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On September 14, 2020, 3-D Matrix Ltd. (3DM) announced earnings results for Q1 FY04/21.

Cumulative (JPYmn)	FY04/20 Q1	Q2	Q3	Q4	FY04/21 Q1	Q2	Q3	Q4	FY04/21 % of Est.	FY Est.
Operating revenue	142	316	507	672	210				-	1,289~2,339
YoY	170.1%	163.3%	161.4%	104.5%	48.0%					91.7%~247.8%
Sales	142	316	507	672	210					
YoY	170.1%	163.3%	161.4%	104.5%	48.0%					
R&D operating revenue	-	-	-	-	-					
YoY	-	-	-	-	-					
R&D expenses	789	1,591	2,400	3,209	825					
YoY	26.7%	30.0%	31.1%	23.6%	4.6%					
Cost of sales	111	242	398	560	168					
YoY	161.4%	135.9%	105.1%	79.5%	50.7%					
Cost ratio	78.5%	76.5%	78.6%	83.3%	79.9%					
R&D expenses	182	401	592	801	209					
YoY	-7.8%	-1.6%	3.5%	1.9%	14.7%					
SG&A expenses	495	948	1,409	1,847	449					
YoY	29.5%	32.9%	32.3%	23.3%	-9.4%					
Operating profit	-647	-1,275	-1,893	-2,536	-616				-	-2,345~-1,295
YoY	-	-	-	-	-					-
OPM	-	-	-	-	-					-
Recurring profit	-794	-1,405	-2,038	-2,955	-375				-	-2,350~-1,300
YoY	-	-	-	-	-					-
RPM	-	-	-	-	-					-
Net income	-839	-1,476	-2,139	-3,096	-409				-	-2,448～-1,398
YoY	-	-	-	-	-					-
Net margin	-	-	-	-	-					-

Quarterly (JPYmn)	FY04/20 Q1	Q2	Q3	Q4	FY04/21 Q1	Q2	Q3	Q4
Operating revenue	142	174	191	166	210			
YoY	170.1%	158.0%	158.2%	22.7%	48.0%			
Sales	142	174	191	166	210			
YoY	170.1%	158.0%	158.2%	22.7%	48.0%			
R&D operating revenue	-	-	-	-	-			
YoY	-	-	-	-	-			
R&D expenses	789	802	809	809	825			
YoY	26.7%	33.5%	33.1%	5.7%	4.6%			
Cost of sales	111	131	157	162	168			
YoY	161.4%	117.8%	70.8%	37.4%	50.7%			
Cost ratio	78.5%	74.9%	82.0%	97.9%	79.9%			
R&D expenses	182	219	191	209	209			
YoY	-7.8%	4.4%	16.1%	-2.3%	14.7%			
SG&A expenses	495	453	462	438	449			
YoY	29.5%	36.7%	31.3%	1.1%	-9.4%			
Operating profit	-647	-628	-618	-643	-616			
YoY	-	-	-	-	-			
OPM	-	-	-	-	-			
Recurring profit	-794	-611	-633	-917	-375			
YoY	-	-	-	-	-			
RPM	-	-	-	-	-			
Net income	-839	-637	-663	-958	-409			
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)	FY04/20 Q1	Q2	Q3	Q4	FY04/21 Q1	Q2	Q3	Q4
Operating revenue	142	316	507	672	210			
YoY	170.1%	163.3%	161.4%	104.5%	48.0%			
Product sales	142	316	507	672	210			
YoY	170.1%	163.3%	161.4%	104.5%	48.0%			
Europe	68	162	282	395	97			
YoY	81.3%	118.9%	128.9%	105.6%	44.1%			
Australia	72	152	221	271	97			
YoY	412.2%	270.6%	231.6%	113.6%	34.4%			
COVID-19 antibody test cassettes	-	-	-	-	8			
YoY	-	-	-	-	-			
R&D operating revenue	-	-	-	-	-			
YoY	-	-	-	-	-			

Quarterly (JPYmn)	FY04/20 Q1	Q2	Q3	Q4	FY04/21 Q1	Q2	Q3	Q4
Operating revenue	142	174	191	166	210			
YoY	170.1%	158.0%	158.2%	22.7%	48.0%			
Product sales	142	174	191	166	210			
YoY	170.1%	158.0%	158.2%	22.7%	48.0%			
Europe	68	94	120	113	97			
YoY	81.3%	157.0%	143.9%	64.0%	44.1%			
Australia	72	80	69	51	97			
YoY	412.2%	196.4%	169.1%	-16.3%	34.4%			
COVID-19 antibody test cassettes	-	-	-	-	8			
YoY	-	-	-	-	-			
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 FY04/21 results

- ▷ Operating revenue: JPY210mn (+48.0% YoY)
- ▷ Operating loss: JPY616mn (versus loss of JPY647mn in Q1 FY04/20)
- ▷ Recurring loss: JPY375mn (versus loss of JPY794mn in Q1 FY04/20)
- ▷ Net loss*: JPY409mn (versus loss of JPY839mn in Q1 FY04/20)

*Net loss attributable to owners of the parent

Operating revenue rose YoY. Sales of absorbable local hemostat TDM-621 were JPY202mn (JPY97mn from Europe, JPY97mn from Australia, JPY1mn from Asia, and JPY7mn from other regions). The company also booked JPY8mn in research reagent sales, including those from COVID-19 antibody test cassettes.

