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On **March 14, 2019**, 3-D Matrix Ltd. (3DM) announced earnings results for Q3 FY04/19 .

Cumulative	FY04/18				FY04/19				FY04/19	
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of FY	FY Est.
Operating revenue	66	105	167	229	52	120	194		-	512 to 2,562
YoY	721.3%	233.1%	140.8%	-62.9%	-20.8%	14.1%	16.0%			-
Sales	66	105	167	229	52	120	194		37.9%	512
YoY	721.3%	233.1%	140.8%	113.4%	-20.8%	14.1%	16.0%			-
R&D operating revenue	-	-	-	-	-	-	-		-	-
YoY	-	-	-	-	-	-	-			-
R&D expenses	482	969	1,521	2,103	622	1,223	1,831		-	-
YoY	18.9%	23.8%	19.5%	13.3%	29.1%	26.3%	20.4%			-
Cost of sales	56	81	126	177	43	103	194		-	-
YoY	925.5%	213.7%	83.5%	74.5%	-24.5%	26.5%	53.8%			-
Cost ratio	85.1%	77.0%	75.5%	77.5%	81.1%	85.4%	100.1%			-
R&D expenses	115	257	387	562	198	408	572		-	-
YoY	-4.6%	19.8%	27.7%	19.8%	72.4%	58.6%	47.8%			-
SG&A expenses	311	631	1,008	1,364	382	713	1,065		-	-
YoY	11.1%	16.4%	11.8%	6.1%	22.9%	13.1%	5.7%			-
Operating profit	-416	-863	-1,354	-1,875	-570	-1,103	-1,637		-	-2,217 to 203
YoY	-	-	-	-	-	-	-			-
OPM	-	-	-	-	-	-	-			-
Recurring profit	-332	-724	-1,209	-1,767	-605	-1,161	-1,793		-	-2,217 to 203
YoY	-	-	-	-	-	-	-			-
RPM	-	-	-	-	-	-	-			-
Net income	-355	-777	-1,282	-1,866	-626	-1,230	-1,896		-	-2,242 to 178
YoY	-	-	-	-	-	-	-			-
Net margin	-	-	-	-	-	-	-			-

Quarterly	FY04/18				FY04/19			
(JPYmn)	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Operating revenue	66	39	62	61	52	68	74	
YoY	721.3%	65.6%	63.8%	-88.8%	-20.8%	73.6%	19.2%	
Sales	66	39	62	61	52	68	74	
YoY	721.3%	65.6%	63.8%	62.9%	-20.8%	73.6%	19.2%	
R&D operating revenue	-	-	-	-	-	-	-	
YoY	-	-	-	-	-	-	-	
R&D expenses	482	487	552	582	622	601	608	
YoY	18.9%	29.1%	12.6%	-0.2%	29.1%	23.5%	10.1%	
Cost of sales	56	25	45	51	43	60	92	
YoY	925.5%	21.3%	5.2%	55.7%	-24.5%	143.0%	102.8%	
Cost ratio	85.1%	63.4%	72.9%	83.0%	81.1%	88.7%	124.0%	
R&D expenses	115	142	130	175	198	210	164	
YoY	-4.6%	50.9%	46.9%	5.3%	72.4%	47.4%	26.6%	
SG&A expenses	311	320	377	356	382	331	352	
YoY	11.1%	21.9%	5.0%	-7.3%	22.9%	3.6%	-6.8%	
Operating profit	-416	-448	-490	-521	-570	-533	-534	
YoY	-	-	-	-	-	-	-	
OPM	-	-	-	-	-	-	-	
Recurring profit	-332	-392	-485	-558	-605	-556	-632	
YoY	-	-	-	-	-	-	-	
RPM	-	-	-	-	-	-	-	
Net income	-355	-422	-505	-584	-626	-605	-666	
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 Q1	Q2	Q3	Q4	FY04/19 Q1	Q2	Q3	Q4
Operating revenue	66	105	167	229	52	120	194	
YoY	721.3%	233.1%	140.8%	-62.9%	-20.8%	14.1%	16.0%	
Product sales	66	105	167	229	52	120	194	
YoY	721.3%	233.1%	140.8%	113.4%	-20.8%	14.1%	16.0%	
Europe	27	57	104	153	37	74.0	123.1	
YoY	323.4%	120.2%	76.6%	62.2%	36.0%	30.7%	18.4%	
Asia and Oceania	38	46	59	68	14	41.0	66.6	
YoY	-	-	-	-	-62.6%	-11.5%	13.6%	
Latin America	1.2	2.2	2.7	2.0	1.1	1.1	1.1	
YoY	65.9%	2.6%	-59.9%	-69.9%	-6.8%	-52.3%	-60.0%	
R&D operating revenue	-	-	-	-	-	-	-	
YoY	-	-	-	-	-	-	-	

