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On **June 14, 2019**, 3-D Matrix Ltd. (3DM) announced earnings results for full-year FY04/19.

Cumulative (JPYmn)	FY04/18				FY04/19				FY04/19	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of FY	FY Est.
Operating revenue	66	105	167	229	52	120	194	329	100.3%	328
YoY	721.3%	233.1%	140.8%	-62.9%	-20.8%	14.1%	16.0%	43.8%	-	-
Sales	66	105	167	229	52	120	194	329	100.3%	328
YoY	721.3%	233.1%	140.8%	113.4%	-20.8%	14.1%	16.0%	43.8%	-	-
R&D operating revenue	-	-	-	-	-	-	-	-	-	-
YoY	-	-	-	-	-	-	-	-	-	-
R&D expenses	482	969	1,521	2,103	622	1,223	1,831	2,596	-	-
YoY	18.9%	23.8%	19.5%	13.3%	29.1%	26.3%	20.4%	23.4%	-	-
Cost of sales	56	81	126	177	43	103	194	312	-	-
YoY	925.5%	213.7%	83.5%	74.5%	-24.5%	26.5%	53.8%	76.1%	-	-
Cost ratio	85.1%	77.0%	75.5%	77.5%	81.1%	85.4%	100.1%	94.9%	-	-
R&D expenses	115	257	387	562	198	408	572	786	-	-
YoY	-4.6%	19.8%	27.7%	19.8%	72.4%	58.6%	47.8%	39.8%	-	-
SG&A expenses	311	631	1,008	1,364	382	713	1,065	1,498	-	-
YoY	11.1%	16.4%	11.8%	6.1%	22.9%	13.1%	5.7%	9.8%	-	-
Operating profit	-416	-863	-1,354	-1,875	-570	-1,103	-1,637	-2,267	-	-2,267
YoY	-	-	-	-	-	-	-	-	-	-
OPM	-	-	-	-	-	-	-	-	-	-
Recurring profit	-332	-724	-1,209	-1,767	-605	-1,161	-1,793	-2,426	-	-2,426
YoY	-	-	-	-	-	-	-	-	-	-
RPM	-	-	-	-	-	-	-	-	-	-
Net income	-355	-777	-1,282	-1,866	-626	-1,230	-1,896	-2,555	-	-2,554
YoY	-	-	-	-	-	-	-	-	-	-
Net margin	-	-	-	-	-	-	-	-	-	-

Quarterly (JPYmn)	FY04/18				FY04/19			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Operating revenue	66	39	62	61	52	68	74	135
YoY	721.3%	65.6%	63.8%	-88.8%	-20.8%	73.6%	19.2%	119.6%
Sales	66	39	62	61	52	68	74	135
YoY	721.3%	65.6%	63.8%	62.9%	-20.8%	73.6%	19.2%	119.6%
R&D operating revenue	-	-	-	-	-	-	-	-
YoY	-	-	-	-	-	-	-	-
R&D expenses	482	487	552	582	622	601	608	765
YoY	18.9%	29.1%	12.6%	-0.2%	29.1%	23.5%	10.1%	31.4%
Cost of sales	56	25	45	51	43	60	92	118
YoY	925.5%	21.3%	5.2%	55.7%	-24.5%	143.0%	102.8%	131.4%
Cost ratio	85.1%	63.4%	72.9%	83.0%	81.1%	88.7%	124.0%	87.5%
R&D expenses	115	142	130	175	198	210	164	214
YoY	-4.6%	50.9%	46.9%	5.3%	72.4%	47.4%	26.6%	22.1%
SG&A expenses	311	320	377	356	382	331	352	433
YoY	11.1%	21.9%	5.0%	-7.3%	22.9%	3.6%	-6.8%	21.6%
Operating profit	-416	-448	-490	-521	-570	-533	-534	-630
YoY	-	-	-	-	-	-	-	-
OPM	-	-	-	-	-	-	-	-
Recurring profit	-332	-392	-485	-558	-605	-556	-632	-633
YoY	-	-	-	-	-	-	-	-
RPM	-	-	-	-	-	-	-	-
Net income	-355	-422	-505	-584	-626	-605	-666	-659
YoY	-	-	-	-	-	-	-	-
Net margin	-	-	-	-	-	-	-	-

Source: Shared Research based on company data.

