1st Quarter Consolidated Financial Results for the FY 2025

August 13th 2024

Listed Company Name: Cuorips Inc. — Listed exchanges: Tokyo Stock Exchange
Code: 4894 URL http://cuorips.co.jp
Representative Title: CEO Takayuki Kusanagi
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Scheduled date of dividend payment: _
Preparation of supplementary materials for financial results: Scheduled to be shared via company website
Financial results meeting: Online presentation to be accessible via company website

(Million yen)

1. 1Q Consolidated financial results for FY ending March 31, 2025 (April 1, 2024 - June 30, 2024)

(1) Consolidated operating results (%, yoy)

	Net sales		Operating income		Recurring income		Quarterly net income to shareholders	
	Mil. yen	%	Mil. yen	%	Mil. yen	%	Mil. yen	%
1st Qtr FY 2025	0	—	△195	—	△191	—	△192	—
1st Qtr FY 2025	—	—	—	—	—	—	—	—

(Note) Comprehensive income: FY ending March 2025, 1Q △192 Mil. yen (—%); FY ending March 2024, Q1 — Mil. yen (—%)

	Quarterly earnings per share	Fully diluted earnings per share
	Yen	Yen
FY ending March 2025, 1Q	△24.20	—
FY ending March 2024, 1Q	—	—

(Notes)
1. Consolidated financial statement were first prepared from 3rd Qtr of FY 2024. Therefore, percentage changes for YOY figures are not shown in the above table.
2. Fully diluted earnings per share is not calculated since earnings are negative.

(2) Consolidated Financial Position

	Total assets	Net assets	Shareholders' equity/total assets
	Mil. yen	Mil. yen	%
FY ending March 2025, 1Q	6,010	5,823	96.7
FY ending March 2024, 1Q	6,184	5,983	96.6

(Reference) Shareholders' equity: 1sr Qtr FY 2025 5,812 Mil. yen; 1st Qtr FY2024 5,974 Mil. yen

2. Dividends

	Annual Dividend				
	End of 1st quarter	End of 2nd quarter	End of 3rd quarter	End of term	Total
	Yen	Yen	Yen	Yen	Yen
FY ending March 2024	—	00.00	—	00.00	00.00
FY ending March 2025	—				
FY ending March 2025 (expected)		00.00	—	00.00	00.00

(Note) Corrections from latest dividend projections: None

3. Forecast of consolidated financial results for the fiscal year ending March 31, 2025 (April 1, 2024 - March 31, 2025)

(%, yoy)

	Net sales		Operating income		Recurring income		Net income to shareholders		Net income per share
	Mil. yen	%	Mil. yen	%	Mil. yen	%	Mil. yen	%	Yen
Full business year	20	△15.6	△1,203	—	△1,202	—	△1,206	—	△151.65

(Note) Corrections from latest forecast of financial results: None

※ Notes

(1) Changes in consolidation of its subsidiaries: None

(2) Changes in accounting policies, changes in accounting estimates, and financial statements

(i) Changes in accounting policies due to revisions of accounting standards: None

(ii) Changes in accounting policies due to other reasons: None

(iii) Changes in accounting estimates: None

(iv) Changes in financial statements: None

(3) Number of shares outstanding (common stock)

① Number of shares outstanding at the end of the period (including treasury stock)	FY ending March 2025, 1Q	7,998,116 shares	FY ending March 2024, 1Q	7,968,116 shares
② Number of treasury stock at end of period	FY ending March 2025, 1Q	15,756 shares	FY ending March 2024, 1Q	15,756 shares
③ Average number of shares outstanding during the period	FY ending March 2025, 1Q	7,61,261 shares	FY ending March 2024, 1Q	5,882,183 shares

※ The above financial results are not subject to audit by a certified public accountant or auditing firm.

※ Explanation of appropriate use of earnings forecasts and other special notes

(Caution regarding forward-looking statements, etc.)

The forward-looking statements in this document, including earnings forecasts, are based on information currently available to the Company and certain assumptions that the Company considers reasonable, and are not intended as a guarantee that they will be achieved. Actual results may differ significantly due to various factors. Please refer to "1. Business Results, (4) Outlook for the Future" on page 4 for the assumptions used in forecasting business results and precautions regarding the use of business results forecasts.

