

Business Plan and Growth Potential



(東証グロース：7774)

June 25th, 2025

Japan Tissue Engineering Corporation

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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 (Regenerative Medical Product)
JACC	Autologous Cultured Cartilage manufactured by harvesting the patient's cartilage tissue, isolating cells, and culturing them (Regenerative Medical Product)
NEPIC	Autologous cultured corneal epithelium manufactured by harvesting the patient's limbal tissue, isolating cells, and culturing them (Regenerative Medical Product)
OCURAL	Autologous cultured oral mucosal epithelium manufactured by harvesting the patient's oral mucosal tissue, isolating cells, and culturing them (Regenerative Medical Product)
LabCyte	Cultured human tissue for research use that serves as an alternative to various tests, such as skin irritation tests that use animals.

About the Company

- ✓ As the first company in Japan to successfully commercialize regenerative medicine, we have established a unique business model distinct from those of pharmaceutical and medical device industries, positioning ourselves as a leader in the regenerative medicine sector.
- ✓ In our Regenerative Medical Products Business, **we are implementing innovative therapies** that utilize patients' own cells, contributing to life-saving treatments for severe burn victims and offering fundamental solutions for rare and intractable diseases through the provision of advanced medical technologies.
- ✓ In the Regenerative Medicine Contract Business, we leverage the expertise accumulated in regenerative medicine to **support overall growth and advancement of the industry**.
- ✓ In the Research and Development Support Business, we provide human cultured tissues for research purposes and support the development of cosmetics and new pharmaceuticals, while contributing to the **wider adoption of alternatives to animal testing**.

*Creating a Future for
Regenerative Medicine*

再生医療をあたりまえの医療に

Aiming to help realize
such a society, our company will
continue to evolve going forward.

Our Company's Strengths

Driving Growth by leveraging our strengths as a Platform Provider for Autologous Cells

- ✓ In the Regenerative Medical Product business, we possess all functions, from research and development, regulatory affairs, manufacturing, sales, and marketing to post-marketing support.
- ✓ With manufacturing facilities capable of commercial production of regenerative medical products, we supply autologous cell products in a stable and reliable manner as a regenerative medicine manufacturer.
- ✓ Based on high quality standards in regenerative medicine, we are expanding into contract services and R&D support businesses in regenerative medicine.



Challenge

- ✓ Establishment of a stable supply system using the patients own live cells, an unprecedented approach.
- ✓ Standardization of cultivation methods, establishment of safety and efficacy standards, setting of packaging transportation specifications, optimization of usage methods—all done in-house.



Experience

- ✓ Accumulated specialized development experience in regenerative medical products through in-house research, product design, regulatory compliance etc..
- ✓ Provided regenerative medical products to over 3000 patients to date, solving numerous issues through this process.



History

- ✓ Obtained approval for five regenerative medical products, including Japan's first (Autologous Cultured Epidermis: JACE)
- ✓ Established the industry in parallel with regulatory changes, while promoting business through extensive discussions with regulatory authorities.

2. Measures for Growth

New Management System

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



Toshihiro Otsuka

Director, Senior Executive Officer



Kazuto Yamada

Representative Director, President &
Executive Officer



Akinobu Wakabayashi

Director (In charge of Strategic Planning)

Tadashige Yazaki

(Product Business, Sales)



Norio Sakakibara

(Contract Services Business)



Yoshihide Ninagawa

(R&D Support Business)



Shigeaki Hayashi

(Development Department)



Miho Fujita

(Production Department)



Michiyo Aiba

(Regulatory Affairs, Quality Assurance)



Growth-Oriented Strategy



"JACC"OA Approval

Sales: 5 billion yen

2027

Step1

Build a proprietary platform for regenerative medical products using autologous cells

- Expertise in developing transplant-type medical products, gained through the launch of five products
- Process to stably supply autologous cell products
- Training of specialized personnel
- Collaboration system with medical institutions and regulatory authorities
- Reconfirmation of efficacy and safety, based on the completion of post-marketing surveys

Step2

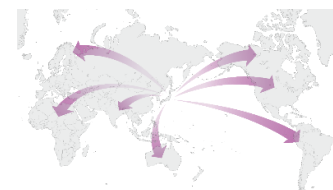
Social implementation of the proprietary platform

- "JACC"OA: A mechanism to deliver autologous cell products to many patients
- Allo-JaCE03 : Application to Allogenic cells
- Maximization of platform utilization in contract projects
- Promotion of open innovation
- Promotion of automation using AI, etc.

