

#### 再生医療をあたりまえの医療に

Creating a Future for Regenerative Medicine

# Financial Report for the Fiscal Year Ending March 2025

Japan Tissue Engineering Corporation

April 30, 2025





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#### (Terminology)

JACE	Autologous cultured epidermis manufactured by harvesting the patient's skin tissue, isolating cells, and culturing them. (Regenerative Medical Product)
JACEMIN	Autologous cultured epidermis manufactured by collecting a patient's skin tissue, isolating the cells, and culturing both keratinocytes and melanocytes

JACC (Regenerative Medical Product)

Autologous Cultured Cartilage manufactured by harvesting the patient's cartilage tissue, isolating cells, and culturing them (Regenerative Medical Product)

OA Osteoarthritis

NEPIC

Autologous cultured corneal epithelium manufactured by harvesting the patient's limbal tissue, isolating cells, and culturing them (Regenerative in Product)

Autologous cultured oral mucosal epithelium manufactured by harvesting the patient's oral mucosal tissue, isolating cells, and culturing them

(Regenerative Medical Product)

Autologous cultured corneal epithelium manufactured by harvesting the patient's limbal tissue, isolating cells, and culturing them (Regenerative Medical

LabCyte Cultured human tissue for research use that serves as an alternative to various tests, such as skin irritation tests that use animals



1. Business Performance and Topics for FY March 2025



#### **Key Points for the Fiscal Year Ending March 2025**

#### 4Q Results (January-March)

✓ In Q4, profits increased significantly compared to the previous quarter, driven by a rise in severe burn cases requiring JACE treatment, the commencement of JACEMIN product sales, and higher entrusted revenue from Teijin.



#### **Cumulative Results**

- ✓ Operating loss was 238 million yen, mainly due to delays in revenue recognition from Teijin and a reduction in subsidies. However, a recovery is expected in the current fiscal period.
- ✓ In relation to the recent downward revision of earnings forecasts, sales of JACC, NEPIC, and OCURAL fell short of expectations, resulting in under performance (operating loss revised from 200 million yen to 238 million yen)





**Net Sales** 



#### **Results for FY March 2025**

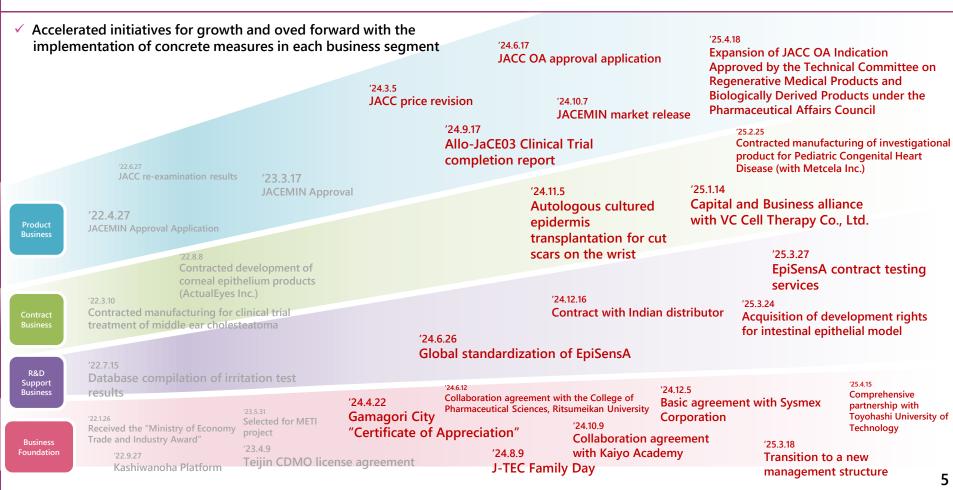
For the fiscal year ended March 2025, net sales totaled 2.455 billion yen (a 2.3% decrease Y-on-Y), and the operating loss amounted to 238 million yen.