(About financial results meeting)

In lieu of a financial results meeting, the Company plans to hold an online financial results presentation on August 15, 2024, accessible through the Company's website. Presentation materials for the financial results will be posted on the Company's website.

(About supplementary materials from financial results meeting)

Supplementary materials from the financial results meeting will be posted on the Company's website on August 15th, 2024.

-Supplementary Materials-

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1. Overview of Our Business Results, etc.

Forward-looking statements in the text are based on judgments made as of the end of the first quarter of the current consolidated fiscal year. Since the Company did not prepare quarterly consolidated financial statements for the first quarter of the previous fiscal year, no comparative analysis with the same period of the previous year has been made.

(1) Summary of operating results for the quarter

During the first quarter of the consolidated fiscal year under review, the Japanese economy saw substantial wage increases due to the spring labor offensive and normalization of monetary policies by the Bank of Japan. However, the business environment surrounding the Group remained uncertain, due in part to the ongoing depreciation of the yen and price hikes resulting from Bank of Japan's monetary policies that differ from those of Western countries.

PJ1: Human iPSC derived cardiomyocyte sheet (Target indication: ischemic heart disease patients within Japan)

We have been supporting an investigator-initiated clinical trial being conducted by the Osaka University to obtain manufacturing and marketing approval for human iPS cell-derived cardiomyocyte sheets for the indication of severe heart failure due to ischemic heart disease ("ICM"). In this investigator-initiated clinical trial, transplantation was performed on the first subject in January 2020, and transplantation on the planned eight subjects was completed in March 2023.

During the first quarter of the current fiscal year, all board members and employees worked together in the approval application process. In preparing materials for the approval application, we are taking measures to incorporate long-term data into the approval application materials to increase the likelihood of appropriate evaluation and approval based on the condition of patients with severe heart failure, which is the target of this investigator-initiated clinical trial. We aim to submit application for approval by the end of this year at the latest.

PJ2: Human iPSC-derived cardiomyocyte sheet (Target indication: dilated cardiomyopathy patients within Japan)

Osaka University is conducting research and development to add dilated cardiomyopathy (DCM) to therapeutic targets for human iPSC derived cardiomyocyte cell sheets. The research and development of DCM has been adopted by the Japan Agency for Medical Research and Development (AMED) as a "Practical Application Research Project for Regenerative Medicine" in FY2023 (publicly solicited project: "Clinical trial using human (allogeneic) iPSC derived cardiomyocyte cell sheets for dilated cardiomyopathy"). As an affiliated organization, we have been subcontracted by Osaka University to conduct a portion of the research and development, and are supporting the clinical trials being conducted by Osaka University.

In the first quarter of the current fiscal year, Osaka University initiated an investigator-initiated clinical trial for DCM. We produced and provided human iPSC cardiomyocyte sheets to be transplanted into the first subject to Osaka University.

PJ3: Human iPSC-derived cardiomyocyte sheet (Target: ischemic caardiomyopathy overseas)

The Company plans to obtain manufacturing and marketing approval for human iPSC derived cardiomyocyte sheets not only in Japan but also overseas.

During the first quarter of the current fiscal year, we held discussions with an American research entity on the research and development plan for commercialization in the United States. In addition, iReheart, Inc. was established as our U.S. subsidiary in the Japan Innovation Campus, a business base established by the Ministry of Economy, Trade and Industry in Palo Alto, California. There, we aim to strengthen local activities such as R&D and commercialization of our products in the U.S. and search for future partners.

PJ4: Catheter

We are developing a treatment to transplant human iPSC-derived cardiomyocytes into the heart

through a new intravascular approach using catheters as a pipeline for treating mild cardiac diseases, in collaboration with Asahi Intecc Corporation (Head office: Seto City, Aichi Prefecture). We aim to create a new method of treatment by combining Asahi Intecc's catheter product development technology with our human iPSC-derived cardiomyocytes.

This product is intended to be used by cardiologists in combination with percutaneous coronary intervention (PCI) (*1) for acute myocardial infarction (AMI) (*2) and chronic total occlusive (CTO) (*3) to develop a treatment product to enhance recovery of cardiac function with minimum intervention on patients.

During the first quarter of the current fiscal year, large animal experiments were conducted in the joint research and development with Asahi Intecc Co.

