[Delayed] Consolidated Financial Report
For the Fiscal Year Ended April 30, 2015
(Under Japan GAAP)

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June 2015

Company name: 3-D Matrix Ltd.
Stock exchange listing: Tokyo JASDAQ
Stock code number 7777
URL: http://www.3d-matrix.co.jp/
Representative: President Kentaro Takamura
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Date of dividend payment (expected): —
Date of ordinary general shareholders' meeting (expected): July 30, 2015
Annual filing date (expected): July 31, 2015
Supplementary earnings explanatory material : Yes
Earnings explanatory meeting : Yes (for institutional investors and analysts)

(figures rounded down to the nearest million yen)

1. Consolidated operating results for FY2014 (May 1, 2014–April 30, 2015)

(1) Consolidated operating results (% are year-on-year changes)

	Business revenue		Operating income		Ordinary income		Net income	
	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)
FY2014	99	-6.9	-1,903	—	-1,795	—	-1,994	—
FY2013	107	234.7	-1,518	—	-1,523	—	-1,525	—

Note: Comprehensive income FY2014 -2,047 million (— %) FY2013 -1,525 million (— %)

	Net income per share	Diluted net income per share	Return on equity	Return on assets	Operating income margin
	(¥)	(¥)	(%)	(%)	(%)
FY2014	-94.89	—	-44.6	-32.8	-1,907.3
FY2013	-77.77	—	-61.8	-42.7	-1,416.9

Reference: Gain/loss on equity method investments FY2014 — million FY2013 — million

(2) Consolidated financial position

	Total assets	Net assets	Shareholders' equity per share	Nets assets per share
	(¥ million)	(¥ million)	(%)	(¥)
FY2014	6,809	6,381	88.7	281.77
FY2013	4,120	3,133	70.5	146.17

Reference: Shareholders' equity FY2014 ¥6,040 million FY2013 ¥2,905 million

(3) Consolidated cash flows

	Cash flow from operating activities	Cash flow from investing activities	Cash flow from financing activities	Closing balance of cash and cash equivalents
	(¥ million)	(¥ million)	(¥ million)	(¥ million)
FY2014	-1,904	-125	4,510	5,136
FY2013	-1,679	-83	2,359	2,640

2. Dividends

	Annual dividends per share					Total dividends	Payout ratio (consolidated)	Dividend to net asset ratio (consolidated)
	1Q	2Q	3Q	End of year	Total			
	(¥)	(¥)	(¥)	(¥)	(¥)	(¥ million)	(%)	(%)
FY2014	—	0.00	—	0.00	0.00	0	—	—
FY2013	—	0.00	—	0.00	0.00	0	—	—
FY2015 (forecast)	—	0.00	—	0.00	0.00		—	

3. Consolidated financial forecasts for FY2015 (May 1, 2015—April 30, 2015)

(% are year-on-year changes)

	Business revenue		Operating income		Ordinary income		Net income		Net income per share
	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥)
FY2015	783 ～2,877	685.7 —	-1,996 ～24	— —	-2,004 ～16	— —	-2,005 ～11	— —	-93.54 ～0.56

* Notes

(1) Changes in number of material subsidiaries during the fiscal year (changes in specific subsidiaries due to a change in the scope of consolidation) : No

(2) Changes in accounting policies, accounting estimates, and restatement

1) Changes in accounting policies due to changes in accounting standards : No
2) Changes in accounting policies other than 1) : No
3) Changes in accounting estimates : No
4) Restatements : No

(3) Number of shares issued (common stock)

1) Number of shares issued as of end of the fiscal year (including treasury shares)	FY2014	21,438,400	FY2013	19,876,400
2) Number of treasury shares as of end of the fiscal year	FY2014	112	FY2013	112
3) Average number of shares during the fiscal year	FY2014	21,023,324	FY2013	19,613,633

Reference: Summary of non-consolidated earnings

1. FY2014 non-consolidated earnings (May 1, 2014,–April 30, 2015)

(1) Non-consolidated operating results

(% are year-on-year changes)

	Business revenue		Operating income		Ordinary income		Net income	
	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)	(¥ million)	(%)
FY2014	123	118.5	-1,190	—	-1,095	—	-1,291	—
FY2013	56	76.1	-1,055	—	-1,067	—	-1,068	—

	Net income per share	Diluted net income per share
	(¥)	(¥)
FY2014	-61.45	—
FY2013	-54.45	—

(2) Non-consolidated financial position

	Total assets	Net assets	Shareholders' equity per share	Nets assets per share
	(¥ million)	(¥ million)	(%)	(¥)
FY2014	8,361	7,984	91.4	356.54
FY2013	4,935	3,980	76.0	188.80

Reference: Shareholders' equity FY2014 ¥7,643 million FY2013 ¥3,752 million

* Note on audit procedures
  - This consolidated financial report is exempt from the audit procedures stipulated by the Financial Instruments and Exchange Act; financial statement audit procedures stipulated by the Financial Instruments and Exchange Act have not been completed by the time this report is released.
* Notes on proper use of earnings forecasts, etc.
  - Forward-looking statements including earnings forecasts appearing in this report are based on currently available information and assumptions that the Company regards as reasonable. Actual earnings, etc., may substantially differ from these forecasts for various reasons. Refer to “Analysis of Operating Results” (page 2) for details on assumptions that the earnings forecasts are based on, notes on the use of the earnings forecasts, etc.
  - The Company plans on holding an earnings explanatory meeting for institutional investors and analysts on June 19, 2015. The earnings explanatory material used on that day and audio of the meeting are expected to be posted on the Company’s website promptly after the meeting.

○ List of Appendixes

1. **Analysis of Operating Results and Financial Position**

(1) Analysis of Operating Results

Operating Results

During FY2014, 3-D Matrix Group continued to focus on developing medical products using self-assembling peptide, which is the group's core technology. Business of the group's pipeline including the surgical hemostat TDM-621 ("Hemostat") and the endoscopic mucosal resection aid TDM-641 ("Endoscopic Mucosal Resection Aid") in the field of surgery and the dental bone filler TDM-711 ("Dental Bone Filler") and the wound treatment material TDM-511 ("Wound Treatment Material") in the field of the regenerative medicine has been expanded.

Hemostat

Japan: The Group had previously submitted an application to the Pharmaceuticals and Medical Devices Agency, Japan (PMDA) for certification to manufacture and sell the product in Japan. However, the Group withdrew the application on March 13, 2015 and decided to submit a new application after conducting clinical trials again in order to test the scientific validity of the effectiveness assessment of the product. The Group will continue the consultation with PMDA going forward and plans to start clinical trials in the first half of FY2015 (fiscal year ending April 30, 2016).

Europe: After the product obtained CE marking on January 14, 2014, the clinical use of the product started in Germany, a major economy in Europe, on August 28, 2014. Since then, the product has accumulated the experience of clinical use as part of pre-marketing targeting prominent doctors and major medical institutions in major European countries including Germany, France, and the U.K. The Group started to sell the product in the fourth quarter through distributors, which led to the recognition of business revenue. At the same time, the Group negotiated distribution license agreements with sales partners in Europe, but no agreement has been concluded as of the end of the fiscal year under review. Consequently, the Group will continue to negotiate the agreement with several candidates going forward.

Asia (Singapore, Indonesia, South Korea, etc.): As CE marking is recognized in this region, the Group is conducting activities toward the submission of an application for product registration as a medical device and the launch of product sales in various countries. In Singapore, an application for product registration was submitted on June 4, 2014 and the registration approval was obtained on September 3, 2014. In Indonesia, an application for product registration was submitted on July 18, 2014 and the registration approval was obtained on April 16, 2015. In South Korea, an application for product registration was submitted on January 29, 2015 and is currently in the examination process. Meanwhile, the Group recognized business revenue as it received milestone payments from the sales partner in Indonesia for securing the registration approval and launched product sales in Hong Kong, where no registration approval is required.

Latin America (Brazil, Columbia, Mexico, etc.): As CE marking is recognized in this region, the Group is conducting activities toward the submission of an application for product registration as a medical device and the launch of product sales in various countries. In Columbia, an application for product registration was submitted on March 9, 2015 and is currently in the examination process. The Group is also preparing for the submission of such an application in Brazil and Mexico.

United States: The Group has been consulting with the U.S. Food and Drug Administration (FDA) regarding the protocol in order to launch a clinical trial in the U.S. scheduled for FY2015.

Endoscopic Mucosal Resection Aid

Japan: The Group moved forward with discussions with PMDA to launch a clinical trial and started clinical trials in Japan on December 11, 2014. However, the Group temporarily halted them at its decision on February 16, 2015 in order to consider the improvement of the test method and pharmaceutical preparations so that the effectiveness of the product can be more clearly demonstrated. The Group currently plans to ensure that the development schedule for the product through the introduction into the market will not be affected by resuming the clinical trials by the end of the third quarter of FY2015. The Group will aim to secure a competitive advantage of the product and resume the clinical trials as soon as possible.

