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On **September 13, 2018**, 3-D Matrix Ltd. (3DM) announced earnings results for Q1 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				-	512 to 2,562
YoY	721.3%	233.1%	140.8%	-62.9%	-20.8%					-
Sales	66	105	167	229	52				10.2%	512
YoY	721.3%	233.1%	140.8%	113.4%	-20.8%					-
R&D operating revenue	-	-	-	-	-				-	-
YoY	-	-	-	-	-					-
R&D expenses	482	969	1,521	2,103	622				-	-
YoY	18.9%	23.8%	19.5%	13.3%	29.1%					-
Cost of sales	56	81	126	177	43				-	-
YoY	925.5%	213.7%	83.5%	74.5%	-24.5%					-
Cost ratio	85.1%	77.0%	75.5%	77.5%	81.1%					-
R&D expenses	115	257	387	562	198				-	-
YoY	-4.6%	19.8%	27.7%	19.8%	72.4%					-
SG&A expenses	311	631	1,008	1,364	382				-	-
YoY	11.1%	16.4%	11.8%	6.1%	22.9%					-
Operating profit	-416	-863	-1,354	-1,875	-570				-	-2,217 to 203
YoY	-	-	-	-	-					-
OPM	-	-	-	-	-					-
Recurring profit	-332	-724	-1,209	-1,767	-605				-	-2,217 to 203
YoY	-	-	-	-	-					-
RPM	-	-	-	-	-					-
Net income	-355	-777	-1,282	-1,866	-626				-	-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			
YoY	721.3%	65.6%	63.8%	-88.8%	-20.8%			
Sales	66	39	62	61	52			
YoY	721.3%	65.6%	63.8%	62.9%	-20.8%			
R&D operating revenue	-	-	-	-	-			
YoY	-	-	-	-	-			
R&D expenses	482	487	552	582	622			
YoY	18.9%	29.1%	12.6%	-0.2%	29.1%			
Cost of sales	56	25	45	51	43			
YoY	925.5%	21.3%	5.2%	55.7%	-24.5%			
Cost ratio	85.1%	63.4%	72.9%	83.0%	81.1%			
R&D expenses	115	142	130	175	198			
YoY	-4.6%	50.9%	46.9%	5.3%	72.4%			
SG&A expenses	311	320	377	356	382			
YoY	11.1%	21.9%	5.0%	-7.3%	22.9%			
Operating profit	-416	-448	-490	-521	-570			
YoY	-	-	-	-	-			
OPM	-	-	-	-	-			
Recurring profit	-332	-392	-485	-558	-605			
YoY	-	-	-	-	-			
RPM	-	-	-	-	-			
Net income	-355	-422	-505	-584	-626			
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			
YoY	721.3%	233.1%	140.8%	-62.9%	-20.8%			
Product sales	66	105	167	229	52			
YoY	721.3%	233.1%	140.8%	113.4%	-20.8%			
Europe	27	57	104	153	37			
YoY	323.4%	120.2%	76.6%	62.2%	36.0%			
Asia and Oceania	38	46	59	68	14			
YoY	-	-	-	-	-62.6%			
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			
YoY	721.3%	65.6%	63.8%	-88.8%	-20.8%			
Product sales	66	39	62	61	52			
YoY	721.3%	65.6%	63.8%	62.9%	-20.8%			
Europe	27	29	47	49	37			
YoY	323.4%	51.8%	42.8%	38.4%	36.0%			
Asia and Oceania	38	9	12	9	14			
YoY	-	209.4%	-	318.2%	-62.6%			
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.

Q1 FY04/19 results

- ▷ Operating revenue: JPY52mn (-20.8% YoY)
- ▷ Operating loss: JPY570mn (versus loss of JPY416mn in Q1 FY04/18)
- ▷ Recurring loss: JPY605mn (versus loss of JPY322mn in Q1 FY04/18)
- ▷ Net loss: JPY626mn (versus loss of JPY355mn in Q1 FY04/18)

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

The difference between operating loss and recurring loss is due mainly to a JPY33mn forex loss. The difference between recurring loss and net loss is mainly because of a JPY20mn impairment loss.

Operating revenue came from European and Asian sales of hemostatic agent TDM-621 that amounted to JPY52mn (JPY37mn from Europe, JPY14mn from Asia and Oceania, and JPY1mn from Latin America).The YoY decline was due to a change in the timeline for product delivery to sales partners, and according to the company, results were in line with the full-year plan. Expenses were also on track with the plan.

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) with a schedule to begin clinical trial in April 2017. The latest clinical trial plan entails comparing the efficacy of TDM-621 with conventional hemostasis methods in gastrointestinal endoscopy. The company enrolled the first patient and performed the first procedure in August 2017 and has continued with the study at several facilities since then. The clinical trial is expected to complete in FY04/19, after which the company plans to file an application to manufacture and sell the product.

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 (November 2018 to April 2019), 3-D Matrix plans to resume discussions with PMDA on the protocol for a clinical trial using the new peptide formulation, and advance R&D with a view to begin clinical trials during 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 has worked toward advancing joint R&D in the subject and related fields. 3-D Matrix also made progress in the joint project 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 reapplied 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 has been continuing discussions with the approval institution but no major risk factors have surfaced. It expects to obtain approval in FY04/19, after which it 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, and the final version is undergoing preclinical studies. The company intends to continue validation for the product and 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

The company had discussions with the Food and Drugs Administration (FDA), and reached an agreement that the anti-adhesion agent would be subject to the Premarket Notification or 510(K) approval process in the area of otorhinolaryngology. The company is undergoing trials aimed at adhesion prevention and minor bleeding control in nasal surgery, and is targeting filing an application in FY04/19.

Absorbable local hemostat

3-D Matrix continued its discussions with FDA on building a protocol in order to begin clinical trials. After filing an application for its anti-adhesion agent in FY04/19, the company plans to advance development eyeing the start of clinical trials in 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, France, and the UK 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 Q1 FY04/19 grew 140% YoY to JPY37mn, trending largely on track with the company's plan.

Improved product sales in Germany, one of its main markets was the primary factor contributing to growth. In France, sales through local agent PENTAX Medical began, but the company has been requiring some time to build a full-scale marketing structure in the region. It anticipates sales activities backed by such structure to start from Q2 FY04/19 or later, which would contribute to results toward end-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 has continued talks. The company plans to build up track records for product sales and usage, and 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 Australia, the company sells the product through a major medical device company Getinge Group; Q1 sales dropped 63% YoY to JPY14mn. The significant YoY decline stemmed from the absence of a large-lot delivery that temporarily raised product sales in Q1 FY04/18. In FY04/19, the company expects to see the order volume balance out, since Getinge Group was able to improve the accuracy of its sales forecasts, and has made progress working out a product sales and inventory cycle. Product application has also expanded into new treatment areas such as ear, nose, and throat treatment and laparoscopic surgery at medical institutions in major cities such as Sydney and Melbourne, so no changes have been made to the sales target.

In South Korea, sales partner Daewoong Pharmaceutical is undergoing discussions with the authorities. 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

The region adopts the CE mark certification. In FY04/18, the company worked to file its absorbable local hemostat as a medical device and also made sales efforts at a number of countries in this region. The company has signed agreements with local sales agents in Brazil, Mexico, and Chile and is working to expand sales. Product sales were JPY1mn in Q1 FY04/19. The company plans to begin sales in Argentina from April 2019, and is looking to expand sales in the region.

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

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