(※1) Percutaneous Coronary Intervention (PCI): A treatment for ischemic heart disease in which a catheter is used to dilate the narrowed portion of the coronary artery lumen.
(※2) Acute Myocardial Infarction (AMI): A disease in which the blood vessels of the heart become clogged and blood flow stops, resulting in inadequate oxygen and nutritional supply to the myocardium leading to necrosis of the myocardium. The condition can be fatal.
(※3) Chronic Total Occlusion (CTO): A condition in which the coronary arteries of the heart are completely blocked for more than three months, stopping blood flow.

PJ5: Body Regenerative Factors

Low-dose use of an oxime derivative (YS-1301) induces regenerative factors (HGF, VEGF, SDF-1, HMGB1, etc.) in the body. Expected results include angiogenesis, tissue regeneration through cytoprotection, antifibrosis, and anti-inflammatory effects. The Company is conducting research and development for the treatment of cirrhosis and non-alcoholic steatohepatitis (NASH) (*4), arteriosclerosis obliterans (ASO) (*5), chronic kidney disease (CKD) (*6), chronic obstructive pulmonary disease (COPD) (*7) and other diseases. The Company has completed the transfer of various patents, know-how, etc. from Ono Pharmaceutical Co., LTD and Cardio Inc. and is proceeding with verification of the drug efficacy mechanism and development of drug formulations for the target diseases.

During the first quarter of the current fiscal year, the Company continued joint research with Osaka University on liver cirrhosis and hepatectomy.

(※4) Non-alcoholic steatohepatitis (NASH) : A form of nonalcoholic fatty liver disease。It is associated with fatty degeneration, inflammation, and hepatocellular damage. If the disease progresses, it can lead to cirrhosis and liver cancer
(※5) Arteriosclerosis obliterans (ASO) : A disease in which blood flow deteriorates as a result of progressive hardening, narrowing, and blockage of the arteries in the limbs. The supply of oxygen and nutrients to the limbs becomes insufficient, resulting in symptoms such as coldness, numbness, intermittent claudication (pain in the legs while walking), pain, ulcers, and gangrene. Progression of symptoms may result in amputation of the limb.
(※6) Chronic kidney disease (CKD) : A condition in which kidneys are unable to adequately filter out waste products due to reduced function. If the disease progresses, regular dialysis or kidney transplantation may be necessary.
(※7) Chronic obstructive pulmonary disease (COPD) : A disease caused by long-term inhalation of tobacco or other toxic substances. It is accompanied by the following symptoms: (1) inflammation of the bronchial tubes causing coughing and sputum production, and reduction of airflow due to narrowing of the bronchial tubes; (2) damage to alveoli at the back of the bronchioles, reducing intake of oxygen and carbon dioxide exchange.

PJ6: Culture Supernatant

In December 2023, we established Cuorips Healthcare Science Corporation as a consolidated subsidiary to make effective use of cell culture supernatant fluid after cell cultivation and to obtain stable earnings.

After cell culture, the culture medium contains various growth factors (cytokines, etc.) and

extracellular vesicles (exosomes, etc.) called secretomes, which are expected to have various positive effects.

In terms of quality and safety, our cell culture and processing facility (CLiC-1) has obtained a "License for the Manufacture of Specified Cell Processed Products" (facility number: FA5210001) based on Article 35, Paragraph 1 of the Law for Ensuring the Safety of Regenerative Medicine, etc., and we have established a stable production system that thoroughly controls the risk of microbial contamination through sanitary management using local clean technology. A stable production system has been established to thoroughly control the risk of microbial contamination through hygienic management using local cleanliness technology. The human iPS cell-derived cardiomyocyte sheets manufactured in CLiC-1 have already been administered to humans through an investigator-initiated clinical trial being conducted by Osaka University, and no safety concerns have been identified at this point. We believe that secretome purification conducted under the same environment and inspection system will be able to ensure high quality and safety.

In the first quarter of the current fiscal year, the Company developed products to be provided to clinics and cosmetics companies, and held periodical product development meetings with our prospective partners.