Units: millions of yen	FY March 2024	FY March 2025			
(rounded down to nearest million yen)		Year-on-Year Fo		Forecast	
(increase/decrease is calculated in yen)	Results	Results	Change (amount)	Change (percentage)	(As of 2025.1.31)
Total Net Sales	2,514	2,455	(58)	(2.3%)	2,500
Regenerative Medical Products Business	1,406	1,493	86	6.2%	1,560
Skin Line(JACE, JACEMIN)	911	985	74	8.1%	950
Cartilage Line (JACC)	321	382	61	19.1%	452
Ophthalmology Line (NEPIC, OCURAL)	173	125	(48)	(28.0%)	158
Regenerative Medicine Contract	865	713	(151)	(17.5%)	695
Business	003	/ 13	(151)	(17.5%)	093
Non-Teijin Clients	395	348	(47)	(11.8%)	-
Teijin	469	364	(104)	(22.3%)	-
R&D Support Business	242	248	6	2.6%	245
Gross Profit	1,690	1,511	(179)	(10.6%)	-
SG&A Expenses	1,546	1,749	203	13.2%	-
Operating Loss	144	(238)	(382)	-	(200)
Ordinary Loss	147	(234)	(381)	-	(202)
Net Loss	143	(255)	(398)	-	(223)

<sup>\*</sup> Milestone revenue from Teijin: 170 million yen in the previous cumulative period (FY ended March 2024) 100 million yen in the current cumulative period (FY ending March 2025)

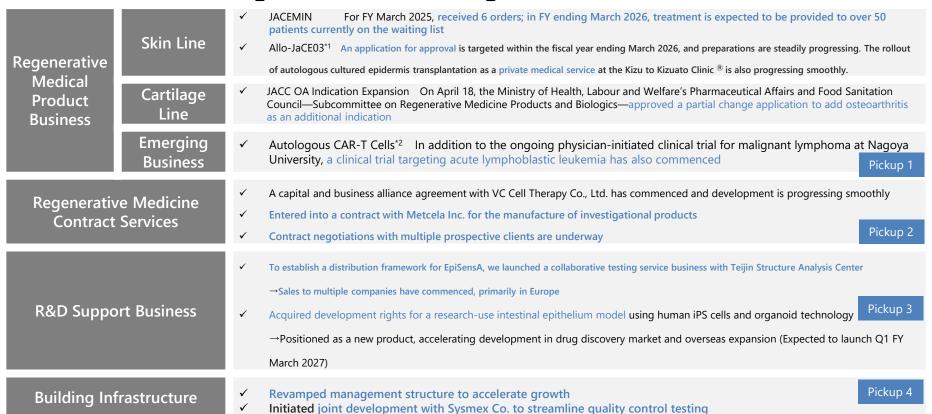
1. Business Performance and Topics for FY March 2025

#### Review of the Fiscal Year Ended March 2025





#### **Progress Status of Strategic Growth Initiatives**

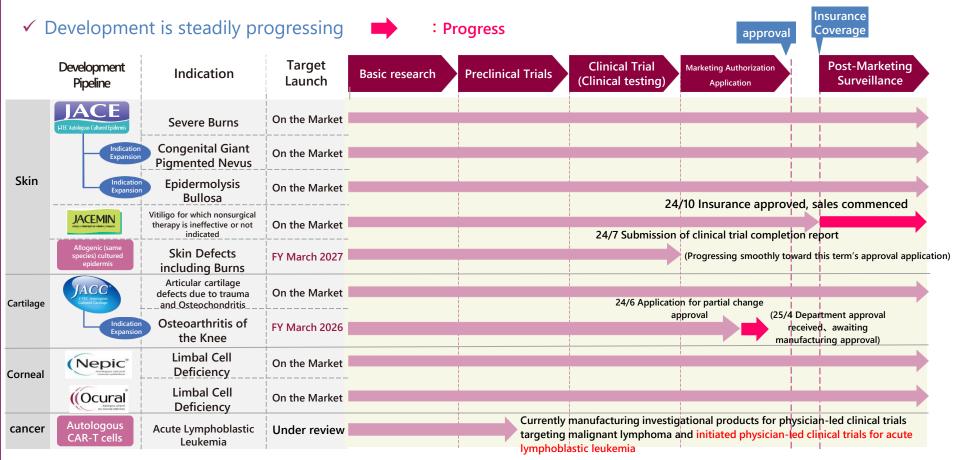


<sup>\*1</sup> An allogenic (same species) cultured epidermis under development, Japan's first off-the-shelf product using another person's skin tissue as raw material.

