Exclusive distribution license agreement concluded
with Fuso Pharmaceutical Industries, Ltd.
regarding mucous membrane raising device (TDM-641)

3-D Matrix, Ltd. (3DM) and Fuso Pharmaceutical Industries, Ltd. (“Fuso”, head office is located at Osaka) reached and entered into an agreement for 3DM to grant Fuso an exclusive distribution right in Japan regarding the mucous membrane raising product (develop code: TDM-641) which is under development and one of the 3DM’s main pipeline.

This agreement is that 3DM grants Fuso an exclusive distribution right in Japan about this product which 3DM develops as a new medical device, Fuso makes initial payment upon signing this agreement and milestone payments according to development stage, and Fuso subscribes the products exclusively from 3DM after manufacturing and marketing approval and distributes them to medical institution in Japan.

Currently, Endoscopic Mucosal Resection (EMR) and Endoscopic Submucosal Dissection (ESD) are prevailing as procedures to remove early-stage tumor or polyp on mucous membrane of gastrointestinal tract such as esophagus, stomach, and large intestine. EMR and ESD are less impact treatments for patients with using endoscope and are techniques contributing to both maintenance of QOL after operation and reduction of medical spending. The mucous membrane raising device, which is used subsidiary upon EMR or ESD, is injected locally to submucous membrane of focus to raise focus and remove all of focus safely. Normal saline solution or existing products using biological hyaluronate sodium are used generally as mucous membrane raising devices.

The mucous membrane raising device developed by 3DM (TDM-641) consists of the same components as the absorbable local hemostat (TDM-621) under application for manufacturing and marketing approval and is made from self-assembly peptide consisting of 3 types of amino acid which is constituents of human body. Self-assembly peptide has an advantage to keep out human or animal derived materials since it is highly biocompatible and is made by chemical synthesis.

Developing the mucous membrane raising device (TDM-641) contributes to strengthening 3DM’s medical device lineup using self-assembly peptide and bringing a greater synergy on marketing strategy like sharing sales channel with the hemostat (TDM-621) targeting at bleeding upon EMR or ESD. EMR and ESD are performed in more than 80 cases per year in
Japan. 3DM is aiming to acquire a strong position in the product market through rapid diffusion of TDM-641 and replacement of existing products.

3DM is now developing the mucous membrane raising device (TDM-641) as a medical device and is planning to start clinical trial from the fiscal year ending April, 2013. Since this product can be marketed at lower cost in shorter term compared to general medical products, 3DM is going to acquire manufacturing and marketing approval as a new medical device from FY April·2014 to FY April·2015 and start marketing under application as Special Treatment Materials.

This agreement does not have a great effect on the earning forecast of this fiscal year of 3DM at this moment. The effect on “Mid-term business plan” on October 24, 2011 is now under review and is going to be disclosed immediately including the effect of this agreement.

[Reference]
Endoscopic Mucosal Resection (EMR)
EMR is a procedure to resect mucous membrane endoscopically and mainly used for treatment of neoplastic lesion of gastrointestinal tract. Constricted part or stalk of membrane can be burned out with high-frequency electric current by hitching wire to the constricted part or stalk (polypectomy). On the other hand, flat or dented part, which can not be hitched with wire, are burned out with high-frequency electric current after injecting liquid like normal saline solution to submucous membrane and raising resection area. Injecting liquid has an effect to take mucous membrane away from intrinsic muscle and prevent perforating gastrointestinal tract. This procedure is called EMR.

(Website of the Japanese Society of Gastroenterology)

Endoscopic Submucosal Dissection (ESD)
ESD is a procedure to dissect lesion at submucous membrane with a high-frequency knife available for endoscope and mainly used for treatment of gastrointestinal tract tumor. The differences from EMR are 1) slitting up circum-mucous membrane and 2) exfoliating submucous membrane. Owing to these procedures, the resecting area can be decided freely (resected accurately), and the lesion with ulcer firmly fixed to intrinsic muscle can be resected.

(Website of the Japanese Society of Gastroenterology)