Expenses were in line with the company's forecast. The difference between the operating loss and recurring loss owed mainly to forex gains of JPY242mn (forex losses of JPY136mn in Q1 FY04/20).

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

R&D status

R&D status in Japan

Absorbable local hemostat

In Japan, 3-D Matrix completed the clinical trial evaluating hemostatic effects on hemorrhage per diapedesis in endoscopic surgery in July 2019. It submitted an application for manufacturing and marketing approval to the Pharmaceuticals and Medical Devices Agency (PMDA) in October 2019, and received PMDA approval in July 2020.

Next-generation hemostat

The company is proceeding with development, while investigating whether it will be possible to apply for approval as an improved medical device (without clinical trials) with TDM-621 (approved in July 2020) as its predecessor.

Mucous membrane protuberance material

The company developed the material with a new peptide sequence to improve its performance advantage. After discussions with PMDA regarding development policy, the company was told that it could submit an application for approval as an improved medical device, which does not require clinical trials, if it could demonstrate the same level of efficacy and safety as existing products in preclinical trials. The company plans to fulfill the required criteria for approval in preclinical trials and plans to submit its application in FY04/21.

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). Regarding TDM-812, which is a continuation of this study, the company submitted to the PMDA in March 2020 a clinical trial plan for an investigator-initiated Phase I study with refractory breast cancer patients at St. Luke's International Hospital. 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. In addition, 3-D Matrix is advancing joint development with Hiroshima University, for which it provides surfactant peptide for use in an innovative anti-tumor nucleic acid medicine targeting malignant pleural mesothelioma.

Antibody testing

3-D Matrix and Prometheus Bio Inc., which has a track record of selling COVID-19 antibody test kits in Europe and North America, are jointly developing coronavirus antibody test kits for the Japanese market. Prometheus Bio's antibody test kit Coronavirus IgG/IgM Antibody (COVID-19) Test Cassette is an in-vitro diagnostic immunoassay that detects 2019-n-CoV antibodies in whole blood, serum, or plasma. It can detect antivirus antibodies that suggest acquired immunity to COVID-19.

The company will also participate in joint development of a DNA vaccine against the novel coronavirus using plasmid DNA manufacturing technology announced on March 5, 2020 by AnGes Inc. and Osaka University. AnGes and 3-D Matrix will collaborate in gathering clinical trial data in Japan to consider potential for use of antibody test kits to check the existence of antibodies in trial participants before they receive the vaccine in clinical trials.

R&D status in Europe

Absorbable local hemostat

The company in January 2014 received the CE marking in Europe for TDM-621, which is on sale throughout Europe. The company plans to continue expanding indications in multiple disease areas, including central nervous system disorders, as well as expand its functions including wound healing.

Hemostatic agent to prevent post-operative bleeding

Prevention of post-operative bleeding under endoscopic surgeries was approved as an additional indication in December 2017.

Next-generation hemostat

The next-generation hemostat under development uses a new peptide sequence that is different from that of the absorbable local hemostat. The next-generation hemostat is being developed using the self-assembling peptide technology for which 3D-Matrix was granted a license from MIT. It plans to advance R&D with a view to make the next-generation hemostat its mainstay product in the future as it is superior to absorbable local hemostat in hemostatic effect and can be manufactured at lower cost. The company has established a commercial manufacturing method compliant with good manufacturing practice (GMP, the standard for manufacturing and quality management) and preclinical trials of the final product are largely complete. It is preparing to launch clinical trials in Q3 FY04/21 or later.

R&D status in the US

Anti-adhesion material

In April 219, 3D-Matrix received approval from the Food and Drug Administration (FDA) to sell anti-adhesion material in the otorhinolaryngology field. It is the company's first product approved for sale in the US. Being the only product with simultaneous

hemostatic, anti-adhesion, and wound-healing effects, the company believes it can deliver high clinical value used in otolaryngology procedures such as turbinectomy and nasal septoplasty.

Absorbable local hemostat

3DM will begin development of absorbable local hemostat in the US in the area of gastrointestinal endoscopy treatment, and by considering to utilize the 501(k) submission process, it aims to file for approval during FY04/21. The company commented that it is exploring a development policy that will provide not only hemostatic effects, but also high value added such as wound-healing and anti-adhesion effects.

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. However, the company enrolled 12 more patients to continue the clinical trial in April 2018, because there was scope for improvement of the protocols. The company plans to discuss the next step after completing clinical trials with the FDA in FY04/21.

Wound-healing material

The product was approved by FDA in February 2015, allowing for the start of sales. The company expects increased therapeutic effects in combination with other pharmaceuticals (such as antibiotics and anticancer drugs) and is progressing research in the fields of skin burn treatments and skin cancer treatments. Further, to move into the giant market of cosmetic surgery, the company submitted an application for approval of the additional indications to the FDA in November 2019; it obtained approval in May 2020. Cosmetic surgery requires a different marketing approach to the general medical market. In the first instance, the company said it planned to obtain clinical data necessary to make inroads into the market, while developing plans for sales strategy and sales channels suited to the market's needs and structure.

