



# Mid-term Business Plan Fiscal Year 2020 to Fiscal Year 2022

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Company Name: CellSeed Inc. (TSE 7776)

Representative: Setsuko Hashimoto, President and CEO

Contact: Jun Onodera, CFO and Board Director

Telephone: +81 3-6380-7490

- 1. Mid-term Business Plan for the Next 3 Years
- (1). Summary of the previous consolidated fiscal year at the time of submission of this mid-term business plan

The Japanese economy during the current consolidated fiscal year underwent gradual recovery in the first half against the backdrop of upturns in corporate earnings and favorable employment and income trends. However, the second half is presenting uncertainties, firstly with the dampening of domestic demand due to the rise in consumption tax in October and the aftereffects of powerful typhoon damage, accompanied by global developments such as the trade friction between the USA and China, difficulties in Japan-Korea relations, Brexit, and the spread of the novel coronavirus.

In the realms of advanced medicine and regenerative medicine, in which the CellSeed Group operates, new market entries are increasing in number including major corporations, in the wake of the Act on the Safety of Regenerative Medicine (ASRM) coming into effect on November 25, 2014. Thus, regenerative medicine is likely to grow into a huge market. After Professor Shinya Yamanaka successfully generated human iPS cells, many R&D projects aimed at practical applications of iPS cells are being undertaken for their use in regenerative medicine. Expectation and interest in the future use of regenerative medicine are mounting greatly.

This is the context in which CellSeed's cell sheet regenerative medicine business operates. CellSeed is promoting research and development on epithelial cell sheet for esophageal regeneration, regenerated cartilage sheet and other cell sheet regenerative medicine products that are in its product development pipeline. We have begun investigating the possible development of regenerated periodontal ligament cell sheet, which will be the third in the line of cell sheet products to follow the epithelial cell sheet for esophageal regeneration and the regenerated cartilage sheet.

In our regenerative medicine supporting business, CellSeed looked to expand the cultureware business segment, engaging in R&D on new lines focused on customer requests and on customized products. In marketing, we aimed to expand sales of intelligent cell cultureware, mainly temperature responsive cell cultureware. To do so, we gathered and analyzed sales and other data from our key marketing agents and engaged in joint sales activities. We exhibited our products in the display booth at the exhibition organized alongside the 18th Congress of the Japanese Society for Regenerative Medicine in March 2019. Thanks to

such strong sales promotion of our products, the cultureware business posted the largest ever sales for the segment due to a huge year-on-year increase in sales, especially overseas.

CellSeed launched a new line of business in Fiscal Year 2019, Contract Development and Manufacturing Service to support regenerative medicine using our Cell Processing Facility. We succeeded in posting sales in the first quarter of Fiscal Year 2019 for the first cell sheet regenerative medicine contract service to be used in investigator-led clinical study on periodontal ligament cell sheet commissioned by the Tokyo Women's Medical University in 2018. With the aim of raising CellSeed's profile and enhance recognition of the growth potentials of regenerative medicine business, we organized the 1st Cell Sheet Engineering Innovation Forum in July 2019. We were pleased to welcome many participants from academia and the private sector totaling some 160. The Forum was well received, with active discussions ensuing on research into cell sheet engineering and its clinical application. The Forum was instrumental in forging new relationships such as partnering, collaboration and contract manufacture, which has led us to organize the 2nd Cell Sheet Engineering Innovation Forum to be held in October 2020.

