients. Many clinicians also propose applications for cell sheets based on their own experiences. Doctors believe that regenerative medicine technology for cell sheets can solve a variety of problems in their daily clinical interactions with patients. We want to meet the expectations of these doctors.

Future Prospect

Hashimoto: I would like to hear about your future plans. What new business alliances would you expect from MetaTech and CellSeed?

General Manager Tang: We plan to construct a world-class R&D and production center at HsinChu Science Park. We will introduce state-of-the-art automated manufacturing facilities, promote the development of various technologies, and strive to develop professional human resources. I hope that CellSeed will be involved in these efforts and provide technical assistance.

Hashimoto: You have very big plans, and we will not only provide support, but also hope to pioneer new businesses together. You talked about future plans, and in the future we will work together to contribute to the development of regenerative medicine in the world. Would you like to provide some concluding comment on this matter?

General Manager Tang: We have already established an advanced alliance with many hospitals in Taiwan. We will continue to research and develop new medical technologies and devices so that doctors in Taiwan can present their patients with many options. In addition, we hope to further collaborate with CellSeed and expand this collaboration to include Southeast Asia, China, Europe, and

other countries.

Hashimoto: Thank you. Although CellSeed is still a small company, we are constantly trying to make the world's first cell sheet engineering undertaking from Japan more widespread.

We are very pleased with this opportunity to partner with MetaTech, Taiwan, and to strengthen our alliances for the future. I hope that you will be able to do so in the future. I wish you continued success. Thanks.

*GTP

Abbreviation for Good Tissue Practice. It's a norm of a laboratory for cell culture.

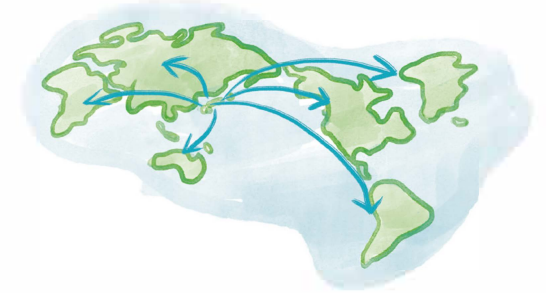


Setsuko Hashimoto

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 President and CEO in June of the same year.



Aiming for global expansion of the cell sheet regenerative medicine business



Business Alliance with Taiwanese Company

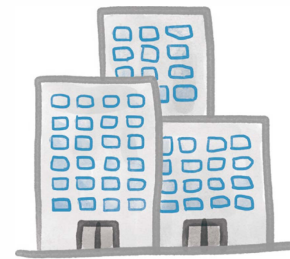
In 2017, we entered into a business alliance agreement with MetaTech (AP) Inc., an over-the-counter company in Taiwan, aimed at licensing the cell sheet regenerative medicine business in Taiwan. We are currently providing support for the manufacture and development of cell sheets to MetaTech. We also aim to expand the cell sheet regenerative medicine business to Asian countries other than Taiwan as well as Europe and the U.S., and are continuing our efforts directed at business alliances with overseas companies.



Mid-Term Business Plan (2019 – 2021)



A New Start Heading Toward Commercialization



CellSeed Management

Executive Team

Our management team works together closely to promote the company's business activities. We appreciate your continued support and confidence.



2017 / 2018 Performance and Mid-Term Business Plan (2019 – 2021) Financial Targets

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

	Sales	Operating income	Ordinary income	Quarterly profit attributable to owners of parent
FY2017 (Performance)	85	-956	-964	-966
FY2018 (Performance)	1,026	140	140	129
FY2019 (Estimate)	300	-1,100	-1,100	-1,100
FY2020 (Target)	350	-1,300	-1,300	-1,300
FY2021 (Target)	2,000	300	300	225

The First Step Toward Growth



CellSeed Financials

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

Consolidated Income Statement

FY2018

(January 1 – December 31, 2018)

Sales	1,026 million yen
Sales, general and administrative expenses	854 million yen
Operating income	140 million yen
Yearly profit attributable to owners of parent	129 million yen

Consolidated Financials

End of FY2018

(Current as of December 31, 2018)

Total assets	1,586 million yen
Cash and securities	1,057 million yen
Liabilities	174 million yen
Net assets	1,411 million yen