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

Q3 FY04/19 results (cumulative)

- ▷ Operating revenue: JPY194mn (+16.0% YoY)
- ▷ Operating loss: JPY1.6bn (versus loss of JPY1.4bn in cumulative Q3 FY04/18)
- ▷ Recurring loss: JPY1.8bn (versus loss of JPY1.2bn in cumulative Q3 FY04/18)
- ▷ Net loss*: JPY1.9bn (versus loss of JPY1.3bn in cumulative Q3 FY04/18)

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

Operating revenue of JPY191mn came from European and Asian sales of hemostatic agent TDM-621 (JPY123mn from Europe, JPY67mn from Asia and Oceania, and JPY1mn from Latin America); research reagent sales were JPY3mn. 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 JPY159mn in forex losses. The difference between recurring and net losses was due mainly to JPY107mn in asset impairment charges booked as an extraordinary 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. 3-D Matrix has continued with the study at several facilities since then. The company expects the clinical trial to be completed in FY04/19, after which it expects to file for regulatory approval of manufacturing and marketing during Q1 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. The company has begun consultations with PMDA regarding clinical trials and the process of filing for regulatory approval. It will continue consultations with PDMA to determine the clinical trial protocols and structure of the application for regulatory approval to be filed in FY04/20.

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. It has also entered a joint research agreement with the Neutron Therapy Research Center of Okayama University regarding development of a new drug for boron neutron capture therapy (BNCT) to treat cancer.

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. It now plans to commercialize and cross-sell the product using the existing sales channel to maximize synergistic effects.

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. The company intends to move forward to the clinical trial stage at an early timing. 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

With regard to the inspection process under the 510(K) premarket notification application for uses in the field of otorhinolaryngology that the Food and Drug Administration (FDA) had already approved, in October 2018 3DM filed an application with the FDA to sell the product as a class 2 medical device. The target applications are hemostatic, anti-adhesion, and wound-healing effects mainly for use in otolaryngology procedures such as turbinectomy and nasal septoplasty. Based on the progress of current inspection, the company anticipates to receive approval sometime between Q4 FY04/19 and Q2 FY04/20, therefore it is making preparations to begin manufacturing and marketing of the agent in parallel. The agent will create a market worth roughly JPY20bn and will be the company’s first product to be launched in the US.

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 the nine-month through Q3 FY04/19 grew 118% YoY to JPY123mn.

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. The company also began sales in the Middle East (including the UAE and Saudi Arabia). With growth underpinned by sales in Germany and England, the company plans to continue stepping up its marketing efforts in other countries and expects to see contributions to sales from these areas by the end of FY04/19.

3-D Matrix has been exploring a comprehensive sales partnership covering all of Europe. It narrowed down the candidates for a sales partner (must have sales networks spanning the entire region and strong promotion capabilities), and is making steady progress in talks with a number of companies. The company plans to work to conclude an agreement during FY04/19.

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 sells the product through a major medical device company Getinge Group; sales for the nine-month period through Q3 FY04/19 came to JPY66mn (+114% YoY), as deliveries to medical institutions in major cities such as Sidney and Melbourne continued to log strong, above-plan growth. The sales agency agreement with Getinge Group will likely be terminated as a Chinese healthcare company acquired its bio-surgery division, so 3-D Matrix will independently market its products and is establishing its own direct-sales network. By moving to direct sales, in February 2019 the company already had its best month ever in terms of sales and is sticking with its full-year forecast for sales in FY04/19. 3-D Matrix expects the establishment of a direct sales network will also help when it comes to marketing in such areas as otorhinolaryngology, endoscopy, and laparoscopy, which will contribute to sales from 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. 3-D Matrix intends to assist Daewoong Pharmaceutical in the continuing process, and jointly work toward obtaining sales approval during FY04/19.

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 JPY1mn during the nine-month period through Q3 FY04/19. The company plans to begin sales in Argentina and Peru in April 2019, and is looking to expand sales in the region.

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. The company plans to begin marketing once preparations for manufacturing are completed.

This note is the most recent addition to the full report.

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