In our overseas business, CellSeed signed an exclusive alliance agreement in April 2017 on cell sheet regenerative medicine business in Taiwan with a Taiwanese company MetaTech (AP) Inc. ("MetaTech"). Under this agreement, we granted MetaTech the rights to develop, manufacture and market exclusively in Taiwan with regard our cell sheet regenerative medicine business (epithelial cell sheet for esophageal regeneration, regenerated cartilage sheet). Accordingly, MetaTech is now the key promoter of the development and commercialization of cell sheet regenerative medicine business in Taiwan with support from CellSeed. Operating under this agreement. milestone sales in the fiscal year ended December 2019 was 150,000 thousand yen. The 20,000 thousand yen out of this total was autologous cartilage milestone payment resulting from MetaTech's partner institution, E-Da Hospital of the E-Da Healthcare Group (Kaohsiung City, Taiwan) applying for autologous regenerated cartilage sheet transplant and receiving approval as a cell therapy technology action plan (comparable to what is classed as Advanced Medicine in Japan) on December 18, 2019 by the Ministry of Health and Welfare of Taiwan (equivalent of the Ministry of Health, Labour and Welfare in Japan). When treatment commences and 10 cases are completed, there will be a milestone payment of 50,000 thousand yen to be posted on our accounts. MetaTech will pay CellSeed royalty of several % of sales in line with MetaTech sales once the regenerated cartilage sheet being developed by MetaTech gets launched (sold) on the market. We will continue to provide support to MetaTech for their effort in epithelial cell sheet for esophageal regeneration and regenerated cartilage sheet businesses.

Meanwhile, the business alliances relating to the development, manufacture and marketing of the pipeline products other than esophageal and cartilage sheets will materialize under the joint venture company set up in Taiwan in January 2020, jointly funded by CellSeed and MetaTech and supported by the Taiwanese authorities.

What this means is that the joint venture company that we established will utilize the seeds technology provided by Japanese or Taiwanese universities and research institutions in order to develop regenerative

medicine products and therapies using cell sheet engineering, examining product profiles and optimizing manufacturing methods to achieve their development. Seeds developed by Dr. Yuan-Kun Tu of E-Da Hospital, E-Da Healthcare Group (Kaohsiung City, Taiwan) represents one candidate in this flow. Our regenerative medicine support business intends to give support in the form of consulting on clinical development and in manufacturing and sales approval application submission.

Other future options are the out-licensing of product lines developed by CellSeed other than the esophageal and cartilage regenerative sheets. Not only that but there is also the option of in-licensing into Japan the products developed by the joint venture company with a view to obtaining manufacturing and sales approval. If all goes well, the product sales will be included in CellSeed's business results, boosting our sales total.

As a result of the activities above, we recorded sales of JPY275,824 thousand (down JPY750,269 thousand year on year), and operating loss of JPY780,796 thousand (down from an operating income of JPY140,062 thousand in the previous consolidated fiscal year), with ordinary loss of JPY786,234 thousand (down from an ordinary income of JPY140,675 thousand in the previous consolidated fiscal year). Net loss attributable to owners of parent was JPY782,398 thousand (down from net profit attributable to owners of parent of JPY129,745 thousand in the previous consolidated fiscal year).

## Performance results by segment is as follows:

## (i). Regenerative medicine supporting business

We promoted sales activities on intelligent cell cultureware, mainly temperature responsive cell cultureware. As described above, overseas sales in particular grew hugely year on year and the cultureware business posted record sales. In Japan, we strategically consolidated key agents, sharing marketing information and collaborating in marketing activities, which greatly contributed to increasing sales. 2019 saw sales figures being posted by the regenerative medicine contract manufacture business which we started up in November 2018 as a new business supporting regenerative medicine through the effective use of our Cell Processing Facility.

As a result of the activities above, we recorded sales of JPY117,134 thousand (up JPY51,040 thousand year on year), and operating loss of JPY46,531 thousand (up from an operating loss of JPY70,272 thousand in the previous consolidated fiscal year).

#### (ii). Cell sheet regenerative medicine business

In the cell sheet regenerative medicine business, CellSeed is promoting research and development into epithelial cell sheet for esophageal regeneration, regenerated cartilage sheet and other cell sheet regenerative medicine products that are in its product development pipeline.