Note: Figures may differ from company materials due to differences in rounding methods.

Note: FY estimates are latest figures.

Operating revenue breakdown

Cumulative (JPYmn)	FY04/18				FY04/19			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Operating revenue	66	105	167	229	52	120	194	329
YoY	721.3%	233.1%	140.8%	-62.9%	-20.8%	14.1%	16.0%	43.8%
Product sales	66	105	167	229	52	120	194	329
YoY	721.3%	233.1%	140.8%	113.4%	-20.8%	14.1%	16.0%	43.8%
Europe	27	57	104	153	37	74.0	123.1	192.0
YoY	323.4%	120.2%	76.6%	62.2%	36.0%	30.7%	18.4%	25.5%
Asia and Oceania	38	46	59	68	14	41.0	66.6	127.0
YoY	-	-	-	-	-62.6%	-11.5%	13.6%	86.8%
R&D operating revenue	-	-	-	-	-	-	-	-
YoY	-	-	-	-	-	-	-	-

Quarterly (JPYmn)	FY04/18				FY04/19			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Operating revenue	66	39	62	61	52	68	74	135
YoY	721.3%	65.6%	63.8%	-88.8%	-20.8%	73.6%	19.2%	119.6%
Product sales	66	39	62	61	52	68	74	135
YoY	721.3%	65.6%	63.8%	62.9%	-20.8%	73.6%	19.2%	119.6%
Europe	27	29	47	49	37	36.7	49.1	68.9
YoY	323.4%	51.8%	42.8%	38.4%	36.0%	25.7%	3.7%	40.6%
Asia and Oceania	38	9	12	9	14	26.9	25.6	60.4
YoY	-	209.4%	-	318.2%	-62.6%	210.8%	109.1%	540.9%
R&D operating revenue	-	-	-	-	-	-	-	-
YoY	-	-	-	-	-	-	-	-

Source: Shared Research based on company data.

Note: Figures may differ from company materials due to differences in rounding methods.

Full-year FY04/19 results

- ▷ Operating revenue: JPY329mn (+43.8% YoY)
- ▷ Operating loss: JPY2.3bn (versus loss of JPY1.9bn in FY04/18)
- ▷ Recurring loss: JPY2.4bn (versus loss of JPY1.8bn in FY04/18)
- ▷ Net loss*: JPY2.6bn (versus loss of JPY1.9bn in FY04/18)

Net income/loss refers to net income/loss attributable to parent company shareholders.

Operating revenue of JPY321mn came from European and Asian sales of hemostatic agent TDM-621 (JPY192mn from Europe, JPY127mn from Asia and Oceania, and JPY2mn from Latin America); research reagent sales were JPY7mn. According to the company, sales were in line with its full-year plan, as were expenses. The difference between operating and recurring losses was due in large part to JPY131mn in forex losses. The difference between recurring and net losses was due mainly to JPY145mn in asset impairment loss.

R&D status by country and sales of absorbable local hemostat by region are as follows.

R&D status in Japan

Absorbable local hemostat (TDM-621)

In Japan, 3-D Matrix prepared a clinical trial plan for comprehensive evaluation covering its hemostatic effects on hemorrhage per diapedesis in endoscopic submucosal dissections and its overall safety including efficacy and safety evaluations. The plan was submitted to the Pharmaceuticals and Medical Devices Agency (PMDA) in April 2017 and the clinical trial began in August 2017. The latest clinical trial plan entails comparing the efficacy of TDM-621 with conventional hemostasis methods in gastrointestinal endoscopy. Currently, clinical trials are being conducted at several facilities. With a change in completion time for case inclusions, however, the scheduled clinical trial end date was pushed back from FY04/19 to Q1 FY04/20. The company changed the planned application submission date for regulatory approval of manufacturing and marketing to H1 FY04/20.

Mucous membrane protuberance material

The company started a clinical study in December 2014. However, in February 2015, it voluntarily and temporarily discontinued the study in order to explore test methods for more evident efficacy and for product development. In exploring product superiority, the company enhanced the peptide and achieved a certain level of results. In 2H FY04/19, the company resumed

discussions with PMDA regarding new clinical trial protocols using improved formulations. Additionally, it is looking into submitting an application for approval as improved medical device, which does not require clinical trials, to get the product to market.