Dental Bone Filler

United States: A clinical trial is currently being conducted in the U.S. The product has been used in 15 cases and the related follow-up has been completed to produce favorable results and data regarding bone formation. Consequently, the clinical trial will move forward to the next phase scheduled for the first half of FY2015.

Wound Treatment Material

United States: On October 23, 2014, the Group submitted to the FDA an application for 510(k) premarket approval, which is part of the approval process for medical devices in the U.S. Subsequently, on February 16, 2015, the Group obtained the approval from the FDA for the sales of the product. Although the Group has been granted the permission to sell the product, the product is expected to have a higher curative effect when it is administered in combination with other pharmaceuticals (administration of a mixture with an antibiotic, anticancer agent, hyaluronic acid, etc.). Therefore, the Group is currently pushing ahead with the commercialization aiming to introduce a high value-added product in the fields of burn treatment, skin cancer treatment, and cosmetic surgery.

Furthermore, the Group and the National Cancer Center are jointly conducting a project which is to cure triple negative breast cancer by nucleic acid-based drugs and the Company received a subsidy as a research grant, which was recognized as business revenue. The Company is providing the self-assembling peptide A6K as a drug delivery system (DDS) in siRNA nucleic acid medicine and an investigator initiated clinical trial has been commenced by the National Cancer Center.

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 and the Company recognized subsidy income as it received a subsidy for this research project. The Company also provides technology for the use of self-assembling peptide as a cell scaffolding material for cartilage regeneration.

As a result, consolidated operating revenue for FY2014 totaled ¥99,776 thousand (down ¥7,384 thousand from the previous fiscal year), with ordinary loss of ¥1,795,211 thousand (compared to ordinary loss of ¥1,523,867 thousand for the previous fiscal year), and net loss of ¥1,994,965 thousand (compared to net loss of ¥1,525,374 thousand for the previous year).

Outlook for FY2015

The following is the outlook for the Group in FY2015.

The Group will continue to push ahead with the development of products in the fields of surgery and regenerative medicine using the self-assembling peptide technology, aiming to generate business revenue by promptly launching product sales.

As for Hemostat, the Group is having consultation with PMDA regarding the protocol for clinical trials toward the commencement of a new round of clinical trials. The Group plans to conduct them sometime in the first half of FY2015 and submit a new application in the second half of the fiscal year. As for the implementation of manufacturing and sales of the product, the Group has established a system to support the introduction of the production into the market by entering into an agreement with FUSO Pharmaceutical Industries. The Group recognizes that the important next step is to promptly obtain the certification to manufacture and sell the product and launch the sales of the product in Japan.

In Europe, the Group, in order to secure business revenue from Hemostat, intends to start selling the product through wholesalers and distributors (who will be specialized in the sales in their respective home country) targeting major medical institutions in Germany, France, the U.K., etc. To this end, the Group plans to enter into sales tie-up agreements covering the entire EU region with sales partner candidates (that have a distribution network and promotion function covering the entire target region) to start selling the product through the sales partners by the end of the third quarter of FY2015.

In the U.S., the Group is currently preparing the protocol for clinical trials of Hemostat and the commencement of clinical trials is scheduled for FY2015. In Asia and Latin America, the Group will start selling the product mainly in Southeast Asia, such as Indonesia, and in Columbia and Chile.

As for other products in the pipeline, the Group will continue to conduct clinical trials of Dental Bone Filler in the U.S. Although the clinical trial of Endoscopic Mucosal Resection Aid has been temporarily halted, the Group aims to resume it by the end of the third quarter of FY2015 after securing a competitive advantage of the product. In addition, since an investigator initiated clinical trial has already been started by the National Cancer Center in a joint project between the Center and the Company, the Group will also move forward with development in the field of drug delivery system (DDS).

Given the development outlook discussed above, the Group plans to recognize business revenues consisting of revenue from Hemostat product sales and initial and milestone payments based on contracts (“Initial and Other Payments”).

(Revenue and profit and loss)

(¥ million)

	Business revenues	Operating income	Ordinary income	Net income
FY2015 (Forecast)	783—2,877	-1,996—24	-2,004—16	-2,005—11

Breakdown of business revenues	Hemostat		Others		Total
	Product sales	Initial and milestone payments	Product sales	Initial and milestone payments	
FY2015 (Forecast)	582—675	176—2,175	7	18	783—2,877

Note 1: The Group has prepared the business revenue forecast above by estimating the amount and timing of future business revenues in accordance with the development plans of each product in the pipeline and based on the assumptions developed for the preparation of earnings forecasts.

Note 2: “Others” in the above table include plans for Dental Bone Filler, Endoscopic Mucosal Resection Aid, and embolization material, but does not include plans for Wound Treatment Material and others.

Note 3: The Group has prepared the earnings forecast for FY2015 by presenting ranges between the upper limit and the lower limit in consideration of the possibility that the recognition of revenues from initial payments and product sales could be delayed until FY2016 depending on the status and the progress of negotiation with sales partner candidates in Europe for Hemostat.

As part of the assumptions developed for the preparation of earnings forecasts, the Group plans to sell Hemostat and receive initial and milestone payments (“Initial and Other Payments”) based on contracts for the product.

The Group plans to sell Hemostat in Europe, Asia, and Latin America, where CE marking is recognized. In Europe, sales efforts will be targeted at major medical institutions in Germany, France, the U.K., etc. In Asia, the Group expects to sell the product mainly in Southeast Asia, such as Indonesia and Malaysia. In Latin America, product sales in Columbia, Chile, etc. are expected.

The table above reflects the Group’s plan to increase product sales significantly from the previous fiscal year. The planned range of product sales between ¥582 million and ¥675 million above represents the sum of estimated product sales of ¥266 million in Asia and Latin America and a product sales range between ¥316 million and ¥409 million in Europe. In other words, the significant increase in product sales in the forecast is primarily based on the Group’s plan to sell Hemostat through sales partners in addition to sales through wholesalers/distributors in Europe. The product sales range for Europe was prepared by aggregating sales forecasts calculated based on the Group’s marketing forecasts including market size and other market forecasts, which were prepared based on interviews with wholesalers/distributors in Germany and the U.K. The product sales forecast in Asia and Latin America was prepared by aggregating sales forecasts calculated based on the Group’s marketing forecasts including an estimated amount of orders from tie-up partners based

on contracts in Indonesia and market size and other market forecasts in other Southeast Asian countries such as Malaysia and Latin America.

The amount of Initial and Other Payments for Hemostat above is based on initial payments expected to be received under sales tie-up agreements with sales partner candidates in Europe, which are currently in the process of negotiation. The total amount of Initial and Other Payments was derived based on the Group's past experience in Japan and Asia and in consideration of the market size, product value, expected market share, risk, etc. in the target regions, after considering several calculation methods such as comparison with the experience of other companies and comparison with the Group's past experience.

Currently, the Group continues to negotiate distribution license agreements for the sales of Hemostat in Europe. The Group was unable to conclude such agreements by the end of FY2014 as there was a candidate that did not respond promptly to the terms and conditions proposed by the Group after completing the due diligence of the candidate and there were other candidates that became a target of group-wide or business unit reorganization. However, as the candidates have been narrowed down to three companies, product evaluation results have been accumulated, and there has been a progress in negotiation, we plan to conclude distribution license agreements by the end of the third quarter of FY2015.

Initial payments under sales tie-up agreements with sales partner candidates in Europe and product sales based on the sales tie-ups account for a significant portion (¥2,094 million) of the upper limit of the forecasted range of business revenues (¥2,877 million). For this reason, the conclusion of these agreements is the critical prerequisite for the achievement of the upper limit of the range.

As for expenses forecasts, research and development expenses are forecasted by aggregating estimated research and development expenses by development pipeline on a project basis, mainly consisting of clinical trial expenses for Hemostat (Japan and the U.S.), CE marking registration expenses for Hemostat (each country in the world), and clinical trial expenses for Dental Bone Filler (the U.S.) and Endoscopic Mucosal Resection Aid (Japan). As for selling, general and administrative expenses, an estimated amount has been calculated in consideration of actual amounts in the past by expense item and in accordance with future business plans.

Based on the assumptions discussed above, the Group has prepared the consolidated earnings forecast for FY2015 by presenting ranges between the upper limit and the lower limit in consideration of the possibility that the recognition of revenues from Initial and Other Payments could be delayed depending on the status and the progress of negotiation with sales partner candidates in Europe for Hemostat.

