



April 19, 2013

Company Name	3 - D M a t r i x , L t d .
A d d r e s s	3-2-4, Kojimachi, Chiyoda, Tokyo
P r e s i d e n t	Kentaro Takamura
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### **Revision of Mid-term Business Plan**

The company hereby announces a revision to its mid-term business plan (FY2012 to FY2014) which was previously announced on February 1, 2013. The revised mid-term business plan has been submitted to Osaka Securities Exchange today.

#### 1. Reason of revision of mid-term business plan

The company's first pipeline, hemostat (TDM-621) is currently under review by the Pharmaceuticals and Medical Devices Agency, Japan (PMDA) for manufacturing and marketing approval, application submitted to PMDA in May, 2011. As it is taking longer than anticipated to obtain this approval, business progress including the approval originally budgeted for FY2012, is likely to be postponed to FY2013.

Therefore, milestone payment and product sales resulting from this business progress will be received in FY2013 rather than in FY2012, and the previously forecasted operating revenue of ¥1,850 million for FY2012 is revised downward to ¥32 million. However, development of our hemostat (TDM-621) business in the U.S. and Europe is on track, and business expansion in Asia (mainly in South East Asia) is underway from our subsidiary in Singapore. Hence, operating revenue of ¥4,495 million for FY2013 is revised upward to ¥4,747 million. The forecast of operating revenue for FY2014 has not been changed from its original.

Despite our effort to reduce costs including subcontract fees, operating loss for FY2012 is also revised to ¥1,077 million (down ¥1,229 million from previous forecast) with ordinary loss of ¥1,069 million (down ¥1,230 million) and net loss of ¥1,070 million (down ¥1,201 million) primarily because of the operating revenue decrease. For FY2013, we forecast operating income of ¥2,055 million (up ¥363 million from previous forecast), with ordinary income of ¥2,049 million (up ¥363 million) and net income of ¥1,752 million (up ¥311 million). The forecast for FY2014 has not been changed from its original.

Note: The performance forecast was prepared based on information obtained as of the time of announcement. Actual results may differ from the projected figures due to various subsequent factors.

2. Earning forecast of this fiscal year and future targets

(Millions of yen)

	Operating revenue	Operating income (loss)	Ordinary income (loss)	Net income (loss)
FY2011 (actual)	1,107	354	309	308
FY2012 (original forecast)	1,850	152	160	130
FY2012 (revised forecast)	<u>32</u>	<u>(1,077)</u>	<u>(1,069)</u>	<u>(1,070)</u>
FY2013 (original target)	4,495	1,691	1,685	1,441
FY2013 (revised target)	<u>4,747</u>	<u>2,055</u>	<u>2,049</u>	<u>1,752</u>
FY2014 (target)	8,006	3,521	3,515	2,222

Note: Figures above are extracted from the company's revised mid-term business plan.

3. Premises for earning forecast of mid-term business plan

Other than manufacturing and marketing approval for hemostat (TDM-621) to be obtained in FY2013, there is no significant change from "Mid-term Business Plan" announced on February 1, 2013. As for financial plan, we plan to continue to strengthen our financial base. In addition to public offering upon stock listing and commitment line contract with Sumitomo Mitsui Banking Corporation (SMBC), credit line was committed by SMBC and Mizuho Bank, Ltd. for respective ¥500 million and a total of ¥500 million was drawn in November, 2012. This was mainly used to purchase peptide as material of hemostat and to enhance our working capital. In April, 2013, we obtained new credit line for ¥600 million from SMBC.

4. Others

For details, please refer to attached reference information "FY2012-FY2014 Mid-term Business Plan (Revised)".

Note: The performance forecast was prepared based on information obtained as of the time of announcement. Actual results may differ from the projected figures due to various subsequent factors.

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### **FY2012-FY2014 Mid-Term Business Plan (Revised)**

(This information reflects the revision announced today.)

#### 1. Mid-term business plan over the next three years

##### (1) Review of FY2011 (prior fiscal year), as of submission of this mid-term business plan.

During the fiscal year ended in April, 2012, the European sovereign debt crisis had an impact on the actual business and the economic slowdown spread not only in Europe but all over the world including developing countries.