Step3

Overseas expansion and early growth through new products

- Inbound from overseas demand for Japan-originated regenerative medicine models creating an outbound mechanism
- Acquisition of new pipelines that can utilize the platform



Established
1999

New Organizational Policy

Fundamental Policy

Placing the highest priority on **achieving 5 billion yen in sales** for the FY March 2028, we will promote team-based management under a new structure. By doing so, we will maximize the combined strength of our **accumulated business foundation, expertise, and human resources**.

《Priority Measures》

Regenerative Medical Product Business

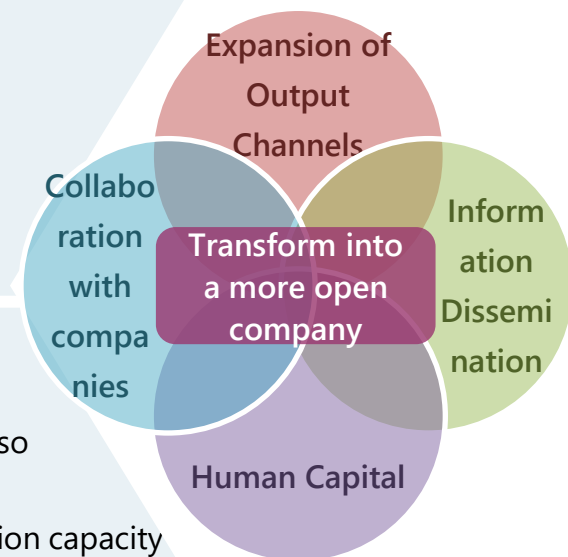
- ✓ **"JACC"OA (Expansions of Indications for Osteoarthritis of the knee)**
Aim for 1000 cases and maximize sales through new sales structure
 - ✓ **Allo-JaCE03 (Allogenic Cultured Epidermis)**
Aiming for market launch in FY March 2027, maximizing sales by leveraging the strengths of allogenic-derived products that can be stored long-term.
- **Develop the Regenerative Medical Product Business into a core business that generates profit**

Regenerative Medicine contract Business

- ✓ Expand into new technological fields and increase contract capacity to expand the customer base **both domestically and internationally**.
- ✓ Aim not only to support development and conduct clinical trials, but also to accept large scale commercial manufacturing contracts
- ✓ Planning **expansion of GCTP-compliant facilities** to strengthen production capacity

R&D Support Business

- ✓ Development of **new product "human iPS cell derived intestinal epithelial model"**
- ✓ **Global expansion** targeting Europe and India



Overview of Business Achievements and Progress



Regenerative Medical Product Business

Realizing stable product supply
with a patient-first approach

Total number of patients:

over **3,000**

Key Milestones

'24.10.7

JACEMINE launched

'25.5.13

"JACC"OA Indication expansion-
partial change approval obtained



Regenerative Medicine Contract Business

Supporting the commercialization
of regenerative medicine

Number of contracts received※

232

※ Excludes contracts from parent company;
includes only independently acquired projects

'25.1.14

Capital and business alliance with
VC Cell Therapy Co., Ltd.

'25.2.25

Contracted for manufacturing of
investigational product for
congenital pediatric heart disease.
(Contracted by Metcela, Inc.)