(2) Analysis of Financial Position

(i) Assets, liabilities, and net assets

As of the end of FY2014, total assets stood at ¥6,809,245 thousand (up ¥2,688,276 thousand from the end of FY2013).

Current assets totaled ¥6,203,920 thousand (up ¥2,611,295 thousand). That was due mainly to an increase of ¥2,496,300 thousand in cash and deposits.

Non-current assets totaled ¥605,325 thousand (up ¥76,981 thousand). That was due mainly to an increase ¥48,852 thousand in patent right and ¥79,616 thousand in right of using patent included in intangible non-current asset, despite a decrease ¥70,000 thousand in amortization of goodwill.

Liabilities totaled ¥427,722 thousand (down ¥559,894 thousand). That was due mainly to a decrease

¥600,000 thousand in short-term loans, despite an increase ¥46,554 thousand in account payable included in current liabilities.

Net assets totaled ¥6,381,523 thousand (up ¥3,248,171 thousand). That was due mainly to a retained earnings fell due to a net loss for the fiscal year. Although retained earnings declined ¥1,994,965 thousand because of a net loss for the quarter, capital stock increased ¥2,591,449 thousand for reasons including a capital increase through raising capital by issuing new shares for abroad, and the capital surplus rose ¥2,591,417 thousand.

Net assets totaled ¥6,381,523 thousand (up ¥3,248,171 thousand). That was due mainly to an increase ¥2,591,449 thousand in capital stock and ¥2,591,417 thousand in capital surplus through raising capital by issuing new shares for abroad, despite a decrease of ¥1,994,965 thousand in retained earnings.

(ii) Cash flows

At the end of FY2014, cash and cash equivalents (referred to as “cash” below) increased ¥2,496,300 thousand compared to the end of FY2013 to ¥5,136,835 thousand.

The following is a summary of cash flows for FY2014.

(Cash flow from operating activities)

Net cash used for operating activities totaled ¥1,904,814 thousand. That was mainly the result of ¥135,045 thousand in share-based compensation expenses, a loss before income taxes and minority interests of ¥1,990,220 thousand.

(Cash flows from investing activities)

Net cash used for investing activities totaled ¥125,552 thousand. That was mainly because of ¥72,979 thousand for the purchase of intangible non-current assets, and ¥43,622 thousand for the purchase of long-term prepaid expenses.

(Cash flows from financing activities)

Net cash provided by financing activities totaled ¥4,510,632 thousand. This chief reason for this was ¥5,128,465 thousand in proceeds from issuing new shares for abroad, etc.

Reference: Cash flow–related indicators

	FY2010	FY2011	FY2012	FY2013	FY2014
Equity ratio (%)	95.0	93.9	67.3	70.5	88.7
Equity ratio (market value) (%)	—	534.8	2,814.9	1,760.5	473.2
Debt to cash flow ratio (%)	—	(50.6)	(130.3)	(50.1)	(12.0)
Interest coverage ratio (times)	—	362.2	(85.7)	(145.8)	(226.1)

Equity ratio = shareholders’ equity/total assets

Equity ratio (market value) = market capitalization/total assets

Debt to cash flow ratio = interesting-bearing debt/cash flow

Interest coverage ratio = cash flow/interest payments

Note 1. All indicators are calculated using figures from consolidated financial statements.

Note 2. Market capitalization is calculated using issued shares minus treasury shares.

Note 3. Cash flow refers to cash flows from operating activities.

Note 4. Interest-bearing debt refers to all debt appearing on the consolidated balance sheet that entails interest payments.

(3) Basic Policy on Distribution of Profits and Dividends for the Current and Coming Period

The Company's basic policy is to pay both an interim dividend that is proportional to income and end-of-year dividend. However, the Company is still at a stage where it continually allocates funds to R&D activities in order to develop medical devices and has not paid a dividend since being founded. Furthermore, as of the end of FY2014, the company is still not in a position to pay a dividend. The plan is to prioritize the use of funds for R&D activities for the time being, but the Company is aware that paying shareholders a return is an important management issue. After eliminating accumulated losses, the Company will examine paying a dividend taking into consideration its earnings and financial position.

In addition, the shareholders' meeting is where decisions on dividends are made, but the Company's articles of incorporation stipulate that the decision to pay an interim dividend prescribed in Article 454.5 of the Companies Act can be made by a resolution of the board of directors.

(4) Business Risks, etc.

The following are the main potential risks related to not only expanding the Group's business but also other issues.

In order to actively disclose information to investors, the Group lists issues that perhaps do not necessarily deserve to be considered risks related to expanding its business but are probably important for making investment decisions. The policy of the Group is after recognizing a risk, to strive to avoid it or if the risk materializes, to respond to it; however, it is important that potential investors make decisions regarding investing in the Company's shares after carefully examining not only the following items but other information included in this report. It should also be kept in mind that the following risks are not all the ones that the Company faces.

Forward-looking comments included in this material are based on the judgment of the Group as of the time the material was submitted.

(i) Risks related to the medical device business

A. Items related to legal regulations such as the Pharmaceutical Affairs Act

A. Items related to legal regulations such as the Pharmaceutical and Medical Device Act

The Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics ("Pharmaceutical and Medical Device Act") was established to ensure the effectiveness and safety of pharmaceuticals, medical devices, etc. The Act stipulates that it is necessary to obtain a license from the governor of the prefecture with jurisdiction to manufacture and sell medical devices. There is also a requirement to obtain certification or approval from the relevant authorities for each medical device.

Having obtained a type 1 license from the governor of Tokyo to manufacture and sell medical devices on August 18, 2010, (the license is valid until August 17, 2015 and the Company will apply for a renewal in July 2015), the Company develops and researches medical devices and conducts manufacturing and sales activities. The Group not only strives to comply with the Pharmaceutical and Medical Device Act and related legislation but also has developed in-house systems as the business has progressed. However, the Company's type 1 license could be revoked (Article 75.1 of the Pharmaceutical and Medical Device Act) if the Company were to violate the Pharmaceutical and Medical Device Act, laws or rules related to pharmaceutical affairs or measures taken in accordance with these laws and regulations or if one of the

conditions stipulated in Article 5.3 of the Pharmaceutical and Medical Device Act (with Article 12.2.3 applied *mutatis mutandis*) were true for the Company or one of its directors. If this were to occur, it could have a major impact on the earnings and financial position of the Group.

In May 2011, the Company also applied to the Minister of Health Labour and Welfare for certification to manufacture and sell Hemostat (TDM-621), the product that is the farthest along in the Group's product pipeline. However, in the course of consultation with PMDA, the Company reached the conclusion that the effectiveness of TDM-621 in controlling hemorrhaging needs to be further demonstrated with more precise testing. As a result, the Company withdrew its initial application for certification to manufacture and sell the product as of March 13, 2015 in order to submit a new application after conducting clinical trials again.

During the initial application process, the Company started a human clinical trial in January 2010 after conducting a GLP safety test in accordance with PMDA guidelines, and for 97 cases through April 2011 that Hemostat was used, there were no adverse events, such as serious problems or side effects whose causal relationship could not be rejected.

The Company will conduct clinical trials again in accordance with an appropriate protocol based on the prior consultation with PMDA. However, if the effectiveness of the product in controlling hemorrhaging that is currently expected is not confirmed by the future clinical trials or if there are major revisions to the Pharmaceutical and Medical Device Act or related legislation, and it becomes impossible to obtain certification to manufacture and sell TDM-621, this could have a major impact on the earnings and financial position of the Group.

Even if the Company obtains certification to manufacture and sell TDM-621, the certification can be revoked for various reasons such as the product did not have the efficacy, effect, or impact applied for (Article 74.2.1 and Article 14.2.3 of the Pharmaceutical and Medical Device Act) or one of the conditions prescribed in Article 74.2.3 of the Pharmaceutical and Medical Device Act were true for the Company. If the Company's certification to manufacture and sell TDM-621 were revoked, this could have a major impact on the earnings and financial position of the Group.

B. Earnings uncertainty

Hemostatic agents are widely used in surgeries, and there are a stable number of surgeries and suitable cases. If TDM-621, a hemostatic agent, is commercialized, it is expected that there will be stable demand. Because the Pharmaceutical and Medical Device Act have introduced stricter safety controls for biologically derived products, TDM-621, an artificial compound that is extremely safety, can probably be sufficiently differentiated from existing products. However, the product is now at the development stage where the Company is planning to conduct new clinical trials for the product, and the effectiveness of the product in controlling hemorrhaging that is currently expected may not be confirmed by the future clinical trials, in which case it would become impossible to obtain certification to manufacture and sell the product. Even if the certification is obtained, the national health insurance (NHI) may not cover the product or the NHI listed price may differ from the expected price.