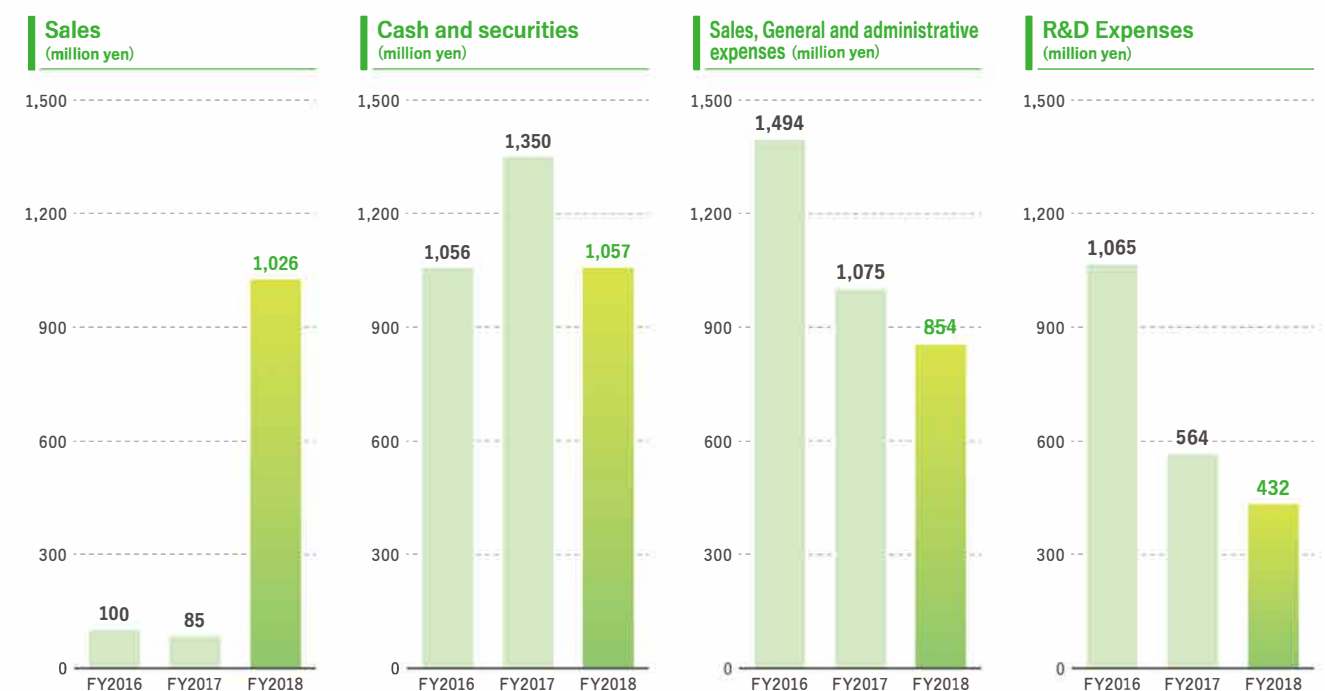
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Profit Achieved for First Time Since Establishment

The cell sheet regenerative medical business recorded segment sales of 960 million yen in the fiscal year ended December 31, 2018 based on the exclusive business alliance agreement for Taiwan concluded in the cell sheet regenerative medicine business with a Taiwanese company (MetaTech (AP) Inc.) The regenerative medicine support business recorded segment sales of 66 million yen in the fiscal year ended December 31, 2018, which roughly maintained the same level of 69 million yen in segment sales recorded in the fiscal year ended December 31, 2017. In addition, on the expenditure front, development outsourcing expenses and maintenance costs for cell culturing facilities were lower than initial estimates.

As a result, net sales for the fiscal year ended December 31, 2018 were 1,026 million yen. Operating income amounted to 140 million yen and ordinary income was 140 million yen. Yearly profit attributable to owners of parent was 129 million yen, achieving profitability for the first time since our establishment.