The Japanese economy, recovering from the effects of the Great East Japan Earthquake, is still in a challenging situation due primarily to the global economic slowdown, the strong Yen, and a steep rise in crude oil prices.

Under these circumstances, 3DM group has been developing medical devices with self-assembling peptide, which is our main technology. Our first pipeline, hemostat (TDM-621) is now under review by Pharmaceuticals and Medical Devices Agency, Japan (PMDA) for manufacturing and marketing approval, to which we applied in May, 2011. We have been preparing the production line of TDM-621 with our subcontractor. Sales partnership for TDM-621 was agreed between Fuso Pharmaceutical Industries, Ltd. (Fuso), who holds the exclusive distribution license in Japan, and Kaken Pharmaceutical Co., Ltd. (Kaken) in April, 2012, which strengthens product sales system and expands sales channels. The payment from Kaken for the consideration of this agreement of sales partnership was allocated to operating revenue.

As to our second pipeline, dental bone filler (TDM-711), our subsidiary acquired IDE approval from the US Food and Drug Administration in July, 2011 and the clinical trial started at Forsyth Institute, a research institute of medical and dental school of Harvard University in February, 2012.

Endoscopic mucosal resection aid (TDM-641) is under development as our third pipeline. The exclusive distribution license in Japan was agreed between Fuso and 3DM in February, 2012 and the initial payment for the consideration was allocated to operating revenue. The clinical trial of TDM-711 is planned to start in FY2012.

Note: The performance forecast was prepared based on information obtained as of the time of announcement. Actual results may differ from the projected figures due to various subsequent factors.

The joint project with National Cancer Center Research Institute, which is to cure triple negative breast cancer by nucleic acid medicine, was nominated for one of the projects of Grants-in-Aid for Scientific Research by Ministry of Health, Labour, and Welfare, and the research grant was recognized as operating revenue.

For global business expansion, a new consolidated subsidiary “3-D Matrix Europe SAS.” in Lyon, France, which is solely owned by 3DM Ltd., was found in April, 2012. This subsidiary will be our base for research and development in Europe.

As a result, consolidated operating revenue for FY2011 totaled ¥1,107,387 thousand (up ¥949,067 thousand from the previous year), with ordinary income of ¥309,569 thousand (up ¥819,203 thousand), and net income of ¥308,610 thousand (up ¥842,562 thousand).

## (2) Overview and background of mid-term business plan

### Basic policy of mid-term business plan

3DM group has been developing medical devices and drugs in the field of surgery, regenerative medicine, and DDS with our fundamental technology, self-assembly peptide.

Based on a search of application pipeline leveraging our fundamental technology, our basic policy is to aim to develop and market medical devices and to secure revenue through products sales. Products will be sold to business partners to whom we grant distribution rights, and we also aim to secure revenues from initial income or milestone income as compensation for the distribution rights.

Detailed plans are as follows.

- Focus and specialize on commercialization strategy development and business planning functions, and aim to strengthen lineup of our product pipelines
- Bring multiple products to market quickly to secure stable product sales revenues
- Strengthen our business model, which is to supplement manufacturing and marketing/sales functions through partnerships

### Mid-term business goals

- Acquire manufacturing and marketing approval of hemostat, secure income through marketing/sales of product, and promote to increase market share
- Establish a framework for overseas development and marketing/sales of hemostat, through business partnerships
- Complete preclinical trial of endoscopic mucosal resection aid and embolism, start clinical trial, and enter into business partnership for domestic sales
- Complete clinical trial of alveolar rebuilding device, enter into business partnership in U.S., and establish structure for manufacturing and marketing

## (3) Business progress / forecast and those premises

- 3DM group is currently researching and developing four pipeline applications using self-assembling peptide technology in the field of surgery and regenerative medicine. We are also engaged in the medical device business to secure income through marketing the pipeline products.

Note: The performance forecast was prepared based on information obtained as of the time of announcement. Actual results may differ from the projected figures due to various subsequent factors.