The Group has already started to sell TDM-621 in Europe and Asia. However, if there are major changes in the legal systems or related laws of these regions, it may be impossible to sell the product.

The Company has also applied for certification to manufacture and sell the product in South Korea and Latin America. However, there is a possibility that major changes in the legal systems or related laws of these regions may occur, that, as a consequence of the examination in each region, it may only obtain approval to manufacture the product for a narrower range of surgical uses, or that the effectiveness or safety of the product may not be recognized and the necessary approval cannot be obtained as a result.

If any of these situations were to occur, it could affect the Group's sales plans and have a major impact on the Group's financial position and earnings.

C. Reliance on business revenue from specific counterparties

The Group's business revenue is highly dependent on Fuso Pharmaceutical Industries—in FY2012, about 94.8% of the Group's business revenue was from Fuso Pharmaceutical Industries (in FY2014, and FY2015, Fuso Pharmaceutical Industries accounted for no business revenue). Therefore, if the agreement with Fuso Pharmaceutical Industries is terminated or ended for some other reason or if it becomes impossible to generate the earnings expected from the agreement for some reason, this could have a major impact on the Group's financial position and earnings.

In addition, until the Group starts generating stable sales, the main source of business revenue is initial payments and milestone payments related to Hemostat. Therefore, if it is impossible to obtain certification to manufacture and sell the product or the product is not covered by national health insurance or if either one does not progress as expected, it could be impossible to generate these earnings or could take longer to generate them, and this could have a major impact on the Group's financial position and earnings.

D. Major contracts

If important agreements related to expanding the Group's business are terminated, if these agreements are amended in a way that is disadvantageous to the Group, or if these agreements are not renewed when they expire, this could have a major impact on the Group's financial position and earnings.

E. Production and sales

The Group has concluded a business tie-up agreement with ITOCHU Chemical Frontier. The agreement is related to the supplier of raw materials for products based on self-assembling peptide technology, the selection of companies that manufacturing of the product will be outsourced to, and selection of distributors. The Group has outsourced the production of peptide raw materials to several companies. In addition, the Company has concluded a manufacturing outsourcing agreement regarding Hemostat with Fuso Pharmaceutical Industries, but in the future, the Company plans on outsourcing manufacturing to several overseas companies.

In this way, the Group is working to create a backup system to strengthen the product delivery system after obtaining certification to manufacture and sell TDM-621, but if there are delays in the supply of raw materials or outsourced manufacturing due to any of various reasons including unexpected accidents, this could have a major impact on the Group's financial position and earnings.

In addition, the Group concluded an exclusive distribution license agreement with Fuso Pharmaceutical Industries regarding sales in Japan. The agreement stipulates the minimum amount that Fuso Pharmaceutical Industries must purchase, but if for some reason the company does not fulfill its obligations, this could not only affect the Group's sales projections but also have a major impact on its financial position and earnings.

F. Product liability

Designing, developing, manufacturing, and selling medical devices entails risks related to product liability. The product TDM-621 is based on self-assembling peptide technology. The Group completed a human clinical trial, and for all 97 cases, there were no adverse events, such as serious problems or side effects whose causal relationship could not be rejected. The Group has already started the sales of TDM-621 in Europe and Asia and the product is manufactured and sold in accordance with the quality control standards of the Group, which are based on the standards of the regulatory authorities. However, medical devices developed by the Group including TDM-621 could damage the health of patients, and if an improper aspect of the clinical trial, production, or sales is discovered, the Group might be held liable for such damage and this could have a major impact on its financial position and earnings, although the Group's product liability is covered by a product liability insurance.

In addition, in this case, even if the Group is not found negligent, the negative image created by factors

such as claims for damages due to product liability could undermine trust in the product and consequently have a major impact on the Group's financial position and earnings.

G. Medical products other than hemostatic agents

As for the Dental Bone Filler TDM-711, the Group's subsidiary obtained IDE approval from the FDA in July 2011 and started clinical trials in the U.S. in February 2012. If the results of the clinical trial do not demonstrate the effectiveness and safety of the product, it could be impossible to manufacture and sell the product, and this could affect the Group's business strategy and earnings.

With respect to the Endoscopic Mucosal Resection Aid TDM-641, clinical trials started in December 2014. However, since sufficient results have not been obtained in the clinical trial subjects as compared with the level of effectiveness expected from the results of the pre-clinical trial studies, the Company has temporarily halted the clinical trials at its decision in order to improve the test methods and the development of pharmaceutical preparations. If these efforts to improve test methods and develop pharmaceutical preparations fail to demonstrate sufficient effectiveness, the product cannot be commercialized and this could affect the Group's business strategy and earnings.

In the field of surgery, the Group is researching and developing the embolization material TDM-631. This product, however, is at the research and development stage, and there is no guarantee that research and development will progress as planned. If commercialization of the product does not progress smoothly, this could have an impact on the Group's business strategy and thus its financial position and earnings.

The Dental Bone Filler TDM-711, Endoscopic Mucosal Resection Aid TDM-641 and embolization material TDM-631 discussed above are all based on the self-assembling peptide technology that uses the same peptide (RADA16) as TDM-621. A human clinical trial of TDM-621 has already been conducted, and for all 97 cases there were no adverse events, such as serious problems or side effects whose causal relationship could not be rejected. Therefore, if the results of future clinical trials of these products demonstrate their effectiveness, it is unlikely that the Group will not obtain certification or a license from the responsible government agencies. However, if questions arise about the safety of the technology itself or if major amendments are made to the Pharmaceutical and Medical Device Act or related regulations, it could become impossible to obtain certification or a license for the products, which could have a major effect on the Group's business strategy and thus a substantial impact on its financial position and earnings.

In the field of the DDS, the Group mainly conducts research and development on pharmaceuticals. Because clinical trials for pharmaceuticals entail more stages than those for medical devices, it takes a longer time until one can apply for certification, and there are more uncertainties. Therefore, if research and development does not progress as the Group expects, this could affect the Group's business strategy and thus have an impact on its financial position and earnings.

H. Risks related to research and development activities

The Group strives to create applied technologies for the basic patents related to self-assembling peptide technology licensed from Massachusetts Institute of Technology ("MIT") (see "(ii) Risks Related to Intellectual Property") and develop new medical products. As of this report's filing date, the Group is conducting joint research with about one hundred research organizations in Japan and the U.S., has filed or is preparing to file patents in various fields including myocardial regeneration technology, hepatocyte culture technology, and pancreatic islet cell culture/transplantation technology, and has also published papers in various other fields. The following are some of the major products in the product pipeline that are the next candidates for commercialization: (a) regenerative treatments that do not make use of cells such as wound healing, myocardial regeneration, and chondrocyte/intervertebral disk regeneration; (b) treatments that make use of cells but do not entail implantation, such as treatments using external artificial pancreases and embedded artificial pancreases; (c) treatments that entail implanting cells such as pancreatic islet transplantation and spinal injury treatments; and; (d) peptide preparation and protein preparation such as

BMP and DDS for nucleic acid, etc. The Group expects that it may be possible to include these in development plans on account of their applied technologies. These candidates for commercialization are at the basic research stage, and they have not been included in the business plan, but if steady progress is not made in their commercialization, the Group could lose important future upside potential.

(ii) Risks related to intellectual property rights, lawsuits, etc.

A. Acquiring patents, etc.

The Company's subsidiary has obtain from MIT exclusive licenses (with sublicensing rights) for composition-of-matter patents related to self-assembling peptide technology and basic utility patents for these composition-of-matter patents listed in the following table (referred to collectively as the "group of basic patents" below), and the subsidiary has sublicensed the patents to the Company. The Group has also filed its own patents.

As for the composition-of-matter patent for self-assembling peptides that MIT is the right-holder to (country patent filed in: U.S.), the Company has concluded a non-exclusive sublicense agreement with ARCH Therapeutics Inc., a biotech venture company founded by MIT researchers related to self-assembling peptide applied technology. U.S.-based ARCH Therapeutics Inc. is not actually conducting business now, and as of now, there is little concern that it will become a competitor of the Group. However, the two companies could become rivals in the future.

The group of basic patents covers all peptide groups that self-assemble and form hydrogel. Although there are differences depending on the country and region, the main patents have already been registered. For some of the patents in the group of basic patents that have not been registered yet, however, it may ultimately be impossible to register them. In this case, it may not be possible to fully protect the Group's future business. Furthermore, in the bio-material industry, which the Group's business falls under, research and development result in daily advances, and the development of a technology superior to the Group's technology could make the group of basic patents obsolete.

Furthermore, the Group conducts joint research on applied technologies with various research institutes using this group of basic patents, and several utility patents related to items other than the main products in the pipeline have already been jointly filed, but this does not mean that all the patents have been registered. Even though the Group has already secured the group of basic patents, if these patents are not approved, it could become impossible to fully protect the Group's future business since some of the patents could not be used.