Drug-delivery system (DDS)

3-D Matrix is collaborating with the National Cancer Center on treatment for “triple negative” breast cancer with nucleic acid medicine that targets the RPN2 gene. The company provided siRNA nucleic acid medicine that uses the self-assembling peptide A6K as a drug-delivery system (DDS). The company has a joint patent with the National Cancer Center regarding treatment and diagnostic method for cancer stem cells, and is working toward advancing joint R&D in the subject and related fields. 3-D Matrix also is advancing joint development such as with Hiroshima University, for which it provides surfactant peptide for use in an innovative anti-tumor nucleic acid medicine targeting malignant pleural mesothelioma.

R&D status in Europe

Hemostatic agent to prevent post-operative bleeding

In December 2017, the company applied for the CE marking to expand application of its hemostatic agent to include use in preventing post-operative bleeding under endoscopic surgeries. Following the application, the company continued discussions with the approval institution and obtained approval for the indication on December 10, 2018.

Next-generation hemostatic agent

The next-generation hemostatic agent under development uses a different peptide sequence from the absorbable local hemostat PuraStat. The agent is being developed using the self-assembling peptide technology for which 3D-Matrix was granted a license from MIT. Productization is nearly complete and preclinical trial with the final product is in progress. It plans to advance R&D with a view to make the next-generation hemostatic agent its mainstay product in the future as it is superior to PuraStat in hemostatic effect and can be manufactured at lower cost.

R&D status in the US

Anti-adhesion agent

A 510(K) premarket notification application previously submitted to the Food and Drug Administration (FDA) for sales of the product as a class 2 medical device to the Otorhinolaryngology field was approved in April 2019. With simultaneous hemostatic, anti-adhesion, and wound-healing effects delivering high value-add, the company is expecting high demand of the product for use in Otolaryngology procedures such as turbinectomy and nasal septoplasty. The market size for the product is approximately JPY20bn in the US, and the company starts manufacturing the product and preparing the sales network in order to start selling in FY04/20.

Absorbable local hemostat

3-D Matrix has continued its discussions with FDA on building a protocol in order to begin clinical trials. In light of the progress of the application it has already filed in the US for use as an anti-adhesion agent, the company plans to start clinical trials during FY04/20.

Alveolar bone regenerator

In clinical trials in the US, the company completed treatment and observations of 15 patients during the first pilot study, collecting good results and data in terms of bone formation. After the FDA approved the trial protocols for a second pilot study, the company moved onto the next clinical trial phase in Q1 FY04/17. Notwithstanding time-consuming observations to confirm the process of bone formation, 3-D Matrix is still conducting clinical trials and will continue development with a view for commercialization.

Wound-healing agent

In October 2014, 3-D Matrix submitted a 510(k) premarket notification to the US Food and Drug Administration (FDA), which was approved in February 2015, allowing for the start of sales. The company expects increased therapeutic effects in combination

with other pharmaceuticals (antibiotics, anticancer drugs, and hyaluronic acid) and as of Q3, it is working on commercialization with higher added value for the fields of skin burn treatments, skin cancer treatments, and cosmetic surgery.

Sales of absorbable local hemostat by region

Status in Europe

After receiving European CE marking certification in January 2014, the company began marketing the product in all areas of Europe including major countries such as Germany, England, and France to establish a viable business. Marketing is done through sales agents specialized by country with the aim of reaching prominent doctors and medical institutions. Product sales in FY04/19 grew 125% YoY to JPY192mn.

Working through its German sales agent, Nicolai Medizintechnik GmbH, during the period the company expanded sales in Germany, one of its main markets, with the help of WERFEN Group, a major in-vitro diagnostic agent manufactures and medical equipment distributor. In England, working through its local sales subsidiary Aquilant, 3DM also moved ahead with sales through the Healthcare 21 Group, a medical equipment distributor. Meanwhile, full scale sales haven't started with French sales agent PENTAX, and the sales agreement has not completed. Thus, the company could not expect bulk orders, resulting in a deviation from forecast.