In addition to the PJs 1-6 detailed above, the Consortium for Cell Mass Production Value Chain Development was launched in Nakanoshima Qross, the International Center for Future Medicine recently opened in Kita-ku, Osaka City, Osaka Prefecture. Technologies using human and animal cells are advancing globally in many fields, beyond that of regenerative medicine and pharmaceuticals. There is a need to bring together the technologies and expertise of various companies in the development of manufacturing equipment and systems, devices, raw materials, and other applications. The Group also needs to further expand its manufacturing capacity and advance its production and manufacturing technologies with a view to expanding its business not only in Japan but also on a global scale and expanding its culture supernatant business. The Consortium for Cell Mass Production Value Chain Development meets those needs by promoting the development of next-generation modalities.

Our group will participate in this consortium with our manufacturing and quality control technologies for iPSC-derived regenerative medical products and our unique cell culture and processing facility design technologies to realize mass production, and will jointly develop with the participating companies a platform system that integrates the processes of "culture - collection - filling/dispensing - freezing - storage" that constitute the mass production of cells. We will lead the world in the development of a platform system that integrates the "culture, collection, filling, dispensing, freezing, and storage" processes that comprise the mass production of cells, and the applications used in this system. The results of the Consortium's activities will not only be introduced into the Company's businesses, but will also be used domestically and internationally as a packaged system created in cooperation with each party. In addition, the Consortium is intended to be an innovation center to promote the use of the Consortium's results in each company's own business, and will promote development with companies that possess various technologies and know-how, with the policy of not allowing exclusive development or monopoly of results of the Consortium's activities by the any party including the Company.

As for net sales, the Company recorded sales related to contract manufacturing and development services (CDMO services). In the first quarter of the current consolidated cumulative period, the Company worked on projects for which sales will be recorded in the second quarter of the consolidated accounting period and thereafter.

As a result, the Company reported net sales of 186 thousand yen, operating loss of 195,314 thousand yen, recurring loss of 191,969 thousand yen, and net loss attributable to parent company stockholder of 192,712 thousand yen for the first quarter of the current fiscal year.

Research and development expenses (total amount) incurred in the first quarter under review were 212,883 thousand yen. However, the Company received joint research and development expenses (hereinafter referred to as "joint research and development expenses received") from joint research and development partners, and the amount of 86,888 thousand yen, less the amount of joint research and development expenses received, was recorded as research and development expenses in selling, general, and administrative expenses.

As the Group has only one segment, the regenerative medicine business, segment information is

omitted.

(2) Summary of financial position for the quarter

(Assets)

Current assets at the end of the first quarter of the current fiscal year decreased 235,921 thousand yen from the end of the previous fiscal year to 5,376,216 thousand yen. This was mainly due to a decrease of 470,322 thousand yen in cash and deposits resulting from expenditures for research and development and business operation expenses and an increase in working capital, while securities (foreign currency denominated MMF) increased by 93,768 thousand yen. Fixed assets increased 61,255 thousand yen to 633,856 thousand yen. This was mainly due to a 31,189 thousand yen increase in tangible fixed assets resulting from the acquisition of machinery and equipment, and a 30,131 thousand yen increase in investments and other assets.

As a result, total assets decreased 174,665 thousand yen to 6,010,072 thousand yen.

(Liabilities)

Current liabilities at the end of the first quarter of the current fiscal year decreased 14,389 thousand yen from the end of the previous fiscal year to 151,626 thousand yen. This was mainly due to a decrease of 34,499 thousand yen in income taxes payable resulting from the payment of pro forma standard taxation. Noncurrent liabilities decreased 126 thousand yen to 34,818 thousand yen.

As a result, total liabilities decreased 14,515 thousand yen to 186,445 thousand yen.

(Net assets)

The balance of net assets at the end of the first quarter of the current consolidated fiscal year was 5,823,627 thousand yen, a decrease of 160,150 thousand yen from the end of the previous consolidated fiscal year. This was mainly due to the net loss attributable to parent company shareholders for the quarter.

(3) Explanation of Consolidated Financial Forecasts and Other Forward-Looking Statements

There is no change to the consolidated earnings forecast for the full year announced in the “Summary of Financial Results for the Year Ended March 31, 2024” on May 13, 2024.