B. Lawsuits, etc.

At least for product development using self-assembling peptide technology, it is probably very unlikely that the Group is infringing on the intellectual property rights of third parties, such as patents. In addition, the Group continually examines the intellectual property rights of third parties, and as of this report's filing date, the Group's business activities have not infringed on the intellectual property rights of third parties, and no lawsuits have been filed or complaints made by third parties. However, it may be impossible to fully avoid the problem of infringing on intellectual property rights considering the Group plans to expand its business on various fronts. If in the future a lawsuit such as a claim for damages is filed because the Group's business activities infringe on the intellectual property rights of a third party, it could be expensive and take a long time to resolve the case, and this could have a major impact on the Group's business strategy, financial position, and earnings. In addition, there is the possibility of lawsuits related to business activities other than those concerned with intellectual property rights, and depending on the details of the lawsuit and how they are resolved, it could have an impact on the Group' earnings and financial position.

In addition, in this case, even if the Group is not found liable, the negative image created by aspects such as claims for damages due to infringement of intellectual property rights could undermine trust in the product, affect business activities, and consequently have a major impact on the Group's financial position and earnings.

Patents in the group of basic patents

Product/pipeline	Name of discovery	Registration Number	Country filed in	Patent holder
Composition-of-matter patent				
Hemostatic agent, endoscopic mucosal resection aid, embolization material, dental bone filler, PuraMatrix	Self-assembling peptide composition-of-matter patent (including self-assembling and blocking method)	US 6548630	U.S. (issued)	MIT
	Purified Amphiphilic Peptide Compositions and Uses Thereof	No. 5730828	Japan (issued)	3-D Matrix, Inc.
		WO 06/014570	U.S. (filed)	
			EU (filed)	
Utility patent				
Hemostatic agent, endoscopic mucosal resection aid	Method for making hemostatic agent and tissue plugs using self-assembling peptides	Patent 2008-316133	Japan (filed)	The Company
Dental bone filler, PuraMatrix	Cell culture method using self-assembling peptides	US 5955343	U.S. (issued)	MIT
Dental bone filler, PuraMatrix	Cell culture method using self-assembling peptides	US 6800481	U.S. (issued)	MIT
PuraMatrix DDS	Protein drug delivery method using self-assembling peptides	US 7098028	U.S. (issued)	MIT
PuraMatrix	Chondrocyte culture method using self-assembling peptides	US 7449180	U.S. (issued)	MIT
		EP 1367961	Europe (issued)	
PuraMatrix	Self-assembling peptide composition-of-matter patent modified peptides	US 7713923	U.S. (issued)	MIT
		US 8901084		
PuraMatrix	Neuron regeneration method using self-assembly peptides	US 2005/0287186	U.S. (filed)	MIT
PuraMatrix	Chondrocyte culture method using self-assembling peptides	No. 507629	Japan (issued)	MIT
PuraMatrix	Modified peptide cell culture method using self-assembling peptides	No. 5057781	Japan (issued)	MIT
PuraMatrix	Myocardial tissue regeneration method using self-assembling peptides	EP 2089047	Europe (issued)	3-D Matrix, Inc.
		No. 5558104	Japan (issued)	
		US 9012404	U.S. (issued)	
PuraMatrix	Cell culture method using self-assembling peptides and related cell culture material	No. 5263756	Japan (issued)	Okayama University, the Company
		US 8647867	U.S. (issued)	
		US 8697438		
Wound treatment material, PuraMatrix	Wound treatment and skin reconstruction method using self-assembling peptides	No. 5497451	Japan (issued)	The Company
		EP 2229960	Europe (issued)	
PuraMatrix	Transfection agent	EP 2322608	Europe (issued)	Nippon Medical School, the
		No. 5606318	Japan	

			(issued)	Company
PuraMatrix	Surfactant peptide nanostructures	US 7179784	U.S. (issued)	MIT
PuraMatrix	Chiral amphiphilic peptides form hydrogels	US 13/638152	U.S. (filed)	ASTAR

(iii) Risks related to earnings and financial position, etc.

A. Changes in earnings, etc.

The Company has concluded an exclusive distribution license agreement related to Hemostat in Japan with FUSO Pharmaceutical Industries. As for its product development, the Company has withdrawn its initial application for certification to manufacture and sell the product and plans to submit a new application after conducting clinical trials again. Therefore, no business revenue has been generated from the sale of the product in Japan. Business revenue up to now has mainly been from sales tie-up agreements concluded in the past, including those listed above, and except for FY2011, expenses related to research and development activities have been greater than revenue, and the Company has recorded an operating loss, ordinary loss, and net loss. Therefore, the financial indicators for previous fiscal years are insufficient for comparing earnings between years and projecting future earnings.

B. Recording negative retained earnings,

The Group is a research and development corporation and records research and development expenses up front until one of its medical products is introduced in the market. Therefore, the Group posted negative retained earnings of -¥5,786,552 thousand for FY2015. Among its medical products under development, the Group is aiming to obtain certification to manufacture one of its medical devices; it is expected that the cost and time required to develop a medical device are substantially less that those required to develop a pharmaceutical. The Group is striving to quickly generate a profit by moving forward with research and development as planned. If things do not progress in the future as envisioned in the business plan, however, it could become impossible to generate net income or could take longer to secure positive retained earnings.

C. Matters concerning significant events, etc.

As the Group incurs research and development expenses ahead of revenue, it has continued to post operating losses and negative cash flows from operation. As a result, the Company recognizes the existence of a situation that gives rise to significant doubt about the going concern assumption. However, the Company has determined that there is no significant uncertainty about the going concern assumption as the Company is ready to take measures to eliminate or mitigate this situation. These measures to eliminate or mitigate the situation are described in “(5) Significant Events Concerning the Going Concern Assumption.”

D. Loss carried forward for tax purposes

As of this report’s filing date, the Group has a large loss carried forward for tax purposes. Therefore, if that loss can no longer be carried forward, it will become impossible to take an income tax deduction. In that case, the Group will have to record corporate tax based on the normal corporate tax rate, resident tax,

and business tax, and this could impact net income and cash flows.

E. Fund raising

The Group is a research and development corporation and posts upfront development expenses for products in the pipeline. The Group works to raise funds in various ways such as concluding business tie-up agreements and licensing products. If these efforts do not progress as envisioned in the business plan, the Group could run short of funds, and this could have a major impact on keeping the business going.

F. Dividend policy

Since its founding and through FY2010, the Company recorded a net loss and has not paid a dividend. In addition, the Group recorded a net loss of ¥1,994,965 thousand for FY2015. When the accumulated loss is eliminated, the Group will examine paying a dividend taking into consideration the Group's financial position and earnings.

(iv) Organization-related risks

A. Young company

Established in May 2004, the Company is a young company, and there is insufficient financial data to compare earnings between years. The Company is also a research and development corporation and the business is at the upfront investment stage though the company has started to introduce the Hemostat to the market since FY2015. Therefore, taking into consideration the nature of the business, there is insufficient data to forecast future earnings using only past earnings.

B. Small-scale organization

At the time of the report's filing, the Group is a small-scale organization—the parent company consists of 27 people (5 directors, 3 auditors, and 19 employees) and subsidiaries consist of 23 people (8 directors [two of whom also serve as directors at the parent company] and 15 employees). The Group is working to expand its system for conducting operations; the organization is small, but the internal control system is appropriate for the size of the organization. The Group will further enlarge the organization in order to expand business, but if it is impossible to construct an appropriate system, this could have an impact on business efficiency. However, a rapid increase in the organization's scale will lead to an increase in fixed costs, and this could have a major impact on the Group's financial position and earnings.

C. Reliance on particular individuals

The Company's representative directors Keiji Nagano and Kentaro Takamura are the driving forces behind the Group's business. These two have a strong influence on decisions related to the business and development strategies, the formulation of business plans, and the execution of management operations. Therefore, the Group is strengthening its management system in order to build a system that does not excessively rely on these two; however, it is expected that the Group will remain highly reliant on them for the time being. On account of this, if it becomes difficult for both of them to continue their work for some reason, it could have a major impact on the Group's business strategy and earnings.

D. Securing and training human resources

Since the core of the Group's competitiveness is its research and development abilities and business planning skills, the Group must secure highly specialized researchers and similar types of personnel; in order to expand the business, experts in fields such as sales, production, and internal controls are also necessary. The Group works to secure top personnel and train personnel in house, but if efforts to secure or train personnel do not progress as planned, this could have a major impact on the Group's financial position and earnings.

