

Development of cardiomyocyte sheets derived from human iPS cells

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[4894 Cuorips Sector : Pharmaceutical]

Fiscal Year	Net sales (mn yen)	YoY (%)	Operating profit (mn yen)	YoY (%)	Ordinary profit (mn yen)	YoY (%)	Profit (mn yen)	YoY (%)	EPS (yen)	BPS (yen)	DPS (yen)
Mar.2022	13	-	-373	-	-373	-	-375	-	-66.6	686.2	0.0
Mar.2023	38	2.9x	-450	-	-450	-	-452	-	-79.9	607.2	0.0
Mar.2024 f	215	5.7x	-1,210	-	-1,246	-	-1,249	-	-174.5	-	0.0

Note: Non-consolidated basis. Figures for the fiscal year ending March 2024 are the company's forecasts.

Development of Cardiomyocyte Sheets Derived from Human iPS Cells

Cuorips is a bio-venture company that was established by members centering on Yoshiki Sawa, who currently serves as the company's Director and Chief Technology Officer (CTO). Yoshiki Sawa is also a professor of the Graduate School of Medicine, Osaka University, and is known for his expertise in heart transplantation surgery and related fields. The company was established to commercialize cardiomyocyte sheets derived from human iPS cells to treat severe heart failure. Cuorips is also contracted to develop and manufacture regenerative medical products by leveraging CLiC-1, a laboratory-integrated cell culture and processing facility.

Cardiomyocyte Cell Sheet Made from Allogenic Cells

To make the cardiomyocyte sheet, the company induces the differentiation of allogenic iPS cells into cardiomyocytes. The iPS cells are provided by Kyoto University's Center for iPS Cell Research and Application. The company then conducts a purification process to remove cancer-causing undifferentiated iPS cells and then transplants them into the patient's heart in the form of a sheet.

From January 2020 to March 2023, the company conducted a clinical trial on eight patients with ischemic heart disease and completed the trial as originally planned. Cuorips is currently conducting follow-up examinations of the transplant procedure and is analyzing the data to confirm efficacy and safety. The company expects to apply for and obtain manufacturing and marketing approval under the early approval system for regenerative medical products.

Advancing Development of Subsequent Pipeline

Subsequent pipelines for the company include: 1) addition of efficacy for diastolic heart disease for cardiomyocyte sheets, 2) manufacturing and marketing approval in the U.S. and Europe for cardiomyocyte sheets for use in treating ischemic heart disease, 3) development of technology for transplanting human iPS-derived cells into the heart for acute myocardial infarction and other conditions by combining it with catheter technology developed by Asahi Intecc and 4) drug repositioning of oxime derivatives developed by Ono Pharmaceutical to promote angiogenesis and tissue regeneration for liver, kidney and lung diseases. The company is expected to ramp up R&D investment in these subsequent pipelines considerably going forward.

Financial Statements

Statement of income	Fiscal Year	Mar.2021		Mar.2022		Mar.2023	
		(mn yen)	(%)	(mn yen)	(%)	(mn yen)	(%)
Net sales		0	-	13	100.0	38	100.0
Cost of sales		0	-	3	23.1	17	44.7
Gross profit		0	-	10	76.9	21	55.3
Selling, general and administrative expenses		281	-	383	29.5x	471	12.4x
Operating profit		-281	-	-373	-	-450	-
Non-operating income		0	-	0	-	0	-
Non-operating expenses		-	-	-	-	0	-
Ordinary profit		-295	-	-373	-	-450	-
Profit before income taxes		-295	-	-373	-	-449	-
Net profit		-307	-	-375	-	-452	-

Balance sheet	Fiscal Year	Mar.2021		Mar.2022		Mar.2023	
		(mn yen)	(%)	(mn yen)	(%)	(mn yen)	(%)
Current assets		3,618	82.9	3,367	83.3	2,977	83.0
Cash and deposits		3,542	81.2	3,341	82.6	2,941	82.0
Accounts receivable-trade		-	-	1	0.0	2	0.1
Inventories		0	0.0	0	0.0	4	0.1
Non-current assets		745	17.1	677	16.7	610	17.0
Property, plant and equipment		701	16.1	633	15.7	562	15.7
Intangible assets		-	-	-	-	5	0.1
Investments and other assets		44	1.0	43	1.1	42	1.2
Total assets		4,364	100.0	4,044	100.0	3,587	100.0
Current liabilities		104	2.4	112	2.8	97	2.7
Accounts payable - trade		-	-	-	-	-	-
Non-current liabilities		37	0.8	36	0.9	36	1.0
Net assets		4,222	96.7	3,895	96.3	3,453	96.3
Owners' equity		4,222	96.7	3,879	95.9	3,437	95.8

Statement of cash flows	Fiscal Year	Mar.2021	Mar.2022	Mar.2023
		(mn yen)	(mn yen)	(mn yen)
Cash flows from operating activities		-282	-220	-401
Depreciation		73	92	78
Cash flows from investing activities		-670	-28	-8
Cash flows from financing activities		3,766	48	10
Dividends paid		-	-	-
Net increase in cash and cash equivalents		2,813	-200	-399
Cash and cash equivalents		3,542	3,341	2,941

Note: Non-consolidated

Source: Prepared by Stock Research Center based on the notifiable prospectus.

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