June 19, 2014


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|---|---|
| Company Name | 3-D Matrix, Ltd. |
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# [Delayed] Mid-term Business Plan (FY2014-FY2016)

(This original disclosure in Japanese was released on June 12, 2014 at 15:30 (GMT+9))

The company hereby announces that its mid-term business plan (FY2014 to FY2016) was made. This mid-term business plan has been submitted to Tokyo Securities Exchange as of June 12, 2014.

1. Forecast of mid-term business plan

The company's group has successfully obtained CE marking for the surgical hemostat (TDM-621) in January, 2014, which allows the group to start distribution of the hemostat in EU member countries, though our application for manufacturing and marketing approval in Japan is still pending. The group has begun to manufacture products for EU and is launching distribution to influential medical facilities. In the meantime, the group further plans to promote global marketing by leveraging this CE marking as a reference regulatory agency approval in various countries in Asia-Pacific and Latin America.

For this fiscal year, FY2014, revenue from milestone payment and products sales are budgeted and forecasted business revenue of ¥10,306 million is revised upward to ¥10,418 million. Development of the hemostat (TDM-621) in the U.S. and Europe including IDE application and CE marking obtained is on track, and business expansion in Asia is underway including distribution partnership in Indonesia following Korea and Taiwan. Hence, business revenue of 13,497 million for FY2015 is revised upward to ¥14,307 million and FY2016 is newly planned.

Despite the group's effort to reduce costs including subcontract fees, operating income for FY2014 is also revised to ¥4,483 million (down ¥78 million from previous forecast) with ordinary income of ¥4,466 million (down ¥82 million) and net income of ¥3,564 million (up ¥16 million) primarily because of the conservative estimate of R&D expenses for hemostat in each countries.

The forecasted operating income for FY2015 is revised to ¥6,796 million (up ¥360 million), with ordinary income of ¥6,779 million (up ¥356 million) and net income of ¥4,678 million (up ¥666 million).

Business plan for FY2016 is newly made with this announcement.

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)

| | Business revenue | Operating income (loss) | Ordinary income (loss) | Net income (loss) |
|---|---|---|---|---|
| FY2013 (actual) | 107 | (1,518) | (1,523) | (1,525) |
| FY2014 (original forecast) | 10,306 | 4,562 | 4,548 | 3,548 |
| FY2014 (revised forecast) | 10,418 | 4,483 | 4,466 | 3,564 |
| FY2015 (original target) | 13,497 | 6,436 | 6,422 | 4,011 |
| FY2015 (revised target) | 14,307 | 6,796 | 6,779 | 4,678 |
| FY2016 (target) | 18,473 | 8,213 | 8,196 | 5,450 |

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

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

There is no significant change in premises for this mid-term business plan from "Mid-term Business Plan" announced on March 14, 2014 though the company's revenue and income may be slightly changed.

As for financial plan, the group continues to strengthen its financial base and enhances its working capital. R&D expenses have been secured through the secondary public offering in 2013. Commitment line contract for ¥300 million with Sumitomo Mitsui Banking Corporation (SMBC) and credit lines committed by SMBC and Mizuho Bank, Ltd. for respective ¥500 million are ongoing. At the present moment, a total of ¥800 million was drawn, which is mainly used to purchase peptide as material of hemostat.

4. Others

For details, please refer to attached reference information "FY2014-FY2016 Mid-term Business 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.

June 12, 2014

<Reference Information>


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# Mid-Term Business Plan (FY2014-FY2016)

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

(1) Review of FY2013 (previous fiscal year), as of the announcement of this business plan.

During FY2013, 3-D Matrix group continued to focus on developing medical devices using self-assembling peptide, which is the group's core technology. As for surgical hemostat (TDM-621), the primary product in the product pipeline, the group has applied to the Pharmaceuticals and Medical Devices Agency, Japan, (PMDA) for manufacturing and marketing approval and has been consulting with the U.S. Food and Drug Administration (FDA) in order to launch a clinical trial in the U.S.

In Europe, the group is launching production and working to convince leading medical facilities to start using the hemostat as the product obtained CE marking on January 14, 2014, making it possible to manufacture and sell the hemostat in EU member countries. Furthermore, this CE marking enables the group to apply for manufacturing and marketing approval without conducting clinical trials in various countries in Asia-Pacific and Latin America, where CE marking is recognized as a reference regulatory agency approval.

The group has also launched efforts to convince several leading facilities to conduct clinical researches in Europe and is moving forward with projects to get the hemostat listed in insurance reimbursement system in each country and to increase its use at various medical facilities. At the same time, the group is moving forward with negotiations regarding distribution license agreements with sales partners.