2. Consolidated financial statements and footnotes

(1) Consolidated balance sheets

(Unit : thousand yen)

	Previous consolidated fiscal year (ending March 31, 2024)	1Q Linked Cumulative Period (ending June 30, 2024)
Assets		
Current Assets		
Cash on Hand	5,561,008	5,090,685
Accounts Receivable	55	94
Marketable Securities	21,262	115,030
Inventories	1,043	13,257
Other	28,768	157,147
Total Current Assets	5,612,137	5,376,216
Fixed assets		
Property, Plant, and Equipment	514,104	545,293
Intangible Fixed Assets	17,079	17,014
Investments and Other Assets	41,417	71,548
Total Fixed Assets	572,600	633,856
Total assets	6,184,738	6,010,072
Liabilities		
Current Liabilities		
Account Payable	—	11,860
Accrued Income Taxes	46,097	11,598
Accrued Expense	91,670	111,196
Deposits (received)	28,246	16,970
Total Current Liabilities	166,015	151,626
Fixed liabilities		
Asset Disposal Liabilities	28,437	28,456
Deferred Tax Liabilities	6,507	6,362
Total Long-term Liabilities	34,945	34,818
Total Liabilities	200,960	186,445
Total Net Assets		
Shareholders' Equity		
Capital Stock	1,594,960	1,610,365
Capital Surplus	6,493,705	6,509,196
Retained Earnings	△2,102,138	△2,294,851
Treasury Stock	△12,016	△12,016
Total shareholder's equity	5,974,510	5,812,694
Outstanding Stock Options	7,766	7,686
Minority Interest	1,500	3,246
Total Net Assets	5,983,777	5,823,627
Total Liabilities and Net Assets	6,184,738	6,010,072

(2) Consolidated Statements of Income and Consolidated Statements of Comprehensive Income

Consolidated Statements of Income for 1Q Linked Cumulative Period

(Unit : thousand yen)

	1Q Linked Cumulative Period (April 1, 2024 ～June 30, 2024)
Quarterly sales	186
Cost of sales	11
Gross profit	174
Selling, General, and Administrative Expenses	※ 195,489
Operating Loss (△)	△195,314
Non-operating Income	
Interest Income	2
Gains on Investment in Securities	3,870
Other	28
Total Non-operating Income	3,901
Non-operating Expenses	
Foreign Exchange Loss	395
Other	160
Total Non-operating Expenses	555
Recurring Loss (△)	△191,969
Loss before Income Taxes and Minority Interests (△)	△191,969
Corporate taxes, etc.	911
Quarterly Loss (△)	△192,880
Quarterly Loss attributed to Non-controlling Interests (△)	△167
Quarterly Loss attributed to Parent Company Shareholders (△)	△192,712

Consolidated Statements of Comprehensive Income for 1Q Linked Cumulative Period

(Unit: thousand yen)

	1st Qtr Cumulative Period (April 1, 2024 ～June 30, 2024)
Quarterly Loss (△)	△192,880
Quarterly Comprehensive Income	△192,880
(Breakdown)	
Comprehensive Income attributable to Parent Company Shareholders	△192,712
Comprehensive Income attributable to Noncontrolling Interests	△167

(3) Notes on 1sr Qtr Cumulative Period

(Notes on Segment Information)

This information is omitted because the Group has a single business segment, regenerative medical products.

(Notes on significant changes in shareholders' equity)

Not applicable.

(Notes on Going Concern Assumption)

Not applicable.

(Notes to Quarterly Consolidated Statements of Cash Flows)

No quarterly consolidated cash flow statement has been prepared for the first quarter of the current consolidated cumulative period. Depreciation and amortization expenses for the first quarter of the current fiscal year are as follows.

	1st Qtr Cumulative Period (April 1, 2024 ～June 30, 2024)
Depreciation and amortization expenses	17,803 thousand yen

(Notes on 1st Qtr Cumulative Period)

※ Total research and development expenses are included in selling, general and administrative expenses

The Group conducts joint research and development with pharmaceutical and medical device manufacturers and research institutions such as universities.

Research and development expenses included in selling, general and administrative expenses in the quarterly consolidated statements of income are calculated by subtracting the amount of joint research and development expenses received from joint research and development partners from the (total) research and development expenses, and recording only the amount incurred by the Group.

Research and development expenses incurred by the Group (total amount), joint research and development expenses received from joint research and development partners, and research and development expenses recorded in selling, general and administrative expenses in the quarterly consolidated statements of income are as follows.

	1Q Linked Cumulative Period (April 1, 2024 ～June 30, 2024)
Research and development expenses (total)	212,883 thousand yen
Joint research and development expenses received	△125,995
Research and development costs	86,888