<sup>\*2</sup> We concluded a patent license agreement with Nagoya University and Shinshu University to develop a low-cost, autologous CAR-T cell-derived therapeutic drug aimed at treating CD19-positive acute lymphoblastic leukemia.



#### **Target Market Launch of Development Pipeline**





## Autologous Cultured Cartilage "JACC": Additional Indication for OA Approved by the Ministry of Health, Labour and Welfare Subcommittee



- On April 18<sup>th</sup>, 2025, at the Pharmaceutical Affairs Council's Meeting on Regenerative Medical Products and Biologics Technical Subcommittee, the partial change approval to add osteoarthritis of the knee as an indication was granted, marking significant progress. It is expected to receive formal approval in the near future. (Details to be released once formal approval is granted)
- ✓ Regarding the timing of insurance reimbursement. Although the outlook is highly uncertain and difficult to predict, preparation for sales are being planned on the assumption that it will be covered during Q3 of the FY March 2026.

#### Overview of the Expansion of Indications for "JACC"

- ✓ Osteoarthritis of the knee affects approximately 10 million people who experience subjective symptoms I the knee joint, representing the "true indication" that JACC aims to address.
- For OA of the knee that JACC is indicated for, patients are expected to be those who do not improve with conservative treatments such as exercise therapy and have cartilage defects larger than 2 cm² (patients with severe cases where cartilage is completely lost are assumed to be excluded).
- Compared to the existing indication (just under 200 cases annually), it is anticipated that the number of cases will exceed 1,000 annually in the future, representing significant potential. It is expected to become a key growth driver toward achieving 5 billion yen in sales.
- ✓ Demonstrated statistically significant symptom improvement over hyaluronic acid treatment group.
- ✓ In addition, transplantation of autologous cultured cartilage confirmed repair of cartilage defects caused by knee osteoarthritis with hyaline cartilage-like tissue.



#### Accelerating Expansion into New Areas of the Regenerative Medicine Contract Business

Expansion

into new

Fields

Leveraging the strengths cultivated through the contract business, we aim to accelerate expansion into new technology domains and broaden customer acquisition both domestically and internationally.

#### Our Strengths

Pickup 2

#### Grasping customer needs and providing comprehensive support with a view to commercialization

- ✓ Experience in product development
- ✓ Know-how in manufacturing investigational products
- ✓ Collaboration with physicians for conducting clinical trials
- ✓ Proposal for cost reduction aimed at manufacturing and marketing approval
- ✓ Proposal for post-marketing system structure



 $\bullet$  CELL THERAPY '25/1 $\sim$ Capital and Business Alliance

Joint development for the practical application of regenerative medical products using iPS cells to address retinal degeneration



'25/2~Clinical trial manufacturing consignment

Consignment manufacturing of regenerative medical products for the treatment of functional single ventricle disease→Expansion into cardiovascular field



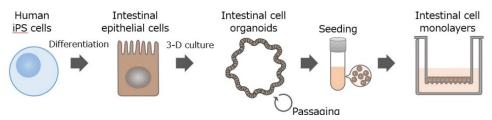
'22/8~Contract Development

Contract manufacturing of regenerative medical products for bullous keratopathy→Implementation of transplantation in domestic Phase II clinical trials. 1. Business Performance and Topics for FY March 2025

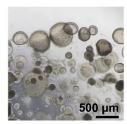


#### Acquired Rights to Develop Research-Use Intestinal Epithelial Model with Human iPS Cells and Organoid Technology

- From the perspective of animal welfare, the global trend toward banning animal testing is accelerating.
- ✓ To meet this demand, we acquired from Takara Bio the development rights for a new product in the LabCyte series: a research-use intestinal epithelial model using human iPS cells and organoid technology
- ✓ As an alternative method to animal testing, we aim to expand into large drug discovery markets and overseas markets. (Targeting Market Release in Q1 FY March 2027)
- ✓ Furthermore, by acquiring advanced expertise in iPS cells and organoid technologies, we aim to enhance our product lineup with organized tissue structures.