- Hemostat is under development in surgery field; the clinical trial has been completed, applied for manufacturing and marketing approval in May 2011, undergoing review by PMDA, and the approval is expected to be granted during FY2013. Manufacturing and marketing framework has been built through a distribution license agreement with Fuso. Sales partnership was agreed between Fuso and Kaken in September 2012, which strengthens product sales system and expands sales channels. Most important issue during FY2013 is to acquire manufacturing and marketing approval and to start distribution in domestic market.
- For overseas operation of hemostat, 3DM concluded partnership and license agreements with business partners in Korea and Taiwan in September, 2010 and we are preparing for bridging. We are in preparation for the clinical trials in the U.S. and Europe. During this fiscal year, IDE was submitted (corresponds to submission of clinical protocol in Japan) in the U.S. and application for CE Mark in Europe is expected. We will continue to establish a framework for stable manufacturing and marketing.
- Concerning other pipelines, clinical trial for alveolar rebuilding device has started, and we recognize that it is important for endoscopic mucosal resection aid and embolism to bring forward the clinical trial start date, by leveraging safety data of hemostat and accumulating efficacy data. Especially for endoscopic mucosal resection aid, we have agreed on an exclusive distribution license with Fuso in February, 2012 and are preparing the clinical trial to be started during FY2012.
- In other fields, we are continuing our efforts on joint research with universities or institutes to seek further pipeline candidates including DDS applications.
- 3DM group's development pipeline is that of a medical device; this results in a considerably shorter time and lower costs for research and development from basic research to commercialization compared to drugs, but still considerable expenses are required. Funds for development of our first pipeline, hemostat has been secured through initial income or milestone income from business partners. By public offering upon listing, we were able to secure funds for additional pipeline applications and international expansion. We are preparing for earlier start of clinical trials and speeding up developments.

Note: The performance forecast was prepared based on information obtained as of the time of announcement. Actual results may differ from the projected figures due to various subsequent factors.

## 2. Earning forecast of this fiscal year and future targets

(Millions of yen)

	Operating revenue	Operating income (loss)	Ordinary income (loss)	Net income (loss)
FY2011 (actual)	1,107	354	309	308
FY2012 (forecast)	32	(1,077)	(1,069)	(1,070)
FY2013 (target)	4,747	2,055	2,049	1,752
FY2014 (target)	8,006	3,521	3,515	2,222

Note) Figures above are extracted from the company's revised mid-term business plan.

### Premises for earning forecast

- Operating revenue
 

Operating revenue is recognized by prediction booking time based on development plan of each pipeline. The revenue amount is estimated with consideration for market size, competitive condition, superiority, latest market trend, and negotiating condition. Operating revenue of FY2011 was calculated with actual record from initial or milestone income. FY2012 to FY2014 are estimated with milestone income with approval of manufacturing and marketing of hemostat, product sales by marketing of hemostat, and initial or milestone income and product sales of other pipelines.
- Operating cost
 

Operating cost is distributed into cost of sales, research and development expense, and selling and general administrative expense. Each cost is calculated by accumulating estimated amount.

Cost of sales

Cost of sales of 3DM group is calculated by accumulating estimated amount of peptide materials and subcontract expenses.

Research and development expense

Research and development expense of 3DM group is calculated by accumulating estimated amount of each pipeline. The amount for hemostat is estimated including development cost in the U.S. and Europe and test or study cost for commercialization though the development expense for medical device is lower than that of drug.

Selling and general administrative expense

Selling and general administrative expense of 3DM group is calculated with estimated amount along future business plan in consideration of result figure of each expense.

Personnel planning

Personnel planning of 3DM group is estimated to build adequate corporate system in line with business expansion, increase of products, and growth of business volume with increase of pipelines.
- Capital investment plan

Note: The performance forecast was prepared based on information obtained as of the time of announcement. Actual results may differ from the projected figures due to various subsequent factors.

3DM group formulates an investment plan including new manufacturing facilities for marketing hemostat and inspection facilities for future research and development.

- Financial plan

Funds required for research and development of 3DM group will increase as we promote research and development, including clinical trials, for developing pipelines. We have secured these funds by public offering upon stock listing, and we will make efforts to ensure stable revenues through initial or milestone incomes and product sales. In addition to commitment line contract with Sumitomo Mitsui Banking Corporation (SMBC), credit line was committed by SMBC and Mizuho Bank, Ltd. for respective ¥500 million and ¥500 million in total was drawn in November, 2012. This was mainly used to purchase peptide as material of hemostat and enhance our working capital. In April, 2013, we obtained new credit line for ¥600 million from SMBC.