Additionally, the company is in talks about a distribution partnership covering all of Europe with 3 distribution partner candidates (with sales network spanning the entire region and strong promotion capabilities). While contracts were not signed in FY04/19, a European 3-D Matrix subsidiary signed an exclusive distribution agreement with FUJIFILM Europe BV (FUJIFILM) in June 2019 which covers all of Europe for hemostatic agent PuraStat. Going forward, the company aims to expand customer coverage and shorten sales periods by selling to FUJIFILM's customer base together with FUJIFILM. As for the cardiovascular surgery and digestive surgery fields, the company plans to continue negotiations with distribution partner candidates.

Status in Asia and Oceania

In this region, which adopts the CE mark certification, the company worked to file its absorbable local hemostat as a medical device and also made sales efforts at a number of countries. In the major market of Australia, the company used to sell the product through a major medical device company Getinge Group, but Getinge Group's biosurgery division was sold to a Chinese healthcare company in October 2018. As a result, the distribution partnership agreement with Getinge Group ended, and 3-D Matrix transitioned to its own distribution channel between Q3 and Q4. With progress in hiring sales personnel, the company booked sales of JPY57mn through its own distribution channel in Q4, marking record high sales. The company also surpassed targets for FY04/19 with product sales of JPY127mn (+187% YoY). The otolaryngology and endoscopic surgery fields are the leading fields, but the company is also expecting to expand sales into new fields like laparoscopic surgery in FY04/20. Additionally, the number of its target medical institutions are expanding as well, and the company plans for sales growth in FY04/20.

In South Korea, sales partner Daewoong Pharmaceutical Co., Ltd. is still in discussions with the authorities as it seeks approval to begin marketing. The company was unable to obtain approval during FY04/19, and intends to assist Daewoong Pharmaceutical in the continuing process to jointly work toward obtaining sales approval during FY04/20.

Status in Latin America and Canada

The region adopts the CE mark certification. The company worked to file its absorbable local hemostat as a medical device and also made sales efforts in major markets including Brazil, Mexico, Columbia, and Chile through local sales agents so product sales were at JPY2mn in FY04/19.

In Canada, 3-D Matrix received product approval in January 2019, paving the way for the approval of product sales. Also in January 2019, the company entered a sales alliance with Diploma Group (listed on the London Stock Exchange) and its local sales subsidiary, Vantage Endoscopy. As of the end of FY04/19, the company is in the process of manufacturing products, which it plans to start selling in FY04/20.

Full-year company forecasts

(JPYmn)	FY04/19 FY Act.	FY04/20 FY Est.
Operating revenue	329	882 to 1,432
YoY	43.8%	-
Sales	329	882
R&D operating revenue	-	550
Operating expenses	2,596	2,748
Cost of sales	312	699
Cost ratio	94.9%	79.3%
R&D expenses	786	596
SG&A expenses	1,498	1,453
Operating profit	-2,267	-1,866 to -1,316
YoY	-	-
OPM	-	-
Recurring profit	-2,426	-1,866 to -1,316
YoY	-	-
RPM	-	-
Net income	-2,555	-1,896 to -1,346
YoY	-	-
Net margin	-	-

Source: Shared Research based on company data

Note: Figures may differ from company materials due to differences in rounding methods.

Operating revenue breakdown (JPYmn)	FY04/19 FY Act.	FY04/20 FY Est.
Absorbable local hemostat	321	862 to 1,412
Product sales	321	862
One-time contract payments and milestone payments	-	550
Others	7	20
Product sales	7	20
One-time contract payments and milestone payments	-	-

Source: Shared Research based on company data

Note: Figures may differ from company materials due to differences in rounding methods.

The FY04/20 forecasts call for operating revenue of JPY882mn to JPY1.4bn (JPY329mn in FY04/19), an operating loss of JPY1.9bn to JPY1.3bn (loss of JPY2.3bn in FY04/19), a recurring loss of JPY1.9bn to JPY1.3bn (loss of JPY2.4bn in FY04/19), and a net income/loss of JPY1.9bn loss to JPY1.3bn income (net loss of JPY2.6bn in FY04/19).