Human iPS cell-derived intestinal organoid

#### **Special Characteristic**

- ✓ By inducing differentiation on human iPS cells under optimal conditions, it becomes possible to reproduce intestinal epithelial cells that have functions similar to those of an actual human small intestine.
- By culturing intestinal organoids under stable conditions, it becomes possible to maintain high-quality cells over the long term, enabling highly efficient manufacturing and the production of high-quality, consistent products with short delivery times.



J-TEC

Pickup 4

#### Revamping the Management Structure to Accelerate Growth



Under the leadership of our new president, we will promote team-based management that unites our expertise and accelerate growth.

#### Proposed Internal Executive Structure After the Shareholders' Meeting

\*Following a resolution by the Board of Directors at the 6/19 Annual General Meetingg of Shareholders, the appointments will take effect. The head of the R&D Support Business will be decided separately.



Toshihiro Otsuka

Kazuto Yamada

Representative Director, President and Executive Officer



Akinobu Wakabayashi

Director (in charge of strategic planning)

Director, Senior Managing Executive Officer

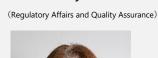
Miho Fujita Shigeaki Hayashi

(Production Division) (Development Division)





Hiroaki Murai (IT·Infrastructure Development)



Michiyo Aiba













2. Earnings Forecast for FY March 2026



#### Earnings Forecast for FY March 2026

- Regarding this forecast, due to the difficulty in predicting the timing of insurance coverage recognition for JACC OA and its significant impact, we have adopted a range format—The upper limit assumes the case where insurance coverage for JACC OA is completed within this fiscal period, the lower limit assumes the case where it is not recognized within this fiscal period.
- ✓ In either scenario, we expect to achieve operating profitability through the expansion of sales in each business segment.

Units: millions of yen	FY March 2025	FY March 2026			
(rounded down to nearest million yen)		Results Forecast	Year-on-Year		
(increase/decrease is calculated in yen)	Results	(As of 2025.4.30)	Change (amount)	Change (percentage)	
Total Net Sales	2,455	2,900~3,100	444~644	18.1~26.2%	
Regenerative Medical Products Business	1,493	1,770~1,970	280~480	18.8~32.2%	
Skin Line (JACE、JACEMIN)	985	1,130	147	15.0%	
Cartilage Line (JACC)	382	400~ 600	17~217	4.6~57.0%	
Ophthalmology Line (NEPIC、OCURAL)	125	240	116	92.7%	
Regenerative Medicine Contract Business	713	810	93	13.1%	
General Clients (Non-Teijin)	348	430	80	23.0%	
Teijin	364	380	13	3.6%	
R&D Support Business	248	320	71	28.9%	
Operating Profit	(238)	100~200	338~438	-	
Ordinary Profit	(234)	110~210	344~444	-	
Net Income	(255)	100~190	355~445	-	

<sup>\*</sup> Milestone revenue from Teijin: 170 million yen in the previous cumulative period (FY ended March 2024) 100 million yen in the current cumulative period (FY ending March 2025)

Building Infrastructure



#### Key Initiatives for the FY March 2026

✓ We will focus on expanding the sales of JACC OA and JACEMIN as a key initiative.					
Regenerative Medical Products Business	Skin Line	JACEMIN: Steady provision of treatment for over 50 waiting patients  Allo-JaCE03: Development aimed at filing for approval within the fiscal year, and preparation of a sales structure for the allogenic products as the new cell therapy field.			
	Cartilage Line	JACC: To expand OA indications, we will concentrate resources on raising awareness among physicians and patients			
	Emerging business	Steady implementation of physician-led clinical trials of autologous CAR-T cells at Nagoya University for malignant lymphoma and acute lymphoblastic leukemia			
Regenerative Medicine Contract Business		VC Cell Therapy Inc., Metcela Inc., and ActualEyes Inc. –Accelerate the provision of added value to existing customers.  Capture new contract opportunities both domestically and internationally by fully leveraging our development knowledge			
R&D Support Business		Build a global expansion framework for EpiSensA  Develop a new intestinal epithelial model product (target launch FY March 2027)			
Building In	ofrastructure	Mechanization and automation of manufacturing and quality control processes (in collaboration with Sysmex Corporation)			