(v) Other

A. Use of funds raised through initial public offering

The Company has allocated funds raised from public offering to research and development, but there are no guaranties that the investments will lead to the desired results for any of various reasons such as longer-than-expected research and development or unforeseen technological innovations due to changes in the environment. In this case, the Company may not generate the earnings expected by investors.

B. Dilution of share value through the exercise of subscription rights

The Company has a system of stock options. Issued stock options include subscription rights allocated in accordance with the stipulations of Article 280.20 and Article 280.21 of the former Commercial Code and approved at the shareholders' general meeting and subscription rights allocated in accordance with the stipulations of Article 236, Article 238, and Article 239 of the Companies Act and approved at the shareholders' general meeting. As of April 30, 2015, if all issued subscription rights are exercised, this will result in 757,600 additional shares. The total of these additional shares and the Company's issued shares (21,438,400) is 22,96,000, and these additional shares would account for 3.4% of the total. If these subscription rights are exercised, it will dilute the value of each share of the Company. The Company is considering continuing to use this type of incentive to secure top personnel. Therefore, if subscription rights issued in the future are exercised, this could further dilute the Company's share value.

C. Foreign exchange rates

Among transactions by the Group, payments for outsourced production of raw materials used in products based on self-assembling peptide technology are primarily made in foreign currencies, and the Group does not specially use foreign exchange hedges.

Therefore, if there is a greater-than-expected change in exchange rates, this could impact the Group's earnings.

(5) Significant Events Concerning the Going Concern Assumption

As noted in "(4) Business Risks, etc., (iii) Risks related to earnings and financial position, etc., C. Matters concerning significant events, etc.," since the Group incurs research and development expenses ahead of revenue, the Company recognizes the existence of a situation that gives rise to significant doubt about the going concern assumption.

In order to eliminate or mitigate this situation, the Group will strive to generate revenue from sales of Hemostat, the product that is sold globally in the medical device business, as well as to secure revenue from initial payments and milestone payments under distribution license agreements mainly in the U.S., Europe, Asia, and Latin America. The Group will also strive to eliminate the significant event by reducing selling, general and administrative expenses and improving its revenue structure through, among others, the sharing and streamlining of basic research in research and development conducted between the parent company and a subsidiary and the improvement of business efficiency to reduce various expenses.

In addition, the Group has secured sufficient operating funds to support the progress of its research and development and business activities by entering into agreements with various financial institutions for the establishment of loan facilities and commitment lines to enable the Group to borrow funds promptly as necessary.

2. The Corporate Group

Composed of the Company and three consolidated subsidiaries, the Group has obtain an exclusive license for patents related to self-assembling peptide technology from MIT and conducts business related to medical products, the goal of which is research, develop, manufacture, and sell products that use this technology.

The main businesses of each Group member company are given below.

Businesses of Group member companies

Name	Main businesses
3-D Matrix Ltd.	Developing medical products and selling research reagents
3-D Matrix Inc.	Developing and selling medical products
3-D Matrix Europe SAS.	Developing and selling medical products
3-D Matrix Asia Pte. Ltd.	Developing and selling medical products
3-D Matrix MedicalTechnology Limited	Developing and selling medical products
3-D Matrix Da America Latina Representação comercial Ltda.	Developing and selling medical products
北京立美基投資咨詢有限公司	Developing and selling medical products

The Group's medical product business consists of developing medical products and selling research agents, details of which are given below.

Composition of the medical product business

Category	Details
Developing medical products	In the field of surgery, regenerative medicine, and DDS, the foundation of which is self-assembling peptide technology, the Group conducts research and development related to medical devices and pharmaceuticals. Hemostat, endoscopic mucosal resection aid, and embolization material are the main products in the development pipeline in the field of surgery, and dental bone filler is the main one in the field of the regenerative medicine. While the Company has received initial payments and milestone payments from distributors for Hemostat and endoscopic mucosal resection aid, the Group has not recorded business revenue for other products.
Selling research reagents	As for the sale of research agents, the Group sells self-assembling peptide PuraMatrix through its U.S.-based sales company. At various entities, including universities and research institutions both in Japan and overseas, the product is used for applied research in numerous fields that make use of self-assembling peptides.

3. Management Policy

(1) Basic Management Policy

Having adopted the corporate philosophy of contributing to the advancement of medical care though bio-materials, the Company continues to develop unique products that differentiate the company in various fields including surgery and regenerative medicine and strives to acquire global competitiveness.

(2) Targeted Business Metrics

As a research and development corporation, the Company strives to continually grow by advancing research and development and generating earnings by introducing or licensing products it has developed. The Company recognizes that the most important issue is quickly, efficiently, and steadily moving each product forward in the product pipeline, the core of its business, as planned.

(3) Medium- and Long-term Business Strategy

As a developer of medical devices, the Company strives to construct both a system to deliver a stable supply of products that the Company expects to receive certification to manufacture and a system to sell these products and then to allocate business resources to the global expansion of products and the broader application of products both in Japan and overseas. In addition, the Company focuses on the next candidate from the product pipeline for commercialization, and more than one hundred research institutes both in Japan and overseas conduct research on applications of these products.

(4) Pending Issues

The Group has analyzed current conditions in the medical field, and according to its analysis, the Group recognizes the following as business issues related to formulating and implementing the best business strategy.

(i) Promoting research and development and the introduction of products into the market

The products in the Group's product development pipeline include Hemostat, Endoscopic Mucosal

Resection Aid, and embolization material in the field of surgery and Dental Bone Filler and Wound Treatment Material in the field of the regenerative medicine, and the Group recognizes that promptly introducing the products into the market and generating earnings from the sale of these products are issues related to stabilizing the Company's business.

As for Hemostat, the Group's major product in the pipeline, the Group has withdrawn its initial application for certification to manufacture and sell the product in Japan and is currently in preparation for submitting a new application after conducting clinical trials again. Meanwhile, in Europe, the product has received the CE marking and the Group has started to sell the product in EU member countries. At the same time, the Group is also preparing for the launch of product sales in Asia-Pacific and Latin America where the CE marking is recognized. In Japan, the Group will now aim to obtain certification promptly and strive to launch sales of the product through an exclusive distribution license agreement with FUSO Pharmaceutical Industries. Overseas, including Europe, the Group will conduct a clinical trial, strive to establish sales tie-ups with partners in each country, and move forward with work with regulatory authorities and the construction of a production and quality management system in order to secure stable business revenue.

In the field of the regenerative medicine, as part of its product development efforts, the Group has conducted clinical trials for Dental Bone Filler in the U.S. and obtained the 510(k) premarket approval for product sales permission from the FDA for Wound Treatment Material. Going forward, the Company will strive to realize prompt formation of business tie-ups and launches of product sales also in this field.

(ii) Promoting business tie-ups

The Group recognizes that the self-assembling peptide technology licensed from MIT is a technology that has wide applications and that the Group's mission is to contribute to medicine by quickly providing products in various fields. Therefore, the Company has adopted a strategy of specializing in planning, such as searching for products for the product pipeline, accumulating medical equipment development knowhow, and developing commercialization strategies. Because it is necessary to supplement manufacturing and sales functions through tie-ups with other companies, one issue is establishing desirable business tie-ups.

For Hemostat, the Group has concluded tie-up agreements related to the following: the company undertaking outsourced production of raw materials for peptides, product manufacturing and sales in Japan, and sales in South Korea, Taiwan, and Indonesia. In cooperation with each partner, the Group will move forward with building a system to provide a stable supply to the market. The Group will also move forward with building a system so that it can maximize sales, which includes expanding sales channel.

With the goal of introducing Hemostat throughout the world, the Group is also moving forward with building a system to manufacture and sell the product in Europe, the U.S., Asia-Pacific, and Latin America. In particular, the Group is moving forward with business alliances in order to launch sales in Europe and the U.S. In the field of the regenerative medicine, the Group will also push ahead with business tie-up negotiations for Dental Bone Filler and Wound Treatment Material.

(iii) Securing operating funds

When moving forward with the development of the Group's product pipeline, demand for funds for research and development expenses (such as expenses for various types of tests and clinical trials) will increase. Therefore, the Group has not only secured operating funds from initial payments and milestone payments through sales alliances related to Hemostat but also raised funds by conducting a public offering and overseas offering.

The Company has also secured a stable supply of operating funds in several ways including the conclusion of a commitment line agreement with Sumitomo Mitsui Banking Corporation and the establishment of loan

facilities with Sumitomo Mitsui Banking Corporation and Mizuho Bank. The Company, however, will also strive to ensure stable business revenue by promoting various business alliances and product sales to secure revenue from initial payments and product sales.

In the future, the Group will not only examine various ways to raise funds, such as obtaining loans from financial institutions, setting up and expanding commitment lines, and making use of leases, and actually raise funds in these ways but also continue to work to strengthen its financial foundation.