The company forecasts JPY862mn (JPY321mn in FY04/19) from sales of absorbable local hemostat and one-time contract payments and milestone payments of JPY0mn to JPY550mn (JPY0mn in FY04/19). The breakdown of product sales forecasts is: Europe, JPY522mn (JPY192mn in FY04/19); Asia and Oceania, JPY299mn (JPY127mn in FY04/19); and Latin America and Canada, JPY40mn (JPY2mn in FY04/19). Operating revenue forecasts are based mainly on sales of absorbable local hemostat (TDM-621). The lower limit is product sales highly likely to be achieved, while the upper limit includes one-time contract payments from sales of the hemostatic agent in Europe.

The company expects operating expenses of JPY2.7bn (JPY2.6bn in FY04/19). This included cost of sales of JPY699mn (JPY312mn in FY04/19), R&D spending of JPY596mn (JPY786mn), and SG&A expenses of JPY1.5bn (JPY1.5bn in FY04/19). Cost of revenue was calculated by the accumulation of costs such as raw materials for peptides and outsourced manufacturing costs. Compared to FY04/19 cost of revenue of JPY312mn, cost of revenue is expected to increase in line with the increase in product sales. Gross profit margin is, however, expected to improve owing to a projected increase in product sales. As for R&D spending, the driving factors are clinical trials for hemostatic agents and development costs for mucous membrane protuberance material in Japan and post-marketing surveillance costs in Europe.

Pipeline assumptions

In April 2017, the company submitted its application to the PMDA regarding clinical studies for its absorbable local hemostat in the field of surgery in Japan.

Based on its clinical trial plan for comprehensive evaluation covering the hemostatic effects and overall safety of TDM-621 on hemorrhage per diapedesis in endoscopic submucosal dissections, 3-D Matrix began clinical trials in August 2017. It aims to obtain manufacturing and marketing approval in FY04/20.

The company is aiming to expand business for this hemostat overseas. 3-D Matrix has reached agreements with sales partners and sales agents in Europe, Asia, Oceania, and Latin America and is progressing with manufacturing and sales. In the US, 3DM is at the protocol discussion stage prior to launching clinical studies, with the aim of launching studies at an early stage.

Among other products in the development pipeline, the company is conducting clinical studies in the US for its alveolar bone regenerator. Once the clinical studies are complete, 3DM intends to apply for manufacturing and marketing approval and produce and sell the product within the US. Other than this, the company is searching for other pipeline candidates. 3-D Matrix is proceeding with joint research in conjunction with universities and research organizations to acquire applied technologies, including developments in the drug-delivery system (DDS) field.

Projections for absorbable local hemostat sales by region

Europe

3-D Matrix assumes sales of JPY522mn for FY04/20 versus JPY191mn in FY04/19. The company intends to grow sales based on Q4 FY04/19 results, and expand sales through its sales agents across Europe including Eastern Europe, as well as the Middle East.

When making its forecasts, 3DM uses average monthly sales in the latest quarter, Q4 FY04/18, as a starting point. This reflected the latest circumstances at the company's sales agents and target medical facilities. When making its calculations, the company also interviewed individual distributors in its key countries of Germany, France, and the UK (regarding size of operations, speed of signing up medical facility customers, and forecast sales per facility), also factoring in projected increases in the number of hospitals available to market to. Additionally, forecasts are based on currently operating 30 sales agents (as of the end of FY04/19) and 250 target facilities.

Asia and Oceania

The company assumes sales of JPY299mn for FY04/20. 3DM aims to focus on growing sales in the key Australian market this year as well. Sales increased in the fields of otolaryngology, endoscopy, and laparoscopic surgery by end-FY04/19. Although the company transitioned to its own distribution network in Q4 FY04/19, sales have remained steady. While the company plans to expand promotion efforts in the general and cardiovascular surgeries in FY04/20, the company's initial plans were made, still centering on otolaryngology, endoscopy, and laparoscopic surgeries.

For other countries, the company included Hong Kong, Thailand, and Vietnam sales in its plans. The company also decided not to include South Korea in the plan due to uncertainties regarding the timing of sales approval.

Latin America and Canada

The company assumes sales of JPY40mn for FY04/20. For the key Brazilian and Canadian markets, the company expects sales growth. The company interviewed the individual partners and distributors in the region regarding size of operations, speed of signing up medical facility customers, and sales forecast per facility; negotiated initial purchasing volume with new distributors; and calculated the sales forecast by summing up projections per medical facility.

One-time contract payments from absorbable local hemostat

Company forecasts include a one-time sales partnership payment of JPY500mn in Europe.