In the product pipeline of epithelial cell sheet for esophageal regeneration, we had been preparing for clinical trials since August 2016. We finished case registration in trial institutions by the end of April 2018. No side effect was reported in the clinical trials, meaning that no safety issues were confirmed; on the other hand, the efficacy rate of the "effectiveness of stricture prevention 8 weeks after endoscopic

submucosal dissection (ESD)", which was an important evaluation item, did not show statistical significance to the threshold response rate (the rate of cases of non-stenosis in patients who did not receive any treatment after ESD). Although the Pharmaceuticals and Medical Devices Agency (PMDA) confirmed safety, it deemed that data on efficacy was insufficient. Accordingly, before manufacturing and sales approval can be granted, we are required to conduct an additional clinical trial to obtain and provide data that confirm efficacy.

The Guideline for Diagnosis and Treatment of Carcinoma of the Esophagus 2017 (complied by the Japan Esophageal Society) strongly recommends as a preventive measure for stenosis after endoscopic treatment of esophageal cancer either local injection or oral administration of steroids. Steroids are now the most common treatment method used to prevent stenosis. Steroids are recognized as inexpensive and effective means of treatment. Therefore, for our additional clinical trial, we need to register patients at risk if given steroids. We are currently in consultation with PMDA regarding details concerning the subjects and the number of cases required.

Such being the situation, we are continuing with our development effort and as soon as our consultation with PMDA is finished due notification will be given swiftly on the timing of our manufacturing and sales approval submission.

The clinical trial in Europe on esophageal cancer was halted because ESD is not widely used in clinical practice in Europe, leading to the decision that there will not be sufficient market demand for the product. In the product pipeline for regenerated cartilage sheet and other products, our joint research partner Tokai University Hospital submitted for approval in January 2019 "the cartilage regeneration treatment with autologous cell sheets." This was approved as Advanced Medicine by the Ministry of Health, Labour and Welfare in the 71st Conference on Advanced Medicine. When this advanced medical treatment starts to be used in Tokai University, CellSeed will undertake the contract processing of autologous regenerated cartilage cell sheets. We hope to post sales in our accounts in FY2020. We intend to continue product development while ensuring income generation.

CellSeed and Professor Masato Sato of Tokai University jointly applied for US patent for cartilage cell sheet. This "Cultured cell sheet, production method thereof, and application method thereof" was granted patent in November 2019. This patent is the basic patent of regenerated cartilage sheet for transplants. This corresponds to the patents already registered in Japan and in Europe (Japanese patent number: 4921353) as notified on February 7, 2012 and March 27, 2018. This now provides intellectual property protection in Japan, Europe and the USA, which constitute the key global pharmaceutical markets, for the regenerated cartilage sheets under development by our company.

With regard the allogeneic regenerated cartilage sheet, CellSeed's R&D proposal, the "establishment of manufacturing methods for the commercialization of allogeneic regenerated cartilage cell sheet (CLS2901C)," was selected for the 2018 Project Focused on Developing Key Evaluation Technology: Evaluation for Industrialization in the Field of Regenerative Medicine (Accelerated Support Project for Regenerative Medicine Seeds Development). This was a grant project publicly advertised and funded by the Japan Agency for Medical Research and Development (AMED). The project term runs for 3 years,

from October 2018 to March 2021. The project entails the building of cell stock from polydactyly patients, optimizing of manufacturing method of regenerated cartilage sheets and quality control tests, obtaining data on safety tests and embarking on early commercial application using data acquired. We are now exploring how private companies can create a system for obtaining human tissue and building cell stock for commercial use. Regrettably, issues exist in medical institutions and public sector bodies as to building up cell stock, with inadequate provision for a system for collecting, storing and supplying cells. This has meant a delay in obtaining necessary tissue, pushing back the intended start of our clinical trial and it was only in January 2020 when tissues became available that we were able to move forward.

Tokai University, our partnering institution, completed in December 2019 transplants of 10 cases involving clinical research it conducted on allogeneic regenerated cartilage sheets. We expect to hear good test results 12 months after transplant.

Outside Japan, we generated sales of JPY150,000 thousand on the strength of the exclusive business alliance contract on cell sheet regenerative medicine business signed with MetaTech of Taiwan.