- Earning forecast

Earning forecast is subject to change due to various reasons including future condition of pipeline development, negotiation with business partners, and product sales post market introduction.

Note: The performance forecast was prepared based on information obtained as of the time of announcement. Actual results may differ from the projected figures due to various subsequent factors.

### 3. Other reference information

#### ○ Development status of main pipelines

		Region	Basic research /Evaluation test	Preclinical trial	Clinical trial	Applying approval of manufacturing & marketing	Approval of manufacturing & marketing	Insurance listing	Marketing
Surgery Field	Hemostat (TDM-621) (*2)	Japan	[Development already done]			[Development goal in FY2012]	[Development goal in FY2013]	[Development plan and goal in FY2014]	
		Korea	[Development already done]			[Development plan and goal in FY2014]			
		Taiwan	[Development already done]			[Development plan and goal in FY2014]			
		U.S.	[Development already done]	[Development goal in FY2012]	[Development goal in FY2013]	[Development plan and goal in FY2014]			
		Europe	[Development already done]	[Development goal in FY2012]	[Development goal in FY2013]	[Development plan and goal in FY2014]			
Regenerative Medicine	Endoscopic Mucosal Resection Aid (TDM-641)	Japan	[Development already done]		[Development goal in FY2012]	[Development goal in FY2013]	[Development plan and goal in FY2014]		
		Japan	Embolism (TDM-631)	[Development already done]	[Development goal in FY2012]	[Development goal in FY2013]	[Development plan and goal in FY2014]		
			Dental Bone Filler (TDM-711) (*3)	U.S.	[Development already done]		[Development goal in FY2012]	[Development goal in FY2013]	[Development plan and goal in FY2014]

(Notes) 1. means development plan and means development already done. means development goal in FY2012, in FY2013, and in and after FY2014

#### 2. Hemostat

Clinical trial finished in April, 2011, and manufacturing and marketing approval was applied in May, 2011 and is under test by PMDA. For development in Korea and Taiwan, 3DM prepares to evaluate safety and efficacy with date of preclinical or clinical trial in Japan (bridging). Manufacturing and marketing approval will be acquired in short term if the bridging is allowed; however, it is possible that the bridging is not allowed or additional test is requested by authorities of each country.

#### 3. Dental bone filler

Note: The performance forecast was prepared based on information obtained as of the time of announcement. Actual results may differ from the projected figures due to various subsequent factors.



IDE application for clinical trial was submitted to FDA by our subsidiary in September, 2010 and was acquired in July, 2011. Clinical trial started in February, 2012.

4. DDS field

In DDS field, we promote development as drug and our business through not independent commercialization but license to major pharmaceutical companies; therefore, DDS field was excluded from main pipelines set forth above.

Main premises, issues, and specific plans of each pipeline to achieve plan in each fiscal year are stated as follows.

<p>● Hemostat (TDM-621)</p>	
Feature	To stop bleeding by blocking contact surface with applying TDM-621, which has a feature to self-assemble, form nano-fiber, and gelate upon contact with body fluid such as blood, to bleeding area in surgery operation
Target	Blood effusion upon surgery operation
Market	Japan (Bridging to Korea/Taiwan, spread to Europe/US)
Stage	Manufacturing and marketing approval applied in FY2011, under test by PMDA
Premise	Manufacturing and marketing approval acquired, Insurance listed in assumed field of operation in FY2013
Issue	To show sufficient test results if an additional test is needed, though big issues to the approval are not expected because positive results were acquired in clinical trial and adverse events including serious failure or adverse effect were not occurred
Specifics	To prepare additional test expected including acquiring data
<p>● Endoscopic Mucosal Resection Aid (TDM-641)</p>	
Feature	To foam an elevation by injecting TDM-641, which has a feature to self-assembly gelate, into submucosal membrane, in order to raise cancer area to resect in endoscopic mucosal resection or endoscopic submucosal dissection for stomach or esophagus cancer
Target	Endoscopic Mucosal Resection, Endoscopic Submucosal Dissection
Market	Japan
Stage	Preclinical trial (Preparing clinical trial protocol) The safety test results of TDM-621 is expected to apply to TDM-641 because TDM-641 and TDM-621 are made from same self-assembly peptide though the concentration is different. We prepare to ensure safety of TDM-641 for clinical trial.
Premise	Clinical trial conducted based on preclinical trial data, Manufacturing and marketing approval acquired, Insurance listed
Issue	To show sufficient results in order to obtain an approval of clinical trial
Specifics	To prepare sufficient test results in order to start clinical trial early

Note: The performance forecast was prepared based on information obtained as of the time of announcement. Actual results may differ from the projected figures due to various subsequent factors.