For distribution partnerships in Europe, the company plans to grant sales and marketing rights by surgical field with the exception of the endoscopic surgery field. The company is in ongoing discussions with partner candidates in Europe. The company takes into account agreements with other companies, past performance, and several other considerations when calculating one-time contract payments. Additionally, the company also references past performance in Japan and Asia as a baseline, taking the FY04/17 licensing agreement in China into consideration, and including factors like market size of region, product value

proposition, projected market share, and risk when calculating one-time contract payments. While there are idiosyncratic challenges in reaching an agreement with each company, many of them are related to collecting clinical trial data, which directly ties into sales. In such cases, the company continues to collect and verify usage data, aiming for an eventual contractual agreement.

Regarding marketing approval in South Korea, the company is planning for a JPY50mn as a milestone payment upon obtaining approval from the authorities. While Korean authorities continue their review, correspondence regarding inquiries, among other things, are progressing through the review process, and the company aims to obtain approval.

Anti-adhesion material sales

The company expects JPY20mn in US sales based on the initial sales projection as it will be selling products in the US for the first time in FY04/20. At the beginning, the company plans to sell directly. The sales forecast was estimated base on hearings with medical institutions and through marketing efforts.

Medium-term outlook

Medium-term management plan

In June 2019, 3-D Matrix announced a revised medium-term management plan. In compiling the plan, the company considered the progress of sales in individual regions and the progress of business in Europe, Asia, Oceania, South America, Japan, and the US.

Targets in the medium-term management plan

Medium-term management plan (JPYmn)	FY04/19	FY04/20	FY04/21	FY04/22
	Act.	Est.	MTP	MTP
Operating revenue	329	882 to 1,432	2,574 to 3,774	5,305 to 7,255
Sales	329	882	1,774	5,305
R&D operating revenue	-	550	2,000	1,950
Operating expenses	2,596	2,748	2,825	3,766
Cost of sales	312	699	-	-
Cost ratio	94.9%	79.3%	-	-
R&D expenses	786	596	629	394
SG&A expenses	1,498	1,453	-	-
Operating profit	-2,267	-1,866 to -1,316	-250 to 949	1,539 to 3,489
Recurring profit	-2,426	-1,866 to -1,316	-250 to 949	1,539 to 3,489
Net income	-2,555	-1,896 to -1,346	-250 to 919	1,509 to 3,459

Source: Shared Research based on company data

Note: Figures may differ from company materials due to differences in rounding methods.

Operating revenue by segment (JPYmn)	FY04/19	FY04/20	FY04/21	FY04/22
	Act.	Est.	MTP	MTP
Total	329	882 to 1,432	2,574 to 3,774	5,305 to 7,255
Absorbable local hemostat	321	1,412	2,974	4,805
Product sales	321	862	1,574	4,805
Europe	192	522	956	3,000
Asia and Oceania	127	299	531	1,005
Latin America and Canada	2	40	87	300
US	-	-	-	-
Japan	-	-	-	500
One-time contract payments and milestone payments	-	550	1,400	-
Others	7	20	800	2,450
Product sales	7	20	200	500
One-time contract payments and milestone payments	-	-	600	1,950

Source: Shared Research based on company data

Note: Figures may differ from company materials due to differences in rounding methods.

Note: Product revenues by region are Shared Research estimates based on company data.

For data on FY04/20, refer to Full-year company forecasts. Highlights of forecasts for FY04/21 and FY04/22 follow.

Assumptions for FY04/21 targets

The company expects operating revenue of JPY2.6bn to JPY3.8bn in product sales and one-time contract payments from its absorbable local hemostat and anti-adhesion material. 3-D Matrix expects product sales of JPY1.7bn (+101% YoY), and one-time contract payments of JPY800mn to JPY 2.0bn. Considering the potential for variations in one-time contract payments, signing contracts is crucial in meeting the higher forecasts.

Product sales

3-D Matrix forecast sales of its absorbable local hemostat to reach JPY1.6bn, broken down to JPY956mn (+83% YoY) from Europe, JPY531mn (+78% YoY) from Asia and Oceania, and JPY87mn (+118% YoY) from Latin America and Canada. Sales of anti-adhesion material in the US is estimated at JPY200mn (JPY20mn in FY04/20).