As a result of the activities above, CellSeed's sales totaled JPY158,689 thousand (down JPY801,310 thousand year on year) and operating loss was JPY424 thousand (down from an operating income of JPY497,664 thousand in the previous consolidated fiscal year).

(2). Outline of the Mid-term Business Plan and Its Background Outline of CellSeed Mid-Term Business Plan FY2020 - 22

## Cell Sheet Regenerative Medicine Business

- •Epithelial sheet for esophageal regeneration: Conduct consultation with PMDA on additional trial, aimed at early submission of application for manufacturing and sales approval.
- Allogeneic cartilage regeneration sheet: Expedite cell stock building system aimed at early clinical trial start.
- •Periodontal tissue regeneration sheet: Begin development of this third cell sheet product to follow epithelial cell sheet for esophageal regeneration and regenerated cartilage sheet.

#### Regenerative Medicine Supporting Business

- •Intelligent cell cultureware: Promote new products, ensure production capacity to meet increased demand, and aim to expand opportunities for generating further income.
- •Contract manufacture/consulting: Promote contract manufacture/consulting and aim to secure further opportunities for generating income.

## Other

- •Business alliance: Promote business alliances actively for the global marketing of made-in-Japan cell sheet engineering and aim to increase income.
- •Collaboration with MetaTech: With a view to boosting investment into regenerative medicine business in Taiwan, step up collaboration with MetaTech and Taiwanese JV company and aim to secure opportunities to generate further income.

CellSeed's business base is cell sheet engineering, an innovative regenerative medical technology made in Japan. We engage in the development of diverse cell sheet regenerative medical products and aim to diffuse them throughout the world.

November 2014 saw the coming into force of the Act on Pharmaceuticals and Medical Devices and the Act on the Safety of Regenerative Medicine. A sea-change followed in the environment surrounding regenerative medicine in Japan, leading to great progress in the commercialization of regenerative medicine products. In fact, in the last five years or so, 7 items underwent clinical trials and were approved for manufacture and sale. CellSeed will unwaveringly pursue development efforts so as to obtain approval for manufacturing and sales of regenerative medicine products.

In the regenerative medicine supporting business and similar segments, we are seeing improvements within and outside our company in such requisites such as the expansion of cultureware business overseas, establishment of the contract business system, as well as stronger collaboration with MetaTech and the Taiwanese JV company.

CellSeed will capitalize on these positive and huge changes in external environments in Japan and globally and drive forward the business plan outlined above.

## (3). Business Update and Outlook, with Preconditions Ongoing Pipeline Development Activities Led by CellSeed

Epithelial Cell Sheet for Esophageal Regeneration
 Special Features: Cell sheet produced from the autologous oral mucosal epithelial cells
 Indications: Prevention of esophageal stricture that develops after removal of early esophageal cancer by endoscopic surgery

Early esophageal cancers are treated today using endoscopic submucosal dissection (ESD), the localized removal of the lesion under endoscopy. ESD produces less stress on the patient's body but often results in post-operative strictures where the cancer was resected. Esophageal stricture is treated by balloon stents to widen the affected area. However, patients suffer severe pain. Also, with repeated recurrence of strictures requiring balloon expansion therapy, patient QOL deteriorates. In order to address such issues of early esophageal cancer treatment, Tokyo Women's University developed treatment using cell sheets. In this treatment, the cell sheet is produced from tissue harvested from the patient's own mouth (oral mucosa) and pasted onto the resected section. Encouraging the healing of the resected section has the effect of decreasing the frequency of esophageal strictures, alleviating physical stress after surgery. Regarding this pipeline effort, clinical trials were initiated in August 2016 and case registration in trial institutions was completed by April 2018. No side effect was reported in the clinical trials, meaning that no safety issues were confirmed; on the other hand, the efficacy rate of the "effectiveness of stricture prevention 8 weeks after endoscopic submucosal dissection (ESD)", which was an important evaluation item, did not show statistical significance to the threshold response rate (the rate of cases of non-stenosis in patients who did not receive any treatment after ESD). Although the Pharmaceuticals and Medical Devices Agency (PMDA) confirmed safety, it deemed data on efficacy was insufficient. Accordingly, before manufacturing and sales approval can be granted, we are required to conduct an additional clinical trial to obtain and provide data that confirm efficacy,