Research & Development Support Business

Supporting domestic and international
clients in alternatives to animal testing

FY March 2025

Annual number of purchasing clients

161

11 of which, are purchases from overseas

'24.6.26

EpiSensA: standardized internationally

'25.3.24

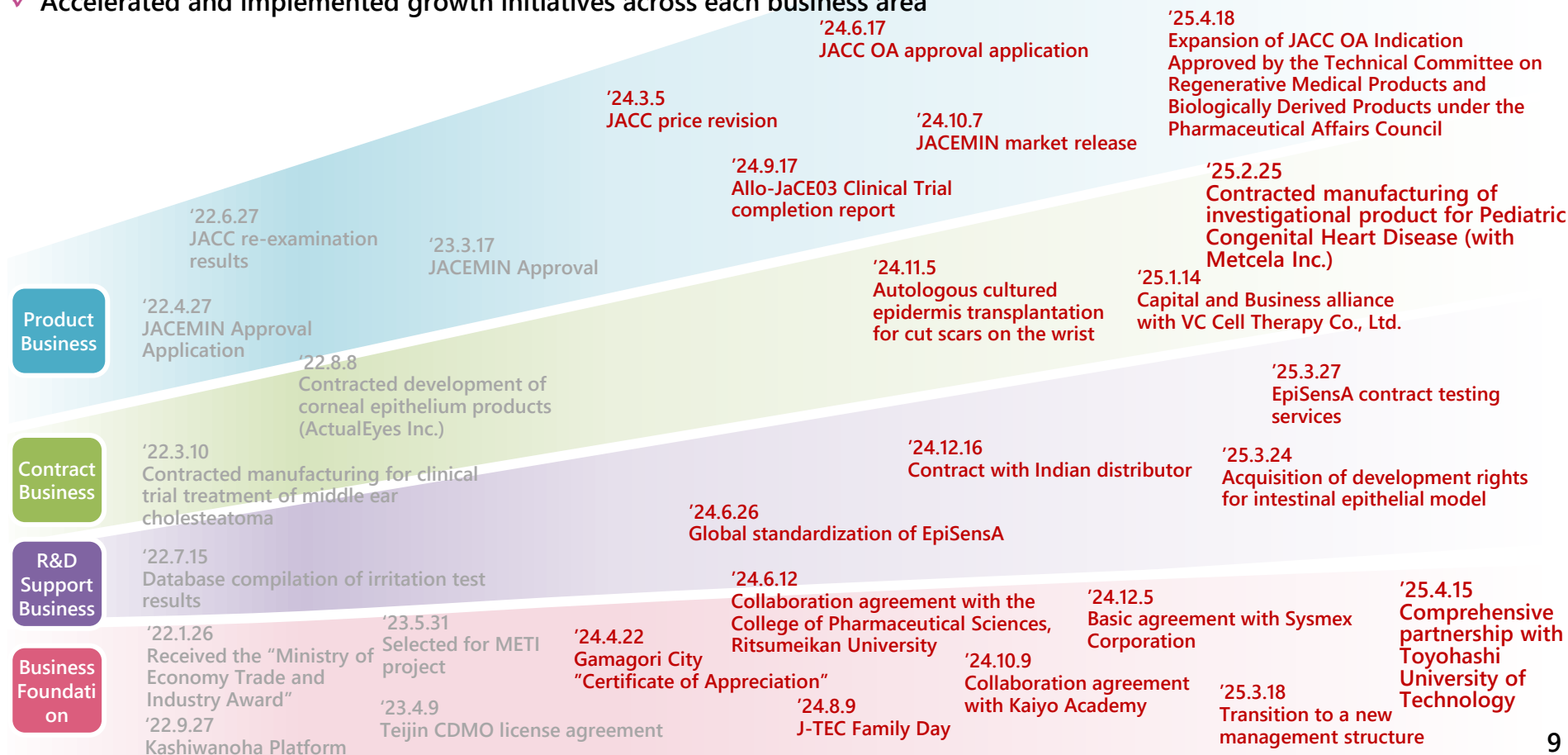
Acquired development rights for
intestinal epithelial model

