Pericardium Sheet “PeriBeam®” Production and Distribution Approval in Japan
~ Second M3 Launch of Riken Product Series Following DuraBeam® ~

M3, Inc. (Headquarters: Tokyo, Japan; CEO: Itaru Tanimura; URL: https://corporate.m3.com/en/; “M3” below) has announced that TamaBio (Headquarters: Tokyo, Japan; CEO: Makoto Sawada; “TamaBio” below), a subsidiary established in April 2016 based on the dominant patent held by RIKEN, Japan. (Headquarters: Saitama, Japan; President: Hiroshi Matsumoto; URL: http://www.riken.jp/en/; “RIKEN” below), has received approval from the Ministry of Health, Labour and Welfare (MHLW) for the production and distribution of “PeriBeam®” (Class IV) in Japan.

M3 operates a Seeds Rocket business through the subsidiary M3i, Inc. (Headquarters: Tokyo, Japan; CEO: Umeda Kazuhiro; “M3i,” below). As a joint founder and founding investor, M3i provides comprehensive operational support such as business strategy consulting, necessary funding, executive placements, counsel from regulatory, doctorate, scientific, and material technologies advisors, as well as business structure development.

Tamabio is currently developing multiple medical treatment devices based on Riken’s research of a special polymer resin processing technology. In September 2017, the initial “DuraBeam®” artificial dura mater product (Class IV) was approved in just merely 17 months after the foundation of Tamabio.

“PeriBeam®,” similar to “DuraBeam®,” is a pericardium sheet developed by TamaBio using Riken’s special polymer resin processing technology. Existing products in clinical practice face difficulties
such as adhesion and calcification upon long-term use that lead to adverse events. “PeriBeam®” was designed based upon direct input from heart surgeons, and is expected to overcome the majority existing clinical issues due to its high biocompatibility, limited risk of adhesion to other organs, and minimal time for abrasion upon re-operation.

TamaBio aims to further continue acquiring approvals not only in Japan, but also across overseas markets. Following the artificial dura mater and pericardium sheet, development plans of artificial organs are also under way.

Through the M3i Seeds Rocket Business initiatives, M3 will endeavor to fill global Unmet Medical Needs (medical needs of patients with currently un-curable diseases) with least delay, to produce pharmaceutical, device, and regenerative products that are truly beneficial for patients, by supporting the development of an ecosystem for local and global medical venture companies.

■ “PeriBeam®” Utilization Image

![PeriBeam® Utilization Image](image)

Photo: PeriBeam® pericardium implantation dissection (pig)
Boxed Area: Implantation area after 2months, facing specially treated surface side
Neointimal formation observed covering entire area of specially treated surface with assimilation to neighboring cells

■ Total Domestic Addressable Market
Estimated annual number of heart surgeries: 64,453 cases (Thoracic and cardiovascular surgery in Japan during 2014)
% applicable for PeriBeam® (ref: TamaBio research): 17% or 11,300 cases annually
Comment from the CEO of TamaBio, Makoto Sawada

The research for this product’s technology began 20 years ago at RIKEN. Initially Durabeam® and now PeriBeam® is the result of endless research efforts contributed by researchers and clinical physicians. With the support of everyone at numerous cooperative companies, the approval we have received today from the MHLW for the production and distribution of this product is truly a gift. Any person or part missing would have prevented both from materializing as medical devices. This technology has potential applications for various other surgical areas, and I am convinced that it holds the key to saving millions of patient lives across the globe.

Comment from the Director of RIKEN Cluster for Industry Partnerships, Akihiro Fujita

I am delighted that the pericardium sheet following the artificial dura mater based on research conducted at RIKEN has gained approval for production and distribution, and anticipate that there will be important medical applications.

TamaBio Overview

Founded: April 2016 (M3 subsidiary)
Address: Akasaka Intercity 10th floor, 1-11-44 Akasaka, Minato-ku, Tokyo 107-0052
Employees: 9 (including directors)
CEO: Makoto Sawada

Development of the advanced medicine business is positioned as the third growth driver for M3, following “internet based services” and “e x real operations” drivers. This initiative expands the development area of this third growth driver into the field of AI.