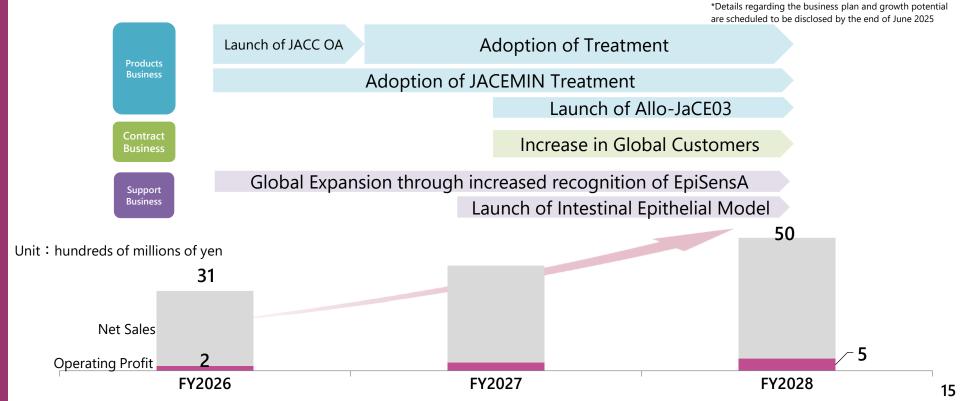
(in partnership with Toyohashi University of Technology)

Strengthening regional collaboration to foster human resource development and revitalize industry



#### **Toward Significant Growth**

- ✓ In the mid-term management plan, the sales target of 5 billion yen (10% of Operating Profit) originally set for achievement by FY March 2026 has been revised to a plan aiming for achievement in FY March 2028, with the expansion of pipeline sales in the regenerative medicine product business as the main growth driver.
- ✓ We will steadily implement each growth strategy and link it to results, and report progress in the IR briefing materials each quarter





3. Reference Materials



Timely disclosure

### List of Topics for FY March 2025 \*\*Main Excerpts

Publish Date	Contents
2024: April 12th	2 Presentations awarded as outstanding at the 23 <sup>rd</sup> Annual Meeting of the Japanese Society for Regenerative Medicine Awarded Presentation: Our Foundational Research on Mesenchymal Stem Cells
April 22nd	Received a Special Certificate of Appreciation at the 70th Anniversary Ceremony of Gamagori City –"Contribution to Gamagori city, the City of Regenerative Medicine"-
June 11th	Notice of Selection for the FY2024 "New Aichi Creative Research and Development Grant"
June 17th	Autologous Cultured Cartilage "JACC": Application for Partial Change Approval Submitted for Expansion of Indication to Osteoarthritis of the Knee
June 26th	The skin sensitization test method "EpiSensA" using "LabCyte Epi-Model 24" has been standardized internationally
September 4th	AcutalEyes Inc. conducted the first transplantation in the domestic Phase II clinical trial for "Regenerative Therapy of the Corneal Endothelium
September 17th	Timely Disclosure Completed World's first clinical trial for allogenic (same species) cultured epidermis capable of long-term room temperature storage
October 7th	Launch of "JACEMIN", an autologous cultured epidermis containing pigment cells
November 5th	Initiated "Cultured Epidermis Transplantation" for wrist-cut scars
December 5th	Basic agreement with Sysmex Corporation to advance manufacturing capabilities in regenerative medicine
December 16th	Notice regarding personnel changes
December 16th	Entered into a distributorship agreement with Shiven Biotech for the sale of cultured human tissues for research use
2025: January 14th	Capital and Business alliance with VC Cell Therapy Co., Ltd. for the practical application of regenerative medical products using iPS cells
January 30th	Regenerative Medicine Public Lecture: "The New Social Value Brought by Regenerative Medicine – Living HAPPY in Gamagori City" held
February 25th	Contracted by Metcela Inc. for the manufacturing of investigational regenerative medical products targeting pediatric congenital heart disease
March 18th	Notice regarding changes in representative director and personnel appointments
March 24th	Acquired development rights for a research-use intestinal epithelial model using human iPS cells and organoid technology
March 27th	Launched a contract service business for skin sensitization testing using alternatives to animal testing, in collaboration with external testing institutions using "EpiSensA"



