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On **June 13, 2018**, SanBio Company Limited announced earnings results for Q1 FY01/19.

Cumulative (JPYmn)	FY01/17				FY01/18				FY01/19				FY01/19	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of 1H	1H Est.
Operating revenue	626	684	758	950	124	250	371	491	158				50.0%	317
YoY	119.7%	66.4%	-31.1%	-19.2%	-80.2%	-63.5%	-51.0%	-48.3%	27.9%					26.8%
Operating expenses	548	1,295	1,973	2,882	1,146	2,399	3,541	4,869	1,163					
YoY	49.7%	33.9%	18.4%	25.3%	108.9%	85.3%	79.5%	69.0%	1.5%					
Operating expenses / Operating revenue	87.7%	189.2%	260.3%	303.5%	924.9%	959.9%	953.6%	992.6%	733.8%					
Cost of revenue	-	-	-	17	-	-	-	0	-					
YoY	-	-	-	-	-	-	-	-	-					
R&D expenses	367	945	1,416	2,058	929	2,001	3,000	4,156	972					
YoY	78.2%	37.9%	15.4%	21.4%	153.2%	111.8%	111.8%	101.9%	4.7%					
Other operating expenses	181	350	556	806	216	398	541	713	190					
YoY	13.2%	24.1%	27.0%	33.5%	19.3%	13.8%	-2.8%	-11.6%	-12.1%					
Operating profit	77	-610	-1,215	-1,932	-1,022	-2,149	-3,169	-4,378	-1,004					-2,305
YoY	-	-	-	-	-	-	-	-	-					-
OPM	-	-	-	-	-	-	-	-	-					-
Recurring profit	-320	-1,228	-1,813	-2,166	-1,099	-2,282	-3,165	-3,948	-836					-2,034
YoY	-	-	-	-	-	-	-	-	-					-
RPM	-	-	-	-	-	-	-	-	-					-
Net income	-277	-1,145	-1,692	-1,835	-1,097	-2,276	-3,159	-3,940	-838					-2,052
YoY	-	-	-	-	-	-	-	-	-					-
Net margin	-	-	-	-	-	-	-	-	-					-

Quarterly (JPYmn)	FY01/17				FY01/18				FY01/19				FY01/19	
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	% of FY	FY Est.
Operating revenue	626	59	74	192	124	126	121	119	158				15.5%	1,025
YoY	119.7%	-53.6%	-89.3%	154.8%	-80.2%	114.6%	64.7%	-37.8%	27.9%					109.0%
SG&A expenses	548	746	678	909	1,146	1,253	1,142	1,328	1,163				25.5%	4,566
YoY	49.7%	24.3%	-3.0%	43.4%	108.9%	67.9%	68.4%	46.1%	1.5%					-6.2%
Operating expenses / Operating revenue	87.7%	1,270.7%	920.4%	474.6%	924.9%	994.3%	940.6%	1,114.2%	733.8%					
Cost of revenue	-	-	-	17	-	-	-	0	-					
YoY	-	-	-	-	-	-	-	-	-					
R&D expenses	367	578	471	642	929	1,072	999	1,156	972				24.7%	3,943
YoY	78.2%	20.6%	-13.1%	37.2%	153.2%	85.4%	111.8%	80.1%	4.7%					-5.1%
Other operating expenses	181	168	207	250	216	182	143	172	190				30.5%	623
YoY	13.2%	38.6%	32.3%	50.4%	19.3%	7.8%	-30.8%	-31.2%	-12.1%					-12.6%
Operating profit	77	-688	-604	-717	-1,022	-1,127	-1,020	-1,209	-1,004					-3,540
YoY	-	-	-	-	-	-	-	-	-					-
OPM	-	-	-	-	-	-	-	-	-					-
Recurring profit	-320	-908	-585	-353	-1,099	-1,184	-883	-783	-836					-2,529
YoY	-	-	-	-	-	-	-	-	-					-
RPM	-	-	-	-	-	-	-	-	-					-
Net income	-277	-868	-546	-144	-1,097	-1,179	-883	-781	-838					-2,564
YoY	-	-	-	-	-	-	-	-	-					-
Net margin	-	-	-	-	-	-	-	-	-					-