(iv) Strengthening the management system

The Group recognizes that strengthening its management system to ascertain and respond to increasingly diverse risks is a business issue in responding to the development of its product pipeline and global expansion.

Although the Group is a small organization, we will examine company-wide controls and various operation processes in order to construct a system of internal controls for the whole Group, which has subsidiaries throughout the world, and work to increase the efficiency of operations and minimize risks. In addition to continuing to move forward with systematically building internal controls, the Group will work to strengthen not only checks between organizations but also its compliance system.

The Group also has a small-scale research and development organization that handles the various stages from basic research to pre-clinical trial studies and clinical trials and has built a system that conforms to standards stipulated by regulatory authorities. Even when expanding its business in the domestic and global markets, the Group will collect the necessary information, revise the various manuals, and continue to conduct employee training to comply with rules, laws, and ordinances.

In order to maintain a system appropriate for the particular business stage, such as product introduction and business alliance expansion, the Group will continue to strive to secure personnel who possess advanced specialized knowledge and experience both in Japan and overseas, train employees, and actively make use of independent resources in line with the human resource plan based on the business plan.

4. Basic Approach to the Selection of Accounting Standards

The Group plans, for the time being, to continue to prepare its consolidated financial statements in accordance with the Japanese accounting standards in consideration of comparability of the consolidated financial statements over periods and with those of other companies.

The Group will also respond appropriately to the application of International Financial Reporting Standards (IFRS) in the future in consideration of the relevant domestic and international trends.

4. Consolidated Financial Statements

(1) Consolidated Balance Sheets

(Thousands of yen)

	Previous Fiscal Year (as of April 30, 2014)	This Fiscal Year (as of April 30, 2015)
Assets		
Current assets		
Cash and deposits	2,640,535	5,136,835
Account receivable	-	52,315
Inventories	789,397	776,640
Advance payments	16,769	142,432
Other, net	145,922	95,697
Total current assets	3,592,625	6,203,920
Noncurrent assets		
Property, plant and equipment		
Buildings and structures	7,728	8,176
Accumulated depreciation	(2,392)	(2,865)
Building and structures, net	5,335	5,311
Machinery, equipment and vehicles	24,750	27,553
Accumulated depreciation	(3,609)	(6,878)
Machinery, equipment and vehicles, net	21,140	20,674
Tools, furniture and fixtures	45,086	53,098
Accumulated depreciation	(22,758)	(31,689)
Tools, furniture and fixtures, net	22,328	21,409
Lease assets	64,000	64,000
Accumulated depreciation	(9,333)	(17,333)
Lease assets, net	54,666	46,666
Total property, plant and equipment	103,471	94,062
Intangible assets		
Goodwill	256,668	186,667
Right of using patent	55,962	135,579
Patent right	21,506	70,359
Other, net	4,790	202
Total intangible assets	338,927	392,808
Investments and other assets		
Long-term prepaid expenses	51,342	80,787
Lease deposits	16,498	17,176
Other, net	18,103	20,490
Total investments and other assets	85,945	118,454
Total noncurrent assets	528,343	605,325
Total assets	4,120,969	6,809,245

(Thousands of yen)

	Previous Fiscal Year (as of April 30, 2014)	This Fiscal Year (as of April 30, 2015)
Current liabilities		
Short-term loans	800,000	200,000
Lease obligations	13,456	14,351
Accounts payable	92,120	138,675
Accrued expenses	37,013	32,679
Income taxes payable	10,469	18,834
Other, net	5,292	4,749
Total current liabilities	958,353	409,290
Noncurrent liabilities		
Lease obligations	28,344	13,993
Deferred tax liabilities	919	4,438
Total noncurrent liabilities	29,263	18,431
Total liabilities	987,617	427,722
Net assets		
Shareholders' equity		
Capital stock	3,338,757	5,930,207
Capital surplus	3,328,660	5,920,077
Retained earnings	(3,791,587)	(5,786,552)
Treasury stock	(59)	(59)
Total shareholders' equity	2,875,772	6,063,673
Accumulated other comprehensive income		
Foreign currency translation adjustment	29,451	(23,029)
Total accumulated other comprehensive income	29,451	(23,029)
Subscription rights to shares	228,128	340,880
Total net assets	3,133,352	6,381,523
Total liabilities and net assets	4,120,969	6,809,245

(2) Consolidated Statements of Income and Comprehensive Income

Consolidated statements of income

(Thousands of yen)

	Previous Fiscal Year (From May 1, 2013 to April 30, 2014)	This Fiscal Year (From May 1, 2014 to April 30, 2015)
Business revenues		
Net sales	6,388	3,404
Research and development revenues	100,772	96,372
Total business revenues	107,161	99,776
Business expenses		
Cost of sales	3,185	1,545
Research and development expenses	598,714	816,211
Selling, general and administrative expenses	1,023,662	1,185,085
Total business expenses	1,625,562	2,002,843
Operating income (loss)	(1,518,401)	(1,903,066)
Non-operating income		
Interest income	614	2,731
Foreign exchange gains	26,799	141,016
Subsidy income	3,617	4,215
Other, net	1,037	4,871
Total non-operating income	32,068	152,835
Non-operating expenses		
Interest expenses	11,518	8,424
Commission fee	5,999	4,263
Stock issuance cost	15,814	32,108
Other, net	4,202	184
Total non-operating expenses	37,535	44,980
Ordinary income (loss)	(1,523,867)	(1,795,211)
Extraordinary loss		
Settlement money	-	160,375
Manufacturing cost differences	-	34,633
Total extraordinary loss	-	195,008
Income (loss) before income taxes and minority interests	(1,523,867)	(1,990,220)
Income taxes-current	950	1,210
Income taxes-deferred	557	3,535
Total income taxes	1,507	4,745
Income (loss) before minority interests	(1,525,374)	(1,994,965)
Net income (loss)	(1,525,374)	(1,994,965)

Consolidated statements of comprehensive income

(Thousands of yen)

	Previous Fiscal Year (From May 1, 2013 to April 30, 2014)	This Fiscal Year (From May 1, 2014 to April 30, 2015)
Income (loss) before minority interests	(1,525,374)	(1,994,965)
Other comprehensive income		
Foreign currency translation adjustment	34	(52,481)
Total other comprehensive income	34	(52,481)
Comprehensive income	(1,525,340)	(2,047,447)
(Breakdown)		
Comprehensive income attributable to owners of the parent	(1,525,340)	(2,047,447)
Comprehensive income attributable to minority interests	-	-

(3) Consolidated Statements of Changes in Net Assets

Previous fiscal year (from May 1, 2013 to April 30, 2014)

(Thousands of yen)

	Shareholders' equity					Accumulated other comprehensive income		Subscription rights to shares	Total net assets
	Capital stock	Capital surplus	Retained earnings	Treasury stock	Total shareholders' equity	Foreign currency translation adjustment	Total accumulated other comprehensive income		
Balance at the beginning of period	2,139,400	2,129,400	(2,266,212)	(59)	2,002,528	29,417	29,417	33,680	2,065,625
Changes of items during the period									
Issuance of new shares	1,199,357	1,199,260			2,398,618				2,398,618
Net income (loss)			(1,525,374)		(1,525,374)				(1,525,374)
Net changes of items other than shareholders' equity						34	34	194,448	194,482
Total changes of items during the period	1,199,357	1,199,260	(1,525,374)	–	873,243	34	34	194,448	1,067,726
Balance at the end of period	3,338,757	3,328,660	(3,791,587)	(59)	2,875,772	29,451	29,451	228,128	3,133,352

This Fiscal year (from May 1, 2014 to April 30, 2015)

(Thousands of yen)

	Shareholders' equity					Accumulated other comprehensive income		Subscription rights to shares	Total net assets
	Capital stock	Capital surplus	Retained earnings	Treasury stock	Total shareholders' equity	Foreign currency translation adjustment	Total accumulated other comprehensive income		
Balance at the beginning of period	3,338,757	3,328,660	(3,791,587)	(59)	2,875,772	29,451	29,451	228,128	3,133,352
Changes of items during the period									
Issuance of new shares	2,591,449	2,591,417			5,182,867				5,182,867
Net income (loss)			(1,994,965)		(1,994,965)				(1,994,965)
Net changes of items other than shareholders' equity						(52,481)	(52,481)	112,751	60,270
Total changes of items during the period	2,591,449	2,591,417	(1,994,965)		3,187,901	(52,481)	(52,481)	112,751	3,248,171
Balance at the end of period	5,930,207	5,920,077	(5,786,552)	(59)	6,063,673	(23,029)	(23,029)	340,880	6,381,523

(4) Consolidated Statements of Cash Flows

(Thousands of yen)