#### Summary of J-TEC's Regenerative Medical Products (As of April 2025)



Japan's first approved regenerative medical product



Japan's second approved regenerative medical product, commercialized with domestic technology



First approved regenerative medical product in the ophthalmology field in Japan



Second approved regenerative medical product in the ophthalmology field in Japan



Regenerative medical product for vitiligo treatment, which has many patients

#### Products

#### Autologous Cultured Epidermis



### Autologous Cultured Cartilage



### Autologous Cultured Corneal Epithelium



### Autologous Cultured Oral Mucosal Epithelium



Autologous Cultured Epidermis
Containing Melanocytes



Product Appearance











Approval Period Manufacturing Approval
October 2007
Included in Insurance
January 2009

Manufacturing Approval July 2012

Included in Insurance April 2013

Manufacturing Approval March 2020

Included in Insurance
June 2020

Manufacturing Approval June 2021

Included in Insurance December 2021

Manufacturing Approval
March 2023
Included in Insurance

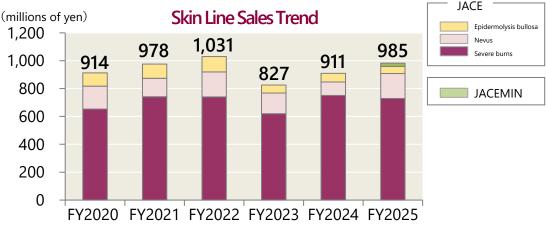
October 2024



#### Regenerative Medical Product Business: Skin Line (JACE, JACEMIN)

- Sales for FY March 2025 were 985 million yen (an 8.1% increase from the previous FY).
- <Skin Line: Autologous Cultured Epidermis "JACE">In the area of burn treatment JACE has become widely recognized and accepted as one of the standard treatments for the condition. As a result of continuous promotional activities, the business recovered form a slump in Q4 and reached a level comparable to the previous fiscal year. Going forward, we aim to contribute to saving more patients' lives by strengthening our sales efforts. For congenital giant melanocytic nevus, the number of orders increased significantly to expanded use of JACE in facilities advancing new combination therapies at the time of transplantation. Moving forward, we will promote initiatives aimed at further improving treatment outcomes and expanding adoption.
- < Skin Line: Autologous Cultured Epidermis Containing Melanocytes "JACEMIN" > Following insurance coverage in October 2024, we worked to promote adoption by core medical institutions and to prepare the usage environment. As a result, we received our first order in January and were able to increase the number of cases during the fiscal year to six. Treatment for patients on the waiting list has also been progressing smoothly since then.
- <Skin Line: Self-Funded Treatment>In November 2024, in collaboration with "Kizu to Kizuato Clinic®", a medical institution specializing in wound and scar treatment, we began supplying cultured epidermis for the treatment of wrist-cut scars in private medical practice.