The Guideline for Diagnosis and Treatment of Carcinoma of the Esophagus 2017 (compiled by the Japan Esophageal Society) strongly recommends as a preventive measure for stenosis after endoscopic treatment of esophageal cancer either local injection or oral administration of steroids. Steroids are now the most common treatment method used to prevent stenosis.

Steroids are recognized as inexpensive and effective means of treatment. Therefore, for our additional clinical trial, we need to register patients at risk if given steroids. We are currently in consultation with PMDA regarding details concerning the subjects and the number of cases required.

Such being the situation, we are continuing with our development effort and as soon as our consultation with PMDA is finished due notification will be given swiftly on the timing of our manufacturing and sales approval submission.

## • Regenerated cartilage sheet

Special features: Cell sheet produced from autologous cartilage cells and allogeneic cartilage cells Indications: cartilage defects, osteoarthritis

Osteoarthritis is a disease where wear or deformation of the cartilage surface of a joint caused by aging, obesity, heredity, external injury and other causes results in difficulty in bending and stretching a knee due to pain. In recent years, the number of osteoarthritis patients is on the rise and it is estimated that 10 million patients suffer from subjective symptoms. Conservative therapies such as rehabilitation, orthosis treatment including joint supporters, and pharmacotherapy including hyaluronic acid injection are carried out for minor symptoms, whereas operative treatment is performed for serious symptoms. Although these treatments have a certain degree of effect, they are not a fundamental therapeutic method.

Regarding the regenerated cartilage sheet using autologous cells, Tokai University, our partnering institution, succeeded in generating a regenerated cartilage sheet from the patient's own cartilage tissue. The cartilage cell sheet is harvested only by means of temperature alteration, without using enzymes. The cell sheet thus retains the adhesive proteins on the cell surface, allowing it to readily graft onto the intended area. The transplanted cartilage cell sheet is thought to protect the damaged areas and to secrete proteins needed for cartilage regeneration, thereby assisting with the cartilage's own tissue repair mechanism.

The Tokai University team applied for designation of this project as Advanced Medicine with the aim of extending the indication to be investigated beyond that of its clinical development so as to collect data that is useful to sponsor-initiated clinical trial, and to include more patients of osteoarthritis. In January 2019, the application was approved by the MHLW in the 71<sup>st</sup> Conference on Advanced Medicine, as "cartilage regeneration therapy using autologous cell sheet." Once the Advanced Medicine treatment is approved by the Ministry of Health, Labor and Welfare, we will conduct contract processing and expect to post sales in FY2020. We will be continuing development activities while generating income.

With regard to the allogeneic regenerated cartilage sheet, in June 2017, the R&D topic put forward by CellSeed as lead organization was selected for the 2017 Project Focused on Developing Key Evaluation Technology: Evaluation for Industrialization in the Field of Regenerative Medicine (Developing Evaluation Methods for Industrialization in the Field of Regenerative Medicine). This was a grant project publicly advertised and funded by the Japan Agency for Medical Research and Development (AMED). In September 2018, CellSeed's R&D proposal, the establishment of manufacturing methods for the commercialization of allogeneic regenerated cartilage cell sheet (CLS2901C), was selected for the 2018 Project Focused on Developing Key Evaluation Technology: Evaluation for Industrialization in the Field of Regenerative Medicine (Accelerated Support Project for Regenerative Medicine Seeds Development). Utilizing the contract manufacture and development business described above, we have been pursuing the development of the allogeneic regenerated cartilage sheet in tandem with the development of the autologous regenerated cartilage sheet. In the development of the allogeneic regenerated cartilage sheet, we started on the building of cell stock and the development of automated manufacturing methods for cell sheet production. Regrettably, issues exist in medical institutions and public sector bodies as to building up cell stock, with inadequate provision for a system for collecting, storing and supplying cells. This has meant a delay in obtaining necessary tissue, pushing back the intended start of our clinical trial and it was only in January 2020 when tissues became available that we were able to move forward. After reviewing our clinical trial execution plan, we will determine the timescale for the execution plan and due notification will be given swiftly.