	Previous Fiscal Year (From May 1 2013 to April 30, 2014)	This Fiscal Year (From May 1 2014 to April 30, 2015)
Net cash provided by (used in) operating activities		
Income (loss) before income taxes and minority interests	(1,523,867)	(1,990,220)
Depreciation	31,556	52,622
Amortization of goodwill	70,000	70,000
Interest income	(614)	(2,731)
Interest expenses	11,518	8,424
Foreign exchange losses (gains)	(12,533)	(83,165)
Stock issuance cost	15,814	32,108
Share-based compensation expenses	198,648	135,045
Decrease (increase) in accounts receivable-trade	-	(52,315)
Decrease (increase) in inventories	(528,693)	12,757
Decrease (increase) in advance payments-trade	135,655	(125,848)
Decrease (increase) in prepaid expenses	(4,175)	(11,238)
Increase (decrease) in accounts payable-other	31,799	39,753
Increase (decrease) in accrued expenses	(6,558)	(4,198)
Other, net	(86,904)	(20,828)
Subtotal	(1,668,353)	(1,898,178)
Interest income received	614	2,731
Interest expenses paid	(11,801)	(8,141)
Income taxes paid	(450)	(1,226)
Net cash provided by (used in) operating activities	(1,679,990)	(1,904,814)
Net cash provided by (used in) investing activities		
Purchase of property, plant and equipment	(14,718)	(8,631)
Purchase of intangible assets	(24,809)	(72,979)
Purchase of long-term prepaid expenses	(24,059)	(43,622)
Other, net	(19,480)	(318)
Net cash provided by (used in) investing activities	(83,068)	(125,551)
Net cash provided by (used in) financing activities		
Net increase (decrease) in short-term loans payable	-	(600,000)
Proceeds from issuance of common stock	2,378,603	5,128,465
Repayments of lease obligations	(12,616)	(13,456)
Other, net	(5,999)	(4,376)
Net cash provided by (used in) financing activities	2,359,987	4,510,632
Effect of exchange rate change on cash and cash equivalents	10,243	16,035
Net increase (decrease) in cash and cash equivalents	607,171	2,496,300
Cash and cash equivalents at beginning of period	2,033,363	2,640,535
Cash and cash equivalents at end of period	2,640,535	5,136,835

(5) Notes to Consolidated Financial Statements

(Notes to going concern assumptions)

Not applicable.

6. Non-consolidated Financial Statements

(1) Non-consolidated Balance Sheets

(Thousands of yen)

	Previous Fiscal Year (as of April 30, 2014)	This Fiscal Year (as of April 30, 2015)
Assets		
Current assets		
Cash and deposits	2,249,775	4,694,172
Account receivable	-	76,281
Inventories	789,397	709,339
Advance payments-trade	38,387	167,098
Advances paid	431,603	62,322
Temporaly payments	355,167	463
Short-term loans to affiliated companies	-	470,027
Other, net	51,294	70,940
Total current assets	3,915,626	6,250,646
Noncurrent assets		
Property, plant and equipment		
Buildings	2,525	2,052
Machinery and equipment	21,140	20,674
Tools, furniture and fixtures	2,968	2,294
Lease assets	54,666	46,666
Total property, plant and equipment	81,301	71,688
Intangible assets		
Patent right	6,772	16,785
Software	293	202
Other, net	227	192
Total intangible assets	7,293	17,180
Investments and other assets		
Stocks of subsidiaries and affiliates	709,991	1,092,184
Short-term loans to affiliated companies	156,900	837,905
Long-term prepaid expenses	51,342	79,023
Lease deposits	12,605	12,605
Other, net	301	301
Total investments and other assets	931,142	2,022,020
Total noncurrent assets	1,019,737	2,110,889
Total assets	4,935,363	8,361,535

(Thousands of yen)

	Previous Fiscal Year (as of April 30, 2014)	This Fiscal Year (as of April 30, 2015)
Liabilities		
Current liabilities		
Short-term loans	800,000	200,000
Lease obligations	13,456	14,351
Accounts payable	68,292	117,408
Accrued expenses	30,323	8,383
Income taxes payable	10,469	18,834
Deposits received	3,702	3,554
Other, net	-	497
Total current liabilities	926,243	363,031
Noncurrent liabilities		
Lease obligations	28,344	13,993
Total noncurrent liabilities	28,344	13,993
Total liabilities	954,588	377,024
Net assets		
Shareholders' equity		
Capital stock	3,338,757	5,930,207
Capital surplus		
Legal capital surplus	3,328,660	5,920,077
Total capital surplus	3,328,660	5,920,077
Retained earnings		
Other retained earnings		
Retained earnings brought forward	(2,914,712)	(4,206,594)
Total retained earnings	(2,914,712)	(4,206,594)
Treasury stock	(59)	(59)
Total shareholders' equity	3,752,647	7,643,631
Subscription rights to shares	228,128	340,880
Total net assets	3,980,775	7,984,511
Total liabilities and net assets	4,935,363	8,361,535

(2) Non-consolidated Statements of Income

(Thousands of yen)

	Previous Fiscal Year (From May 1 2013 to April 30, 2014)	This Fiscal Year (From May 1 2014 to April 30, 2015)
Business revenues		
Net sales	6,388	78,206
Research and development revenues	50,000	45,000
Total business revenues	56,388	123,206
Business expenses		
Cost of sales	3,667	79,403
Research and development expenses	423,008	562,559
Selling, general and administrative expenses	685,550	671,378
Total business expenses	1,112,225	1,313,341
Operating income (loss)	(1,055,836)	(1,190,135)
Non-operating income		
Interest income	1,971	20,500
Foreign exchange gains	16,689	114,333
Subsidy income	3,617	4,215
Other, net	694	216
Total non-operating income	22,972	139,267
Non-operating expenses		
Interest expenses	11,518	8,424
Commission fee	5,999	4,263
Stock issuance cost	15,814	32,108
Other, net	906	-
Total non-operating expenses	34,240	44,796
Ordinary income (loss)	(1,067,104)	(1,095,664)
Extraordinary loss		
Settlement money	-	160,375
Manufacturing cost differences	-	34,633
Total extraordinary loss	-	195,008
Income (loss) before income taxes	(1,067,104)	(1,290,674)
Income taxes-current	950	1,210
Total income taxes	950	1,210
Net income (loss)	(1,068,054)	(1,291,884)

(3) Non-consolidated Statements of Changes in Shreholder's Equity

Previous fiscal year (from May 1, 2013 to April 30, 2014)

(Thousands of yen)

	Shareholders' equity							Subscription rights to shares	Total net assets
	Capital stock	Capital surplus		Retained earnings		Treasury stock	Total shareholders' equity		
		Legal capital surplus	Total capital surplus	Other retained earnings / Retained earnings brought forward	Total retained earnings				
Balance at the beginning of period	2,139,400	2,129,400	2,129,400	(1,846,657)	(1,846,657)	(59)	2,422,082	33,680	2,455,762
Changes of items during the period									
Issuance of new shares	1,199,357	1,199,260	1,199,260				2,398,618		2,398,618
Net income (loss)				(1,068,054)	(1,068,054)		(1,068,054)		(1,068,054)
Net changes of items other than shareholders' equity								194,448	194,448
Total changes of items during the period	1,199,357	1,199,260	1,199,260	(1,068,054)	(1,068,054)	—	1,330,564	194,448	1,525,012
Balance at the end of period	3,338,757	3,328,660	3,328,660	(2,914,712)	(2,914,712)	(59)	3,752,647	228,128	3,980,775

This Fiscal year (from May 1, 2014 to April 30, 2015)

(Thousands of yen)

	Shareholders' equity							Subscription rights to shares	Total net assets
	Capital stock	Capital surplus		Retained earnings		Treasury stock	Total shareholders' equity		
		Legal capital surplus	Total capital surplus	Other retained earnings / Retained earnings brought forward	Total retained earnings				
Balance at the beginning of period	3,338,757	3,328,660	3,328,660	(2,914,712)	(2,914,712)	(59)	3,752,647	228,128	3,980,775
Changes of items during the period									
Issuance of new shares	2,591,449	2,591,417	2,591,417				5,182,867		5,182,867
Net income (loss)				(1,291,882)	(1,291,882)		(1,291,882)		(1,291,882)
Net changes of items other than shareholders' equity								112,751	112,751
Total changes of items during the period	2,591,449	2,591,417	2,591,417	(1,291,882)	(1,291,882)		3,890,984	112,751	4,003,736
Balance at the end of period	5,930,207	5,920,077	5,920,077	(4,206,594)	(4,206,594)	(59)	7,643,631	340,880	7,984,345

(4) Notes to Non-consolidated Financial Statements

(Notes to going concern assumptions)

Not applicable.