June 13, 2013

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Mid-Term Business Plan (FY2013-FY2015)

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

(1) Review of FY2012 (previous fiscal year), as of submission of this mid-term business plan.

During the fiscal year ended in April, 2013, the global economy showed modest recovery primarily due to still having a risk of economic slowdown by the European sovereign debt crisis or the financial conditions in the U.S. The domestic economy is expected to gradually recover driven by improvements in export conditions and bolstered by an economic package as well as monetary policy.

Under these circumstances, 3-D Matrix group has been developing medical devices with self-assembling peptide, which is our main technology. Our first pipeline, surgical hemostat (TDM-621) is still under review by Pharmaceuticals and Medical Devices Agency, Japan (PMDA) for manufacturing and marketing approval. Our preparation of production line is on the final stage and the registration of ISO13485, an international standard of quality management system for medical devices, was certified in March, 2013, which contributes to global export of TDM-621. For overseas business expansion of TDM-621, IDE was submitted to Food and Drug Administration (FDA) in the U.S. in February, 2013 and we are also in preparation for obtaining CE Marking in Europe. In Asia, our subsidiary in Singapore promotes strengthening business relationship with our partners in Korea and Taiwan as well as business development in other Asian countries.

As to our second pipeline, dental bone filler (TDM-711), the clinical trial is underway at Forsyth Institute, a research institute of medical and dental school of Harvard University, and we are discussing for next step with FDA.

Endoscopic mucosal resection aid (TDM-641) is under development as our third pipeline. The preclinical trial was almost finished and we are currently preparing to start clinical trial. The exclusive distribution in Japan was agreed with Fuso Pharmaceutical Industries, Ltd. (Fuso) in February, 2012 and the initial payment for the consideration was recognized as operating revenue. The clinical trial is planned to start in FY2013.

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

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Grants-in-Aid for Scientific Research by Ministry of Health, Labour, and Welfare, and the research grant was received and recognized as operating revenue.

Another joint research project with New Energy and Industrial Technology Development Organization (NEDO), which is to develop new device promoting automatic regeneration of tissues with fewer cells in vivo, has been proceeding since FY2010.

For global business expansion, a new consolidated subsidiary "3-D Matrix Asia Pte. Ltd." in Singapore, which is solely owned by 3-D Matrix Ltd., was found in November, 2012. This subsidiary becomes another base for research and business development in Asian countries.

As a result, consolidated operating revenue for FY2012 totaled ¥32,013 thousand (down ¥1,075,374 thousand from the previous year), with ordinary loss of ¥977,511 thousand (compared to ordinary income of ¥309,569 thousand for the previous year), and net loss of ¥978,331 thousand (compared to net income of ¥308,610 thousand for the previous year).

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

Basic policy of mid-term business plan

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

Based on a search of application pipeline leveraging our fundamental technology, our basic policy is 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 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 targets

- Obtain 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 market
- Complete clinical trial of dental bone filler, enter into business partnership in U.S., and establish structure for manufacturing and marketing

(3) Business progress / forecast and those premises

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- 3-D Matrix group is currently researching and developing five 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.
- Hemostat is under development in surgery field; the clinical trial has been completed, manufacturing and marketing approval was applied in May 2011, the review by PMDA undergoing, and the approval is expected to be obtained during FY2013 rather than FY2012. 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. The most important issue during FY2013 is to obtain manufacturing and marketing approval and to start distribution in domestic market.
- For overseas operation of hemostat, the company concluded partnership and license agreements with business partners in Korea and Taiwan in September, 2010 and we are preparing for bridging. We are also in preparation for the clinical trials in the U.S. and Europe. IDE (corresponds to submission of clinical protocol in Japan) was submitted in the U.S. in FY2012 and application for CE Mark in Europe was submitted in May, 2013. We will continue to establish a framework for stable manufacturing and marketing.
- Concerning other pipelines, clinical trial for dental bone filler has started, and we recognize that it is important for endoscopic mucosal resection aid and embolism to bring forward the clinical trial starting, 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 FY2013.
- In other fields, we are making our efforts on joint research with universities or institutes to seek further pipeline candidates including DDS field.
- 3-D Matrix group's pipeline is developed as 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.

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2. Earning forecast of this fiscal year and future targets

(Millions of yen)

	Operating revenue	Operating income (loss)	Ordinary income (loss)	Net income (loss)
FY2012 (actual)	32	(999)	(977)	(978)
FY2013 (forecast)	4,178	1,658	1,646	1,491
FY2014 (target)	8,474	3,347	3,341	2,241
FY2015 (target)	12,569	5,780	5,780	3,668

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 of booking time based on development plan of each pipeline. The amount of revenue is estimated with consideration for market size, competitive condition, superiority, latest market trend, and negotiating condition. Operating revenue of FY2012 was mainly from grants. FY2013 to FY2015 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 3-D Matrix group is calculated by accumulating estimated amount of peptide materials and subcontract expenses.

  Research and development expense

  Research and development expense of 3-D Matrix 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 3-D Matrix 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.

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- Capital investment plan

  3-D Matrix 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.

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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 listed	Distribution
Surgery	Hemostat (TDM-621) (*2)	Japan							
		Korea							
		Taiwan							
		US							
		EU							
		China							
	Endoscopic Mucosal Resection Aid (TDM-641)	Japan							
	Embolism (TDM-631)	Japan							
Regenerative Medicine	Dental Bone Filler (TDM-711) (*3)	US							
	Wound Treatments (TDM-511)	US							

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.

(Notes) 1. ▭> means development plan and ▭ means development already done.
▭ means development target in FY2013, ▭ in FY2014, and ▭ in and after FY2015.

2. Hemostat
Clinical trial was finished in April, 2011; manufacturing and marketing approval was applied in May, 2011 and is under review 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 obtained in short term if the bridging is allowed; however, the bridging might not be allowed or additional test might be 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 IDE approval was obtained 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/China)
Stage	:	Manufacturing and marketing approval applied in FY2011, under review by PMDA
Premise	:	Manufacturing and marketing approval obtained, 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

● 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

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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 or uterine artery embolization for liver 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

●Wound Treatments (TDM-511)

Feature : To stimulate wound healed due to regenerative environment for dermal tissue made in dermal wound by self-assembly gelating and foaming nano-fiber.

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Target	:	Mild-to-moderate skin wound
Market	:	U.S. and Europe
Stage	:	Preclinical trial
Premise	:	To prepare sufficient data based on preclinical trial in order that efficacy and safety be approved by authorities
Issue	:	To show sufficient test results in order to obtain an approval of clinical trial
Specifics	:	To conduct sufficient tests

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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 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.

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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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