

"Engineered 3D human tissue will bring efficiencies in drug screening and drug safety testing―

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First, could you give the readers a short bio of your company?

Cyfuse is a regenerative medicine startup founded in 2010 to develop its proprietary technology to assemble living cells in three dimensions. Cyfuse has been developing this technology until now with the support of the Japan Science and Technology Agency (JST) and the New Energy and Industrial Technology Development Organization (NEDO).

In 2010, Cyfuse began working with Shibuya Kogyo Co., Ltd. to jointly develop a bio 3D printer called 'Regenova' that automatically assembles cellular aggregates. Shipment of Regenova to Japanese universities began in 2013. Cyfuse's main business activities include the sales of Regenova bio 3D printers, R&D of 3D tissue products, and subcontract manufacturing of 3D tissue products.

Cyfuse is based in Tokyo and is headed by President and CEO Koji Kuchiishi.

Our goal is to facilitate innovative therapeutic approaches through our new bioengineering technologies to make regenerative medicine a reality for patients around the world.

How has Cyfuse taken tissue engineering to an advanced next-gen level?

Cyfuse works on prototyping various tissues into 3D shapes for future clinical application. Cyfuse's 3D tissue construction technology has unique and break-through making features for research and regenerative medicine. Our 'Kenzan' method enables us to construct 3-dimensional tissue without using scaffold material. In addition, the method can provide the suitable maturation environment for the cells to self-reorganize into the proper arrangement as living tissue. In order to ease usage of this technology, we have developed the bio 3D printer, Regenova. With Regenova, researchers now have the possibility to design and make the desired tissue in laboratory.

The company's technology uses a fine needle array to skewer cellular aggregates (0.5mm diameter), which are then stacked three dimensionally. Once the cellular aggregates are fused together, the needles are removed, resulting in elastic tissue

based on the original cells and the collagen within. The Regenova bio 3D printer can automatically create a 3D cellular structure by inputting 3D data and cellular aggregate material. The resulting cellular structure spends several days or weeks maturing in a customized bioreactor, and comes to express its target strength and function. This technology can be used with various cell types, and is able to produce thicker and more elastic tissue than was conventionally possible, so it is expected to bring breakthroughs in drug discovery research and regenerative medicine in a wide range of therapeutic areas.

What are the tissues/organs developed by Cyfuse's in-house technology?

Cartilage/bone, vascular tube, liver, neural cells are the key tissues that are developed by our in-house technology.

Who are the end-users of this technology and how does this technology have an impact on regenerative medicine? Researchers who need engineered 3D tissues will be our technology's end users. In regenerative medicine, we are aiming to apply our methodology as one of the standard methods to construct 3D tissues, which will be in the end used to provide novel therapies to patients.

Market researchers point out that 3D printing technology has the potential of revolutionizing the biomedical industry. Could you explain how this revolution has occurred and its future prospects?

The huge gap between demands and supplies in organ/tissue transplantation provides the need in this area. Physicians and researchers have been working hard to fill this gap. If 3D printing technology can create transplantable organ/tissue, many patients will be saved. If we look at cell therapies, there are still many challenges and rooms for improvement. As the improved cell delivery system, 3D cell construct may be able to provide better therapeutic effects in human body.

Another area in which revolution is taking place is in drug development. Engineered 3D human tissue will bring efficiencies in drug screening and drug safety testing. Disease model study will be accelerated by 3D tissues made with patient derived cells. With 3D printing, researchers will gain access to the technology in their own laboratory.

Could you elaborate on Cyfuse's academic partnerships and collaborations with other institutions?

In Japan we have been collaborating with several universities, including Kyushu University and Saga University. So far we have installed 6 Regenova, at various academic institutions. We are aiming to expand the partnership further in Japan, and will do so in other countries.

It is believed that the toxicity testing of drugs on engineered tissue is cost-effective when compared to animal testing or petri dish testing. Is this true? What is your opinion on this?

Yes. Engineered tissue-based testing will definitely bring considerable improvement in drug screening and toxicity testing. Chemical responses of 3D tissues have been demonstrated as closer to human body when compared to cells cultured in a dish.

Globally what is the market value for 3D printing technology-based medical products? What will be Japan's share in that market value?

A government funded study report indicates that the potential market size for regenerative medicine products by 2030 is as follows:

Japan: 8.3 billion USD (1 trillion yen)

Rest of the World: 100 billion USD (12 trillion yen)

Estimates indicate that of this at least1/3rd of the market share will be taken by tissue-engineered products.

The company had previously raised funds through prominent investors? How was this achieved and has Cyfuse been approached by other investors?

In February 2015, Cyfuse Biomedical raised 1.4 billion yen through Series B funding that was participated by 12 investors, including venture capital funds and corporate investors. With this funding, it brings the total investment in Cyfuse to 1.98 billion yen, including capital reserve. The finances raised through the investors will enable Cyfuse to begin overseas sales of its bio 3D printer for research applications and also accelerate the development of its 3D tissue engineering technology for regenerative medicine applications.

- With this Series B funding, Cyfuse also plans to increase its headcount and launch the overseas sales of the Regenova bio 3D printer and expand research seeds though collaboration with the academic community.
- In addition, Cyfuse will establish a cell processing facility for clinical use and apply its platform technology and expand its use by putting in place a system to subcontract manufacturing of the tissue from university hospitals and other institutions.

Does Cyfuse have any future M&A plans? If yes, then would be in Japan or overseas?

No. However we are open to good opportunities.

Could you elaborate on the awards and success the company has accomplished so far?

Cyfuse was the winner of the Asian Entrepreneurship Award 2015 - an innovation award for young entrepreneurs to compete to change the world.

Besides, we are making progresses in our research, and in our engineering development of bio 3D printer, and in the commercialization of the printer. However, those are just small milestones towards our success in the future.

Is there a roadmap planned for the company's growth for the period between 2015 and 2020?

We will start commercial selling of our Regenova in the US from September 2015. This will provide researchers in the US a unique opportunity to work with 3D tissue engineering technology at their laboratory.

Anusha Ashwin