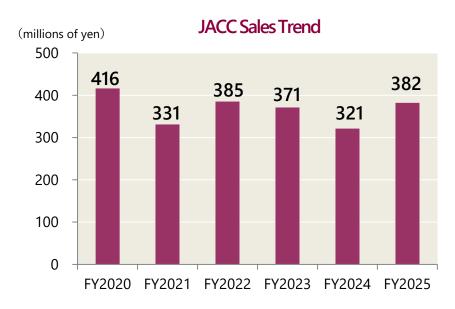




#### Regenerative Medical Product Business: Autologous Cultured Cartilage (JACC)

- Sales for FY March 2025 were 382 million yen (a 19.1% increase from the previous FY)
- ✓ In addition to the increase in insurance reimbursement prices due to the revision of medical service fees in FY 2024, sales also increased as a result of sales activities promoting the effectiveness of JACC, such as holding seminars in conjunction with the Japanese Knee Joint Society.
- At the meeting of the Ministry of Health, Labour and Welfares Pharmaceutical Affairs and Food Sanitation Council, Subcommittee on Regenerative Medical Products and Biologics held on April 18, 2025, approval was granted for a partial change to add osteoarthritis on the knee as an indication. In order for patients to use JACC as a new treatment for OA as soon as possible, we are working to build a supply system aiming for insurance coverage during the FY 2026.







#### Regenerative Medical Product Business: Ophthalmology Line (NEPIC, OCURAL)

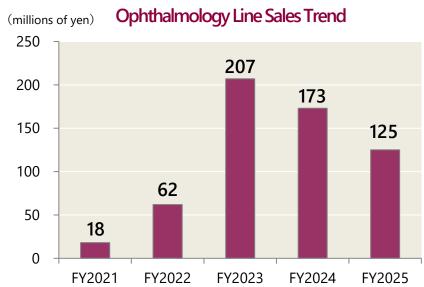
- ✓ Sales for FY 2025 were 125 million yen (a decrease of 28% from the previous FY).
- ✓ Although sales have been sluggish due to delays in transplants for patients on the waiting list, orders have begun to come in for the other eye of patients with bilateral disease who have already received an OCURAL transplant in one eye. In addition, in order to accelerate awareness among corneal specialists and the identification of potential patients, new initiatives are being launched that actively invest our company's resources alongside NIDEK Co., Ltd., which handles sales. As a result of this joint effort between the two companies, progress is being made in developing candidate facilities and uncovering potential patients.













#### **Regenerative Medicine Contract Business**

- ✓ Sales for FY March 2025 were 713 million yen (a decrease of 17.5% from the previous FY). Due to a decline in orders related to Teijin, overall sales decreased. However, sales from contracts with general customers (non-Teijin) increased steadily.
- < General Customer Contracts>We have been providing services related to development and manufacturing outsourcing (CDMO) and clinical development outsourcing (CRO) to our clients. For example, AcutalEyes Inc., a client company, began a Phase II clinical trial in Japan for regenerative medical products, and administration to the subjects has been completed. In addition, we initiated a commission agreement through a capital and business alliance with VC Cell therapy Inc. aimed at commercializing regenerative medical products using iPS cells. Furthermore, we signed a contract with Metcela Inc. For the manufacture of investigational regenerative medical products targeting congenital heart disease. As we expand into new areas such as iPS cells and the cardiovascular field, we will continue to focus on building frameworks for CDMO operations that enhance product value through strong relationships with our clients, thereby contributing to the advancement of regenerative medicine in Japan
- < Teijin > In the current fiscal year, revenue decreased due to delays in the scheduled milestones and a reduction in commissioned work compared to the previous fiscal year when Teijin Regenet Co., Ltd. was launched. Furthermore, there were also delays in the milestones originally planned for this fiscal year. Moving forward, we aim to achieve milestone targets and expand commissioned revenue by promoting initiatives that enhance the value of both companies through collaboration with Teijin





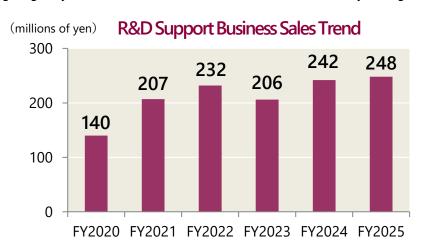
<sup>\*</sup>Milestone revenue from Teijin: 170 million yen in the previous cumulative period (FY ended March 2024) 100 million yen in the current cumulative period (FY ending March 2025)



