

February 10<sup>th</sup>, 2023

OrganTech, Inc.

MEDIA RELEASE

## Resumed Business as OrganTech, Inc.

***With hair regeneration medicine and tooth regeneration business as our core business, we implement the world's first next-generation organ regenerative medicine originating in Japan, and establish QOL medical treatment with scientific evidence.***

OrganTech, Inc. has been preparing to restart its business under a new management structure by changing its former company name: Organ Technologies, Inc. to OrganTech, Inc. effective in January 2023. (Head office: Chuo-ku, Tokyo, CEO: Miho Ogawa \*Ph.D. in engineering, in charge of research and development, Takashi Kondo \*in charge of business strategy and finance). We are currently in the process of raising initial funds through March 2023, and have just received an investment from Kobayashi Pharmaceutical Co., Ltd. (Head office: Osaka, CEO: Akihiro Kobayashi) as a leading company to fully promote activities in two core businesses: hair organ regenerative therapy and ta next-generation implants as teeth regeneration, as the organ regenerative therapy. As one of Japan's revitalization strategies, we aim to implement a healthy long-living society around the world through the implementation of the world's first next-generation organ regenerative medicine originating in Japan and the establishment of a "Quality of Life (QOL)" treatment that improves the QOL based on scientific evidence.

### 1. Social Background

Japan's medical insurance system has the most advanced technology in the world and plays a significant role in protecting Japanese people's health. On the other hand, the national costs for medical care have reached its ceiling of approximately forty-three trillion yen due to the system of the public health insurance for the whole nation, and an effective utilization and taking control of the national costs for medical care is required in this society. As this indicates, the area of healthcare is deeply related to the implementation of a healthy long-living society and is positioned as a priority issue to be improved in the future. It is

expected to expand its market by over two hundred trillion yen from 2020 to 2030. (Source: Japan Revitalization Strategy-Japan is back-) We categorize the area of healthcare into three categories: "healthcare for a prosperous life," "medical healthcare for the pre-symptomatic state," and "QOL treatment" which is a self-paid care. Among them all, we consider "QOL treatment" as a core field which does not affect the national costs for medical care. Further establishment of scientific evidence is considered as a critical issue in QOL treatment with self-paid care. In Japan, the number of alopecia patients is expected to be around twenty-four million, and the market is expected to be worth 5.5 trillion yen by 2028 worldwide since one's hair has an aesthetic impact on the patient's QOL significantly. The market for dental regenerative medicine has a large scale, as it is related to the health and quality of life in people all over the world. We are leveraging the world's first next-generation organ regenerative medicine originating in Japan to contribute to the improvement of health and QOL of many people around the world. With hair and teeth regeneration as our core businesses, we will continue developing "regenerative medicine for life" for patients with no other treatment options, to "regenerative medicine for everyone" which has a large-scaled market and aim to contribute to improving the health and QOL in many people around the world based on solid scientific evidence.

## **2. Background of Business Resumption**

OrganTech, Inc. was established in 2008 under our former company name: Organ Technologies, Inc. and we have been working to implement a healthy society through next-generation artificial skin, organ growing, and hair consulting business, including the fields of hair and teeth regenerative medicine as a wellness innovation since 2015. We have been engaged in joint research and development with the organ regeneration team at RIKEN Center for Biosystems Dynamics Research led by Takashi Tsuji (team leader), utilizing the team's advanced technology and their ability to conduct research. In terms of hair regenerative medicine in particular, we succeeded in the world's first research and development of hair follicle organ regenerative medicine, which regenerates new regenerated hair by transplanting the regenerated hair follicle primordium. In June 2020, we received an approval from the Certified Special Committee for Regenerative Medicine as a "hair regenerative medicine by transplantation of the regenerated hair follicle primordium", and the research and development of the world's first organ regenerative medicine originating in

Japan was progressing smoothly.

However, the managers of the company had failed to raise funds and suspended its operations in October 2020, due to the social background such as the COVID-19 pandemic which led to decline people's motivation in investment. At the end of December 2022, Kobayashi Pharmaceutical Co., Ltd. signed an investment agreement with us as the lead company, and we renewed our management structure on January 1<sup>st</sup>, 2023, restarting our business with two core business fields: hair organ regenerative medicine and the next-generation bio-hybrid implants as a dental regenerative medicine, as the organ replacement regenerative therapy.