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



Company Data

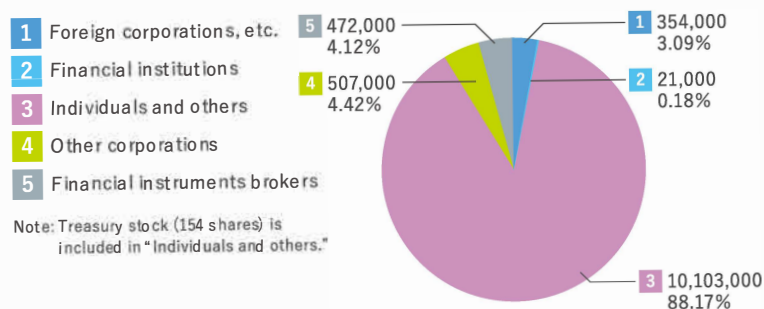
Corporate Overview Current as of April 1, 2019

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	President and CEO Board Director and CFO External Board Director External Board Director Audit & Supervisory Board Member External Corporate Auditor External Corporate Auditor	Setsuko Hashimoto Jun Onodera Kenji Oeda Noriko Taji Masaki Sunaoshi Toshio Yamaguchi Mariko Hirose
Fiscal year end	December	
Listed market	JASDAQ Growth (7776), Tokyo Stock Exchange	
Subsidiary	CellSeed Sweden AB	

Stock Information Current as of December 31, 2018

Total no. of issuable shares	35,537,600
Total no. of issued shares	11,459,419
No. of shareholders	12,522
No. of shares constituting one unit	100

Stock Distribution by Owner

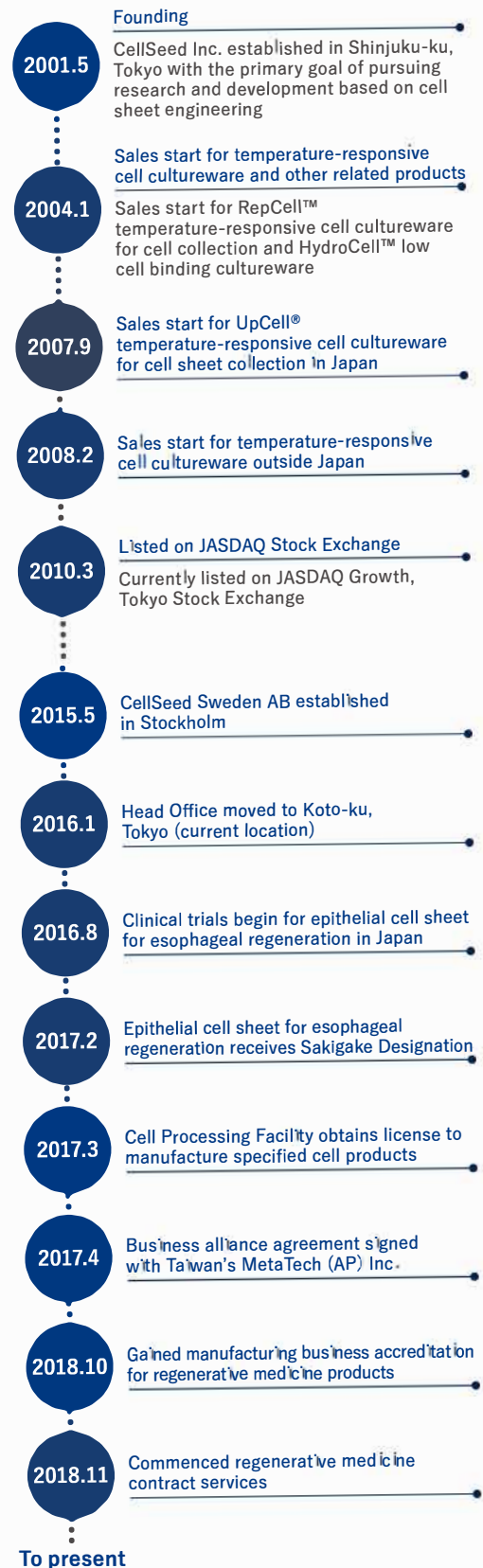


Notes for Shareholders

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

Public notice posted online [URL: https://www.cellseed.com/index.html](https://www.cellseed.com/index.html)
(However, if posting online is not possible due to unavoidable circumstances, public notice will be issued in the Nihon Keizai Shimbun.)

Company History



Notes:

- 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.).
- With regard to procedures related to shares recorded in special accounts, please contact the special account management institution (IR Japan, Inc.).