Europe

Sales forecast: JPY956mn. The forecast is premised on sales growth in individual countries via sales agents across the European region. The key factor in forecast sales growth is the assumption that marketing to the roughly 250 target medical institutions will be in full swing from the start of the fiscal year and an increase of 50% in the number of institutions during the year to 375.

Asia and Oceania

Sales forecast: JPY531mn. 3-D Matrix intends to focus on sales growth in Australia, the key country in the region. As for other countries, the company includes sales in Hong Kong, Thailand, and Vietnam in its forecasts, but excludes South Korean sales as there are variable factors regarding obtaining marketing approval from authorities.

Latin America and Canada

Sales forecast: JPY87mn. The company expects sales growth in its key Brazilian, Canadian, and Mexican markets.

US

Sales forecast for the anti-adhesion material: JPY200mn. Using US products sales from FY04/20 as a baseline, projected market size, demand forecasts, and penetration rates are taken into account for the sales forecast. The company assumes continued direct selling and plans to increase sales and marketing personnel.

One-time contract payments

One-time contract payments include JPY1.0bn as a part of a sales agreement in Europe. Additionally, the company is expecting milestone payments for marketing and manufacturing approval of hemostatic agent and mucous membrane protuberance material in Japan.

Because one-time contract payments can be affected by negotiations with partners and reviews by the authorities, signing contracts is crucial in meeting the higher forecasts in the range.

Operating profit

3DM targets operating profit of -JPY250mn to JPY949mn. It sees losses narrowing in tandem with growth in product sales.

R&D expenditure is planned to be at JPY629mn.

Assumptions for FY04/22 targets

The company expects operating revenue of JPY5.3bn to JPY7.3bn in product sales and one-time contract payments for its sales of its absorbable local hemostat and a sales agreement for anti-adhesion material. 3-D Matrix expects sales revenue of JPY5.3bn (+199% YoY), and one-time contract payments of JPY0 to JPY2.0bn. Considering the potential for variations in one-time contract payments, signing contracts is the key requirement in meeting the upper limit of performance forecast ranges.

Product sales

The company forecast sales of its absorbable local hemostat of JPY4.8bn, comprised of Europe, JPY3.0bn (+214% YoY); Asia and Oceania, JPY1.0bn (+89% YoY); Latin America and Canada, JPY300mn (+245% YoY); Japan, JPY500mn (JPY0mn in FY04/21). The company expects sales of anti-adhesion material in the US to reach JPY500mn (+150% YoY).

Europe

Sales forecast: JPY3.0bn. The forecast is premised on sales growth in individual countries via sales agents across the European region. The key factor in sales growth is the assumption that marketing to the roughly 375 target medical institutions (250 at the start of previous fiscal year) will be in full swing from the start of the fiscal year and increasing by 1.5x over the year in the number of institutions to 550.

Asia and Oceania

Sales forecast: JPY1.0bn. With Australia as a key market, the company created its sales forecast based on projected sales and facility count from the otolaryngology, endoscopic and laparoscopic surgery, general surgery, and cardiovascular surgery fields. As for other countries, the company includes sales in Hong Kong and Thailand in its forecasts, but excludes South Korean sales as there are variable factors regarding obtaining marketing approval from authorities.

Latin America and Canada

Sales forecast: JPY300mn. The company expects sales growth in its key Brazilian, Canadian, and Mexican markets.

Japan

Sales forecast: JPY500mn. The forecast assumes sales generated by the exclusive distribution partner, and includes initial product batches.

US (anti-adhesion material)

Sales forecast: JPY500mn. The company assumes sales of anti-adhesion material in ENT treatment. The company assumes continued direct selling, and plans to increase sales and marketing personnel are included in the forecast.

One-time contract payments

One-time contract payments mainly consists of a one-time contract payment of JPY1.8bn as a part of a distribution partnership for anti-adhesion material sales in the US.

Because one-time contract payments can be affected by negotiations with partners and reviews by the authorities, signing contracts is the key requirement in meeting the upper limit of performance forecast ranges.

Operating profit

3DM targets operating profit of JPY1.5–3.5bn, in anticipation of profit growth driven by an increase in product sales.

R&D expenditure is planned to be at JPY394mn.

This note is the most recent addition to the [full report](#).

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