### **3. Business Synergies with Kobayashi Pharmaceutical Co., Ltd.**

Kobayashi Pharmaceutical Co., Ltd. develops a variety of products including daily necessities and healthcare products, and also contributes to the society in the development of products in the areas of scalp care and dentistry. Kobayashi Pharmaceutical Co., Ltd. has recognized the great potential and high expectations for our company which possesses advanced technology and our ability to carry out further research, and has decided to invest in our company. Through this investment, Kobayashi Pharmaceutical Co., Ltd. will kindly support our company's growth, and thanks to this collaboration, we will further develop human resources for research and development involved in the regenerative medicine business and expand our business beyond our existing business. Through this collaboration with Kobayashi Pharmaceutical Co., Ltd., we will strive to expand the business of both companies.

### **4. Business Details**

#### **1) Hair Organ Regeneration Medicine (Regenerative Medicine)**

The regenerated hair follicle primordium, which is the base of the hair follicle, is artificially created by harvesting the scalp which contains about 100 hairs (1cm<sup>2</sup>) from the back of the head, extracting the epithelial cell and the mesenchymal stem cells (dermal papilla cells) that regenerates the hair follicles, and carrying out cell culture *in vitro*. This makes it possible to amplify the regenerated hair follicle primordium 50-100 times more than the follicle harvested by carrying out cell culture *in vitro* for three-weeks. By transplanting this regenerated hair follicle primordium into the scalp, hair follicles are to be generated and regenerated and new hair follicle and hair shaft is highly

expected. Demonstration experiment using a mouse have demonstrated a life-long regeneration of the regenerated hair follicle and shaft with these technologies (*Nature Methods*, 2007; *Nature Commun.*, 2012). Once our technology is implemented in the society, not only it will be the world's first next-generation organ regenerative medicine originating in Japan, but it will be an innovative hair regeneration technology that will increase the total number of hairs people have. We plan to be reapproved by the Certified Special Committee for Regenerative Medicine in 2023, and plan to conduct clinical research in 2024.

## 2) Dental Organ Regenerative Medicine (Medical Devise)

We were the first in the world to succeed in the functional regeneration of teeth with complete regeneration of biological functions (regenerating periodontal fiber, enabling orthodontic treatment, and restoring perception), by harvesting epithelial and mesenchymal stem cells from the tooth primordium of a mouse's teeth which is in the fetal stage, creating a regenerated tooth germ using the organ germ method (*Nature Methods*, 2007), and transplanting them into areas where the teeth have been lost (*PNAS*, 2009). However, there have been challenges in applying this technology to humans, since it takes time to acquire cells from adult humans and to wait until the teeth to erupt.

The current treatment with osseointegration implants contributes to improve of the QOL. However, this implant system might cause a variety of problems in human body which is becoming a social issue. Since the implants are to be implanted directly into the alveolar bone, there is no dental function such as impact buffering or perception, and this might cause some risk of peri-implantitis. In addition, even if the patient needs to remove a tooth to clean the oral cavity for nursing care, the implant cannot be removed easily which may lead to the risk of a systemic infection starting from a periodontal disease. To implement tooth regeneration treatment promptly, we have developed the basic technology for the next-generation bio-hybrid implant with periodontal ligament, which is an advanced version of the osseointegration implants. This technology is listed in the "Dental Innovation Roadmap to 2040" published by the Japanese Association for Dental Science and is described as a project with high social significance as an initiative contributing to the extension of healthy life expectancy. Further research and development for the first next-generation bio-hybrid implants is underway for implementation on patients who still have

periodontal fiber left after teeth extraction due to cavity or fracture. We aim to conduct specific clinical research in 2025 to implement this in the society in 2026-2027. In the future, we aim to implement the second next-generation bio-hybrid implant that can be adapted to patients with no remaining periodontal ligament.

**5. About us**

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**6. Contact Information**

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