## Regenerative Medicine Supporting Business

• In the regenerative medicine supporting business, we will engage in reinforcing the development of new intelligent cell cultureware with due attention to customer requests. In terms of marketing, we will aim to

expand the sale of temperature responsive cell cultureware and other intelligent cell cultureware. To this end, we will conduct data gathering and analysis of sales and other information from key agents and engage in joint sales activities, aiming to increase not only sales in Japan but also overseas, which showed good results in the previous consolidated financial year. At present, we are outsourcing manufacture to Dai Nippon Printing Co., Ltd. of over-the-counter products, but we will be considering production capacity increase while maintaining stable product supply.

• Our regenerative medicine contracting business supports regenerative medicine using our Cell Processing Facility. We not only provide contract manufacture of cell sheets as consigned by academic institutions and private companies but also promote consulting on the strength of a wide variety of knowhow stockpiled through our cell sheet regeneration medicine business, thereby pushing for more income generating opportunities.

#### Other activities

#### • Business Alliances

In April 2017, CellSeed entered into an exclusive business alliance agreement with MetaTech of Taiwan, giving MetaTech exclusive rights in Taiwan on cell sheet regenerative medicine business. Sales generated through this contract totaled JPY150,000 thousand in FY2019.

We have been promoting new business partnerships and licensing agreements in Asia, especially in China. However, although some companies with whom we have been negotiating have shown interest in items under development as with MetaTech, none had reached the final agreement stage by the end of 2019. Alongside corporate value enhancement by promoting ongoing pipeline development, we will aim to diffuse our cell sheet regenerative medicine business in Asia focusing on China. To this end we will promote business alliance and licensing activities.

## • Joint Venture Company

The joint venture company we established will undertake the development of regenerative medicine products and therapies using cell sheet engineering based on seeds technology that we obtain from academic and research institutions in Japan and Taiwan. In order to commercialize products and therapies, we will examine the product profiles and optimize manufacturing methods. The seeds developed by Professor Yuan-Kun Tu of the E-Da Hospital of E-Da Healthcare Group is an example of such a seeds candidate. CellSeed's regenerative medicine supporting business will engage in clinical development consulting as well as manufacturing and sales approval application support and cell cultureware business. As a result of the activities mentioned above, we will be posting sales from services rendered to the JV company, consulting fee such as technician training and out-licensing of products other than the esophageal and cartilage regenerative sheets that we have developed.

## • Periodontal Tissue Regenerative Sheet

In Aug. 2019, the company started discussions with Tokyo Medical and Dental University on details regarding the clinical development of allogeneic periodontal ligament-derived mesenchymal stem cell sheets (periodontal ligament cell sheets). This will be the third in-house developed product in the CellSeed pipeline to follow the epithelial cell sheet for esophageal regeneration and the regenerated cartilage sheet. They will develop a regenerative medicine product for periodontal regeneration. At Tokyo Medical and Dental University, the leading professor Takanori Iwata is conducting investigator-led clinical trials, transplanting periodontal ligament cell sheets cultured from periodontal ligament cells harvested from healthy donors to patients of serious periodontitis that cannot be cured with the existing treatments. Evaluation of its safety and efficacy is ongoing.

Currently, CellSeed and Tokyo Medical and Dental University are discussing forming a collaborative partnership on which to base the commercial development of periodontal ligament cell sheet clinical research, its clinical trials and manufacturing and sales approval submission. When these discussions are concluded, we will sign a letter of intent on product development and due notification will be given swiftly.