R&D status in Australia

Hemostatic agent to prevent post-operative bleeding

Prevention of post-operative bleeding was also approved as an additional indication in Australia in September 2019. The company sees a need for the prevention of post-operative bleeding (bleeding that occurs after surgery), because it requires further surgery, which adds to patients' physical stress as well as the hospital's workload. Bleeding occurs during endoscopic surgery in 5% of cases, whereas the risk of post-operative bleeding (in high-risk patients and procedures) is around 30%. The company believes that the additional indication more than doubles the scope of the agent's potential market in the endoscopic surgery field.

Other R&D status

Review of manufacturing methods to sharply reduce manufacturing costs

To lower manufacturing costs of its product range, the company is changing its sterilization methods and upscaling its manufacturing systems, with deployment scheduled for FY04/22.

Regional sales status

Sales of absorbable local hemostat and anti-adhesion material and hemostat by region

Status in Europe

Product sales in Europe grew 44.1% YoY to JPY97mn in Q1 FY04/21. 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 absorbable local hemostat PuraStat for use in gastrointestinal endoscopy. FUJIFILM launched the product in October 2019. In January 2020, the company and FUJIFILM reached an agreement to extend the scope of the exclusive distribution agreement to include countries in the Middle East. Utilizing FUJIFILM's sales network, the company plans to launch the product in the region, starting in countries where sales preparation is complete. 3DM seeks to continue growing its business in Europe in partnership with FUJIFILM, with Germany and the UK as the main markets. As for the fields of cardiovascular surgery and digestive surgery, the company plans to continue negotiations with distribution partner candidates.

Product sales in Europe in Q1 were in line with plan, increasing YoY. Due to the COVID-19 pandemic, the company was unable to carry out sales activities to capture new clients. However, doctors and hospitals that had already been using the company's products made repeat purchases, and the company's hemostats are increasingly being seen as a necessity in the field of gastroenterological endoscopy. In regard to new customer acquisition, while in-person visits to hospitals and doctors continued to be restrained with the exception of some countries, the company conducted sales and marketing activities "with COVID-19," rolling out initiatives that were appropriate during the time of pandemic (e.g., marketing activities utilizing online meetings). The company also made preparations to acquire new customers as soon as the pandemic came under control.

Status in Australia

Product sales in Australia were JPY97mn (+34.4% YoY). The impact of COVID-19 was brought under control comparatively quickly versus other countries, and hospital/doctor visits started resuming gradually from June 2020. Further, postponed surgeries were resumed, clawing back demand lost in Q4 FY04/20 (February–April 2020). In addition to otorhinolaryngology, growth in new fields such as endoscopic and laparoscopic surgery from FY04/20 contributed to operating revenue growth. The company plans to continue sales activities targeting multiple medical fields.

Status in the US

In April 2019, 3DM received FDA approval to sell anti-adhesion material and hemostat PuraSinus for use in the otorhinolaryngology field. The company estimates US market for this indication at roughly JPY20bn, based on the number of procedures and existing product prices. The company commented that having already succeeded with the product in the otorhinolaryngology field in Australia, it plans to follow the same strategy of selling direct to customers in the US, preparing its sales structure with the goal of producing results quickly. The first clinical use of PuraSinus in leading facilities planned for FY04/20 were put on hold due to COVID-19, but were carried out from late June through early July 2020. Doctors who tested the product gave positive feedback and indicated intentions to continue using it. It is also in talks with distributor candidates for a quick launch.

COVID-19 antibody test cassettes

The company started supplying COVID-19 antibody test cassettes for research purposes to universities and other research organizations in April 2020. It also started selling to business corporations from July, and booked JPY8mn in sales.

Other

As disclosed in July 2020, the company received a notice that Fuso Pharmaceutical Industries was terminating the exclusive sales agreement for absorbable local hemostat using RADA16 self-assembling peptide technology in Japan. The company is taking action to swiftly find a new sales partner for the domestic Japanese market.

Further, regarding the purported breach of patent representations and warranties by 3DM that Fuso cited as grounds for termination, ARCH Therapeutics, Inc. also has exclusive rights from MIT relating to the patents for some self-assembling peptides used in the hemostat (mainly the RADA16 sequence that 3DM also uses). This may require some coordination with the company's exclusive license.

MIT's licensing approach aims to disseminate technology. Disputes between licensees are not desirable from MIT's viewpoint, and the company has long understood that if some sort of resolution were required among licensees, it would receive assistance from MIT. However, MIT has been reluctant to make a written undertaking to make any necessary adjustments, so if the need arose, the company said it would do so itself. The next-generation hemostat TDM-623 currently under development employs a different peptide sequence to RADA16, while mucous membrane protuberance material TDM-644 has a different sequence and indication, so the company said that development and subsequent sales activities would not be affected.

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

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