●Embolism (TDM-631)

Feature : Expected to use in hepatic artery embolization or uterine artery embolization for liver cancer or uterine cancer. To obstruct artery which is nutrient vessel for cancer, block nutrient and destroy cancer, by injecting TDM-631, which has a feature to self-assembly gelate, into artery as embolizing material through a catheter and by embolizing intravascular lumen physically.

Target : Hepatic artery embolization, Uterine artery embolization

Market : Japan

Stage : Preclinical trial

Premise : Clinical trial conducted based on preclinical trial data, Manufacturing and marketing approval acquired, Insurance listed

Issue : To show sufficient test results in order to obtain an approval of clinical trial

Specifics : To prepare sufficient test results in order to start clinical trial early

● Dental Bone Filler (TDM-711)

Feature : To keep three dimensional structure by self-assembly gelating and foaming nano-fiber, to make a condition where a cell grow in vivo, and to support tissue regeneration, in order to rebuild alveolar for regressive alveolar with periodontal disease to be operated with implant procedure.

Target : Alveolar rebuilding operation

Market : U.S.

Stage : Clinical trial

Premise : Clinical trial finished, Manufacturing and marketing approval acquired in the U.S.

Issue : To prepare sufficient data and additional test results if additional data or test are requested by FDA

Specifics : To conduct additional test with an advice of medical consultant in U.S. about necessary data or test to FDA reference

Note: The performance forecast was prepared based on information obtained as of the time of announcement. Actual results may differ from the projected figures due to various subsequent factors.

<Glossary>

\* Self-assembling Peptide

Peptide group forming nano-fiber by peptide molecules regularly assembled under physiological condition

\* Endoscopic Submucosal Dissection (ESD)

A relatively new surgical procedure for early stage stomach or esophagus cancer, which is to dissect cancer inch by inch with various electric knives after injecting liquid like hyalurnoic acid around tumor and raising submucosal resect area. It is possible to resect large lesion collectively different from endoscopic mucosal resection because resection is operated by electric knives and resecting area can be decided freely.

\* Endoscopic Mucosal Resection (EMR)

An endoscopic operation of early stage cancer or polyp, which is resecting mucosal tissues at a depth of submucosal membrane by passing high-frequency electric current through wire called snare without a damage to submuscle layer.

\* Bridging

To apply for pharmaceutical approval by sharing data of preclinical or clinical trial between countries with different pharmaceutical regulations

\* DDS

Abbreviation of Drug Delivery System, which is a system, device, or technique to make proper drug behave at proper point during proper term.

\* IDE

Abbreviation of Investigational Device Exemption, which is an application of special exemption to FDA relating to clinical trial of new medical device.

Note: The performance forecast was prepared based on information obtained as of the time of announcement. Actual results may differ from the projected figures due to various subsequent factors.

## Consideration

This disclosed statement is described future business plan, which is provided for informational purposes to investors and should not be construed as a solicitation of an investment. You should rely on your own examination of us before evaluation of our business plan and investing in any securities issued by our company.

Furthermore, our company does not guarantee the probability of any future results, performance, or achievements regarding business plans, business goals, and others, and is not responsible for any future results, performance, or achievements.

All contents relating to future described in this disclosed statement, including but not limited to business plans and goals, are examined by our company with available information at this moment. Actual results, performance, achievements, or financial position are expected to be affected by a change of premises of our business plans including a change of future economy or other factors and are possible to be widely different from contents described in this disclosed statement.

Note: The performance forecast was prepared based on information obtained as of the time of announcement. Actual results may differ from the projected figures due to various subsequent factors.