Balance sheet (JPYmn)	FY01/17				FY01/18				FY01/19				
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	
Current assets	7,587	6,623	6,713	6,125	6,251	5,250	4,762	5,077	7,897				
Cash and cash equivalents	7,116	6,219	6,262	5,561	5,547	4,671	4,369	4,655	7,227				
Others	471	404	451	563	704	579	393	422	670				
Noncurrent assets	73	88	113	168	150	137	133	117	110				
Tangible fixed assets	62	76	99	148	132	119	116	101	95				
Investments and other assets	11	12	13	19	18	18	17	16	15				
Total assets	7,660	6,711	6,826	6,292	6,400	5,387	4,896	5,194	8,008				
Current liabilities	1,121	995	807	547	562	709	1,203	2,107	1,804				
Short-term debt	700	500	333	150	67	67	67	67	67				
Other current liabilities	421	495	474	397	495	643	1,136	2,040	1,737				
Noncurrent liabilities	426	380	1,207	1,150	2,283	2,267	2,250	2,233	2,717				
Long-term debt	300	300	1,167	1,150	2,283	2,267	2,250	2,233	2,717				
Others	126	80	40	-	-	-	-	-	-				
Net assets	6,114	5,337	4,812	4,595	3,555	2,411	1,443	853	3,487				
Capital stock	3,813	3,843	3,851	3,852	3,862	3,864	3,869	3,875	5,593				
Capital surplus	7,525	7,555	7,562	7,563	7,574	7,575	7,580	7,587	9,304				
Retained earnings	-5,256	-6,124	-6,671	-6,814	-7,912	-9,090	-9,973	-10,755	-11,592				
Other net assets	32	63	70	-6	31	62	-33	146	181				
Total capital and liabilities	7,660	6,711	6,826	6,292	6,400	5,387	4,896	5,194	8,008				

Source: Shared Research based on company data

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

Q1 FY01/19 results (out June 13, 2018)

▷ Operating revenue	JPY158mn (+27.9% YoY)
▷ Operating loss	JPY1.0bn (JPY1.0bn loss in Q1 FY01/18)
▷ Recurring loss	JPY836mn (JPY1.1bn loss)
▷ Net loss*	JPY838mn (JPY1.1bn loss)

*Net loss refers to net loss attributable to parent company shareholders

Comparison with company target

Consolidated operating revenue for Q1 FY01/19 reached 50.0% of the company's 1H FY01/19 forecast. The company posted an operating loss of JPY1.0bn (against a 1H forecast of a JPY2.3bn loss), recurring loss of JPY836mn (JPY2.0bn loss), and net loss of JPY838mn (JPY2.1bn loss). The progress rate of Q1 consolidated operating revenue versus the full-year forecast was 15.5%.

Operating revenue

Operating revenue for Q1 FY01/19 was JPY158mn, which included development support fees related to phase 2b clinical trial of SB623 for the treatment of chronic motor deficit from ischemic stroke in the US, based on a license agreement with Sumitomo Dainippon Pharma for SB623 in the US and Canada.

Operating expenses

Operating expenses were JPY1.2bn (+JPY17mn YoY), with the R&D expenses accounting for JPY972mn (+JPY43mn) of the total. R&D expenses were mainly expenditures on clinical trials in the US for the two SB623 development programs targeting chronic motor deficit from ischemic stroke and traumatic brain injury.

Recurring loss

Q1 recurring loss narrowed from a loss of JPY1.1bn in the same quarter the previous year to JPY836mn. The company booked JPY135mn in non-operating revenue from receiving a grant from California Institute for Regenerative Medicine (CIRM) and merited from a JPY47mn forex gain (forex loss of JPY65mn in Q1 FY01/18).

Development status of regenerative cell medicine SB623 (as of March 2017)

Chronic motor deficit from ischemic stroke

The company completed patient enrollment for its US-based phase 2b clinical trial and is undergoing a 12-month follow-up observation period. It plans to publish topline results in 1H FY01/20. When the enrollment was at 50% and 75%, the clinical trial plan passed an inspection of the External Safety Data Monitoring Committee for continuation. The company had concluded a licensing agreement with Teijin Limited (TSE1: 3401) in 2009 for the development program in Japan, but the two companies agreed to terminate the agreement on February 14, 2018. As a result, the right to advance the program in Japan was returned to SanBio, which will develop SB623 targeting chronic motor deficit from ischemic stroke independently.

Chronic motor deficit from traumatic brain injury (TBI)

SanBio has also been conducting a phase 2 global clinical trial in Japan and the US for the use of SB623 to treat chronic motor deficit resulting from TBI (for a total of 52 patients in a double-blind method). Patient enrollment started in July 2016 in the US and in October 2016 in Japan, and was completed in April 2018 with a final patient count of 61 (versus the initial target of 52). After a six-month follow-up observation period, the company aims to apply for manufacture and marketing approval for SB623 (the first of the company's SB623 programs) through the use of Japan's conditional and time-limited approval system for regenerative medicine products. Specifically, it plans to publish results in FY01/19 and apply for approval in FY01/20. The program targeting chronic motor deficit from TBI started from phase 2 as the US Food and Drug Administration (FDA) and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan gave a nod to skip a phase 1 trial, based on the results of phase 1/2a clinical trial in the US targeting chronic motor deficit from ischemic stroke. The clinical trial plan also passed an inspection of the External Safety Data Monitoring Committee for continuation when enrollment was at 50%, 75%, and 100%. Following the completion of phase 2 clinical trial, the company aims to commercialize SB623 in Japan, earlier than in any other market, using

the conditional and time-limited marketing approval system for regenerative medicine products under the Revised Pharmaceutical Affairs Act of Japan.

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