#### • Epithelial Cell Sheet for Corneal Regeneration

CellSeed will continue discussing with parties concerned the future development in Japan of the epithelial cell sheet for corneal regeneration.

- 2. FY2019 Earnings Results and Future Performance Targets
- (1). Profit and Loss Targets (FY Ending December 2020 to FY Ending December 2022)

	Sales	Operating Income	Ordinary Income	Net Profit Attributable to Owners of Parent
	million yen	million yen	million yen	million yen
FY 2020 (Plan)	310	-1,020	-1,020	-1,020
FY 2021 (Target)	360	-1,030	-1,030	-1,030
FY 2022 (Target)	1,395	10	10	8

## Share of sales by segment

Regenerative Medicine Supporting Business: FY20: 230 million yen; FY21: 320 million yen; FY22: 390 million yen

Cell Sheet Regenerative Medicine Business: FY20: 80 million yen; FY21: 40 million yen; FY22: 640 million yen

- (2). Specific policies, preconditions, and numerical bases to achieve the business forecasts and planned targets
  - (i). Regenerative medicine supporting business

Promote development of new Intelligent cell cultureware, with good demand trends continuing and sales increasing overseas. Strengthen collaboration with Thermo Fisher Scientific Inc. and Dai Nippon Printing Co., Ltd. to reinforce supply chain to increase income.

Procure more orders for the regenerative medicine contracting service

- (ii). Cell sheet regenerative medicine business
- Regenerated cartilage sheet

#### Autologous cells

Contract manufacture on Advanced Medicine (20 cases of transplants planned in the next 5 years) consigned starting in H1 of FY20 from partnering research institution, Tokai University. Clinical trials to be conducted in line with progress of Advanced Medicine treatment

## Allogeneic cells

Clinical research underway at Tokai University (To be completed in FY20)

In line with research progress, regulatory science strategy meeting/regulatory science comprehensive discussion to be conducted, together with creation of cell bank and development of cell sheet manufacture automation. Sponsor-initiated clinical trials dates are not set at present. Once finalized, due notification will be given swiftly.

• Epithelial cell sheet for esophageal regeneration

Discussion is in progress with PMDA and currently dates have not been set for clinical trials notification, sponsor-initiated trial completion and manufacturing and sales approval submission. Once PMDA consultation is finished, due notification will be given swiftly.

• Business alliances

Continue support of our partner MetaTech. JV company set up in Taiwan with MetaTech and CellSeed as key investors. Form new alliances with Asian companies including Japanese, during the three years of this mid-term business plan.

#### (iii). Companywide Issues

• Human resources

Regenerative medicine products R&D requires human resources with a wide range of expert skills. Cell sheet regenerative medicine is highly interdisciplinary, involving engineering, cell biology and

chemistry, making it essential to employ and train specialist and diverse human resources. Because CellSeed intends to step up focus on joint development and business startup in Taiwan through the Taiwanese JV company, in addition to our existing partnership with MetaTech, we will direct our effort into securing human resources who can be global players as well as be effective members in Japan.

#### • Financial resources

As for capital necessary in the future, we will not only apply the existing funds in hand but also raise money flexibly using public financial support and subsidies, and other multitudinous measures such as financial approaches including equity finance and borrowing from financial institutions.

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The information contained within this document regarding our mid-term business plan is provided to investors solely for informational purposes and is not a solicitation of investment. The responsibility for any evaluation of this mid-term business plan and any investment decision made on our company lies solely upon investors. In addition, our company does not guarantee our ability to achieve and realize the various estimates and targets outlined in this mid-term business plan in any manner, nor accept any responsibility or liability for them. All of the forward-looking estimates and targets (including but not limited to business assumptions, visions, policies, strategies, earnings estimates and targets) mentioned within this document are based upon the best information available at the time of its creation. Therefore, our group's business conditions, earnings, and other details mentioned within this document may be subject to significant changes due to changes in future economic conditions, business assumptions and various other factors.