

FY2012-FY2014 Mid-Term Business Plan

June 14, 2012

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

(1) Overview of FY2011 (prior fiscal year) which this mid-term business plan is designed in.

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

The Japanese economy is still in challenging situation due primarily to the global economic slowdown, the strong Yen, and a steep rise in crude oil price.

Under these circumstances, 3DM group has been developing medical devices with self-assembly peptide which is our main technology. Our first pipeline, hemostat (TDM-621) is now under test by Pharmaceuticals and Medical Devices Agency, Japan (PMDA) for manufacturing and marketing approval which was applied to PMDA 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) which we granted an exclusive distribution license in Japan and Kaken Pharmaceutical Co., Ltd. (Kaken) in April, 2012, which strengthens product sales system and expands sales channel. 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 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 us 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.

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.”

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in Lyon, France which is solely owned by us was found in April, 2012. This subsidiary is going to 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.

We aim to develop and market medical devices after seeking pipelines using this fundamental technology and to secure revenue through products sales as our basic policy. Products will be sold to business partners whom we grant distribution right and initial income or milestone income for consideration of the grant of distribution right will be recognized as revenue which we should secure.

Detail plans are as follows.

- To strengthen lineup of pipelines under development specializing in commercializing strategy and project function
- To market products early in multiple fields and secure stable product sales amount
- To strengthen the business model which manufacturing or marketing functions are complemented with business partnership in

Mid-term business goals

- To acquire manufacturing and marketing approval of hemostat, secure income by marketing products, and promote to increase market share
- To construct a framework with business partnership to manufacture and distribute products for overseas operations of hemostat
- To finish preclinical trial of endoscopic mucosal resection aid and embolism, start clinical trial, and enter into business partnership for domestic sales
- To finish clinical trial of alveolar rebuilding device, enter into business partnership in U.S., and build manufacturing and marketing system

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(3) Business progress / forecast and those premises

- 3DM group researches and develops four kinds of pipeline using self-assembly peptide technology in the field of surgery and regenerative medicine. We also secure income through marketing pipeline products as medical device business.
- Hemostat is under development in surgery field; the clinical trial was finished, manufacturing and marketing approval was applied in May, 2011, is going under test by PMDA, and is expected to be acquired during FY2012. Manufacturing and marketing framework has been built through a distribution license agreement with Fuso. Sales partnership was agreed between Fuso and Kaken in April, 2012, which strengthens product sales system and expands sales channel. The most important issue during FY2012 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 prepares for bridging. The clinical trial is prepared to conduct for business operation in the U.S. and Europe. The framework for stable manufacturing and marketing will be established.
- As to other pipelines, it is important for endoscopic mucosal resection aid and embolism that the clinical trial should start earlier by applying safety data of hemostat and accumulating efficacy data. Especially for endoscopic mucosal resection aid, we agreed the exclusive distribution license with Fuso in February, 2012 and are preparing the clinical trial to be started during FY2012.
- In other fields, we make efforts for joint research with universities or institutes to seek further pipeline candidates including DDS field.
- 3DM group's developing pipeline is development as medical device; considerable expense is needed though it takes shorter time for research and development from basic research to commercialization compared to drug. 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, development funds for other pipelines were ensured. We are starting to prepare for clinical trial earlier and speeding up those developments.

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2. Earning forecast of this fiscal year and future

(Millions of yen)

	Operating revenue	Operating profit	Ordinary profit	Net income
FY2011 (result)	1,107	354	309	308
FY2012	2,491	589	583	529
FY2013	3,845	1,091	1,085	936
FY2014	8,006	3,521	3,515	2,222

Note) Figures above are based on our 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.

Manpower planning

Manpower planning of 3DM group is estimated to build adequate corporate system along business expansion, increase of products, and growth of business volume with

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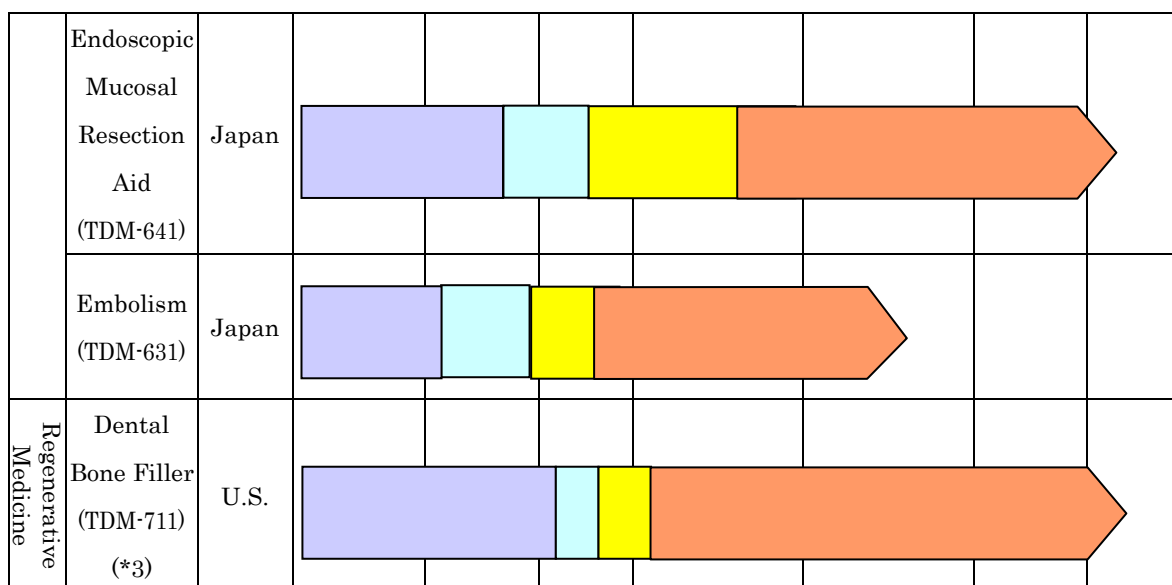
- increase of pipelines.
- **Capital investment plan**
3DM group formulates an investment plan including new manufacturing facilities for marketing hemostat and inspection facilities for future research and development.
 - **Financial plan**
Funds for research and development which 3DM group needs is increasing accompanied by promoting research and development including clinical trial for developing pipeline. The funds were secured by public offering upon stock listing and we will make efforts to ensure stable revenues by initial or milestone income and products sales. Furthermore, we have some fund raising instruments such as commitment line contract with Sumitomo Mitsui Banking Corporation and will strengthen our financial base continuously.
 - **Earning forecast**
Earning forecast is possible to be changed by various reasons including future condition of pipeline development, negotiation with business partners, and product sales after marketing.

3. Other reference information

○ Development condition 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	[Progress bar: Basic research /Evaluation test, Preclinical trial]						
		Korea	[Progress bar: Basic research /Evaluation test, Preclinical trial]						
		Taiwan	[Progress bar: Basic research /Evaluation test, Preclinical trial]						
		U.S.	[Progress bar: Basic research /Evaluation test]	[Progress bar: Preclinical trial]	[Progress bar: Clinical trial]				
		Europe	[Progress bar: Basic research /Evaluation test]	[Progress bar: Preclinical trial]	[Progress bar: Clinical trial]				

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(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

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.

● Hemostat (TDM-621)	
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

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Premise : Manufacturing and marketing approval acquired, Insurance listed in assumed field of operation, in FY2012

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

● Endoscopic Mucosal Resection Aid (TDM-641)

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

● 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

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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
<ul style="list-style-type: none"> • 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

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<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 hyaluronic 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.

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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.

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