In other regions, the company's subsidiary in Singapore, 3-D Matrix Asia Pte. Ltd. concluded an exclusive distribution license agreement for Indonesia in May, 2013 with Indonesia-based PT. Tegushindo Lestaritama. The group continues to prepare for expanding the business of TDM-621 including Asia-Pacific, China, and Latin America.

As for the dental bone filler (TDM-711), the product has been used in 15 cases of clinical trial in the U.S. and the related follow-up has been completed. Based on these results, the group is continuing consultations with FDA regarding launching a pivotal clinical trial.

The group is also moving forward with discussions with PMDA to launch a clinical trial for the

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.

endoscopic mucosal resection aid (TDM-641).

Furthermore, the group and National Cancer Center are jointly conducting a project which is to cure triple negative breast cancer by nucleic acid-based drugs. The project was nominated as one of the projects of Program Year 2011 Grants-in-Aid for Scientific Research by Ministry of Health, Labour, and Welfare, and the company received research grant, which was recognized as business 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.

As a result, consolidated operating revenue for FY2013 totaled ¥107,161 thousand (up ¥75,148 thousand from the previous year), with ordinary loss of ¥1,523,867 thousand (compared to ordinary loss of ¥977,511 thousand for the previous year), and net loss of ¥1,525,374 thousand (compared to net loss of ¥978,331 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 its core technology, self-assembling peptide.

Based on a search of application pipeline leveraging this fundamental technology, our basic policy is to develop and market medical devices and to secure revenue through products sales. Products are 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
- Complete clinical trial of dental bone filler, enter into business partnership in U.S., and establish structure for manufacturing and marketing

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) Business progress / forecast and those premises

- 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 is pending. Manufacturing and marketing framework has been built through a distribution license agreement with Fuso Pharmaceutical Industries, Ltd. (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 FY2014 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 started 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 marking in Europe was submitted in May, 2013 and obtained in January, 2014. We will continue to establish a global 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 FY2014.
- In other fields, we are making our efforts on joint research with universities or institutes to seek further pipeline candidates including DDS field.
- The 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 primary pipeline, hemostat has been secured through IPO and milestone payments from business partners. We were also able to secure funds through public offering 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 | Business income (loss) | Ordinary income (loss) | Net income (loss) |
|---|---|---|---|---|
| FY2013 (actual) | 107 | (1,518) | (1,523) | (1,525) |
| FY2014 (forecast) | 10,418 | 4,483 | 4,466 | 3,564 |
| FY2015 (target) | 14,307 | 6,796 | 6,779 | 4,678 |
| FY2016 (target) | 18,473 | 8,213 | 8,196 | 5,450 |

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

Premises for earning forecast

- Business revenue

  Business revenue is predicted to recognize 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. Business revenue of FY2014 is likely to be mainly from milestone income and product sales for hemostat. FY2015 to FY2016 are estimated with milestone income upon approval of manufacturing and marketing of hemostat, product sales 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 the 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 the group is calculated with estimated amount along future business plan in consideration of result figure of each expense.

  Personnel planning

  Personnel planning of the 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.

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.

- Capital investment plan

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

- Financial plan

  R&D expenditure of the group will increase according to promotion of R&D including clinical trials for developing pipelines. We have secured necessary funds by initial public offering and secondary public offering in July, 2013, and will make efforts to ensure stable revenues through initial or milestone incomes and product sales. Commitment line contract for ¥300 million with Sumitomo Mitsui Banking Corporation (SMBC) and credit lines committed by SMBC and Mizuho Bank, Ltd. for respective ¥500 million are ongoing. At the present moment, a total of ¥800 million was drawn, which is mainly used to purchase peptide as material of hemostat. We continue to strengthen our financial base and enhance our working capital.

- 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 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 FY2014, ▭ in FY2015, and ▭ in and after FY2016.

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/Asia-Pacific/Latin America) |
| Stage | : | Manufacturing and marketing approval pending in FY2014 |
| Premise | : | Manufacturing and marketing approval obtained, Insurance listed in assumed field of operation in FY2014 |
| 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 obtained 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)<br>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. |

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.

| | | |
|---|---|---|
| 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 |
| Issue | : | marketing approval acquired, Insurance listed<br>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. |
| 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 |

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.

| | | |
|---|---|---|
| Issue | : | To show sufficient test results in order to obtain an approval of clinical trial |
| Specifics | : | To conduct sufficient tests |

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.

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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.

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.