

Development of tissue-regenerated ligaments using decellularized biological tissues and their overseas expansion (CoreTissue BioEngineering, Inc)



CoreTissue
BioEngineering

City	Year of Establishment	Founder
Yokohama, Kanagawa	2016	Dr. Kiyotaka Iwasaki

Partner VC	Latest round of Fundraising	Valuation
WERU Investment Co., LTD.	Series A Extension	Non-Disclosure

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○ Business Plan

In this project, we will prototype a mass-production manufacturing device and demonstrate commercial feasibility, with a view to commercializing the "tissue regenerated ligament" that has already undergone FIH. Furthermore, in preparation for sales in the United States, we will complete additional testing necessary for US drug applications based on the non-clinical trials we have conducted, and, based on the plans for ongoing domestic clinical trials, we will complete the planning of additional trials in the United States and the selection of participating physicians.

○ Research Outline

This grant project will achieve the following two goals:

- 1) To confirm the feasibility of commercializing the "tissue regenerated ligament," which achieved FIH status in corporate clinical trials launched last year, we will prototype a commercial manufacturing device and demonstrate commercial viability from a manufacturing perspective.
- 2) Based on the clinical trial design currently being conducted in Japan, we will clarify the clinical trial design to be conducted in the United States, create a protocol, and prepare the clinical trial implementation structure (CRO, clinical trial medical institution, and orthopedic surgeon). We will also conduct and complete the non-clinical trials (biological safety tests, viral clearance tests, and tests using large animal models) required for the FDA's Pharmaceuticals and Medical Devices Approval Application (PMA).

Business Area/Field	Research Period	Research Grant Amount	International collaborative technology demonstration
Healthcare	PCA 2025~2027FY	JPY 494 million	United States

○ International collaborative technology demonstration

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