#### R&D Support Business: LabCyte

- ✓ Sales for FY 2025 were 248 million yen (a 2.6% increase from the previous FY).
- ✓ Although research from a major domestic client declined and impacted revenue, the inclusion of the skin sensitization test method "EpiSensA"-which uses the animal testing alternative product LabCyte-in test guidelines led to increased demand from new domestic and international clients, resulting in a slight increase in sales.
- ✓ In Japan, we have launched a testing service business using EpiSensA. By collaborating with the Teijin Structural Analysis Center as an external testing agency, we aim to expand the availability of EpiSensA in response to growing demand and thereby promote the wider adoption of LabCyte.
- Overseas we have signed a distribution agreement with Shiven Biotech in India and have begin sales promotion activities. In addition, we have also started sales to multiple companies in Europe.
- In March 2025, we acquired the development rights for a research-use intestinal epithelial model using human iPS cells and organoid technology. Aiming for market launch in Q1 of FY 2027, we are advancing development while seeking to expand from our current cosmetics-focused market into the pharmaceutical market. At the same time, we are sequentially expanding in the U.S., Europe, and Asia, targeting early achievement of sales in the several hundred-million-yen range.







#### **Balance Sheet Summary**

	(Unit: millions of yen) (rounded down to the nearest million yen)	As of March 31, 2024	As of March 31, 2025	Change	
	Current Assets	5,339	4,824	(514)	Decrease in cash and deposits, etc.
	Non-Current Assets	1,649	1,688	38	Depreciation
Tot	al Assets	6,988	6,512	(475)	
	Current Liabilities	873	637	(236)	Decrease in unpaid expenses, etc.
	Non-Current Liabilities	34	50	15	
Tot	al Liabilities	908	687	(220)	
	Capital Stock	4,958	4,958	-	
	Capital Surplus	2,788	2,788	-	
	Retained Earnings	(1,666)	(1,922)	(255)	
Net Assets		6,080	5,825	(255)	Increase in net loss for current
Total Liabilities and Net Assets		6,988	6,512	(475)	period



#### **Cash Flow Summary**

	(Unit: millions of yen)  (rounded down to the nearest million yen)	FY March 2024 (Actual)	FY March 2025 (Actual)
	Cash Flow from Operating Activities	274	(148)
	Cash Flow from Investing Activities	(242)	(232)
	Cash Flow From Financing Activities	0	0
Ne	t increase (decrease) in Cash and Cash Equivalents	31	(380)
Ca	sh and Cash Equivalents at Beginning of Period	2,034	2,066
Cash and Cash Equivalents at End of Period		2,066	1,685

✓ CF from Operating Activities : The amount of funds used as a result of operating activities was 148 million yen

(a gain of 274 million yen in FY March 2024)

This was mainly due to a net loss before taxes and depreciation expenses

✓ CF from Investing Activities : The amount of funds used as a result of investing activities was 232 million yen

(242 million yen was used in FY 2024)

Mainly due to expenditures for the acquisition of investment securities.

✓ CF from Financing Activities : 0 yen was used as a result of financing activities (0 yen was used FY 2024)

Mainly due to expenditures for the acquisition of treasury stock

✓ Ending Balance of Cash and Equivalents:

The ending balance was 1.685 billion yen, compared to a beginning balance of 2.066 billion yen. The difference from the cash and deposits shown on the balance sheet (3.855 billion yen) corresponds to time deposits exceeding three months in maturity (2.2 billion yen).



This presentation is intended solely for the purpose of providing information to investors and includes descriptions of future business plans; it is not intended to solicit investment. Investment decisions, including the evaluation of our business plans, should be made at the discretion and responsibility of the investor.

Moreover, the Company makes no guarantees regarding the realization or achievement of business plans, performance targets, or any other matters described herein, nor does it assume any responsibility for such outcomes.

Any forward-looking statements contained in this material, including business performance targets, are based on information available at the time and on the Company's judgement. Please be advised that due to potential changes in various factors—such as future economic conditions or assumptions underlying the business plan— actual business performance and conditions may differ materially form the content described in this presentation.

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