'25.3.27

Launched EpiSensA testing contract
business

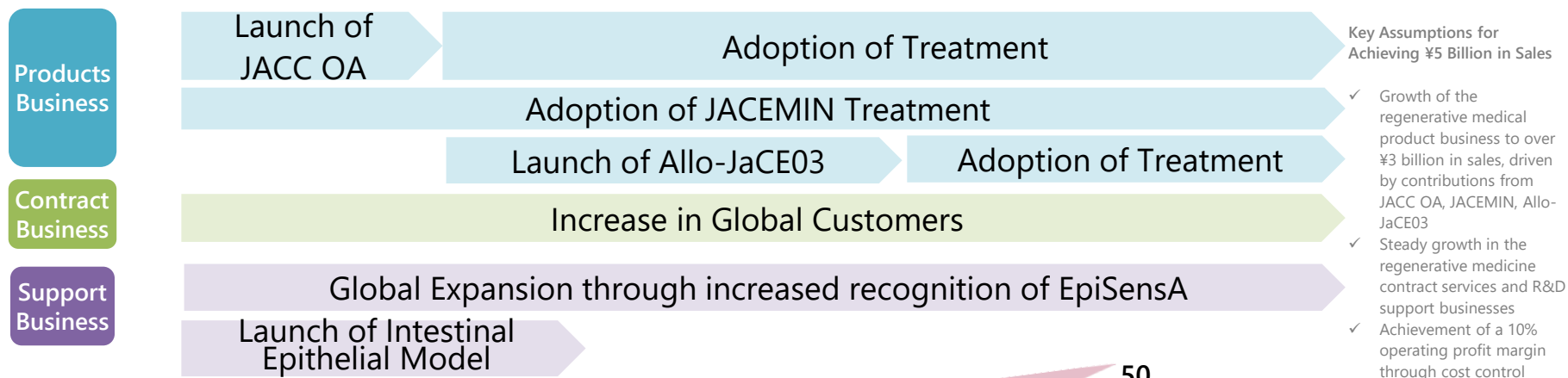
Growth Initiatives to Date

✓ Accelerated and implemented growth initiatives across each business area

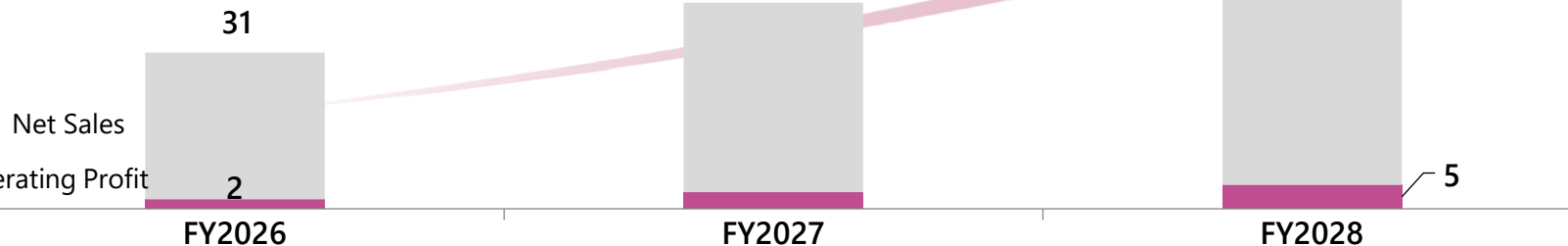


Toward Significant Growth

- ✓ 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



Unit : hundreds of millions of yen



Earnings Forecast for FY March 2026

- ✓ For FY March 2025, sales slightly decreased compared to the previous year due to a decline in revenue from Teijin-related projects (caused by delays in planned milestone payments and a reduction in contract work). However, Regenerative Medical Products Business saw an increase in revenue year-on-year, driven by the market launch of JACEMIN and the increase in the insurance reimbursement price for JACC. Operating profit turned negative, partly due to a decrease in subsidies.
- ✓ For FY March 2026, the company expects to return to profitability, driven by progress in growth initiatives (see next page).

Units : millions of yen (rounded down to nearest million yen) (increase/decrease is calculated in yen)	FY March 2024	FY March 2025			FY March 2026		
	Results	Results	Year-on-Year		Results Forecast As of 2025.4.30	Year-on-Year	
			Change (amount)	Change (percentage)		Change (amount)	Change (percentage)
Skin Line (JACE, JACEMIN)	911	985	74	8.1%	1,130	147	15.0%
Cartilage Line (JACC)	321	382	61	19.1%	400~600	17~217	4.6~57.0%
Ophthalmology Line (NEPIC, OCURAL)	173	125	△48	△28.0%	240	116	92.7%
Regenerative Medical Products Business	1,406	1,493	86	6.2%	1,770~1,970	280~480	18.8~32.2%
General Clients (Non-Teijin)	395	348	△47	△11.8%	430	80	23.0%
Teijin	469	364	△104	△22.3%	380	13	3.6%
Regenerative Medicine Contract Business	865	713	△151	△17.5%	810	93	13.1%
R&D Support Business	242	248	6	2.6%	320	71	28.9%
Total Net Sales	2,514	2,455	△58	△2.3%	2,900~3,100	444~644	18.1~26.2%
Operating Profit	144	△238	△382	-	100~200	338~438	-
Ordinary Profit	147	△234	△381	-	110~210	344~444	-
Net income	143	△255	△398	-	100~190	355~445	-

2. Measures for Growth

Updates since the financial results briefing materials disclosed on April 30, 2025

Progress on Growth Strategies

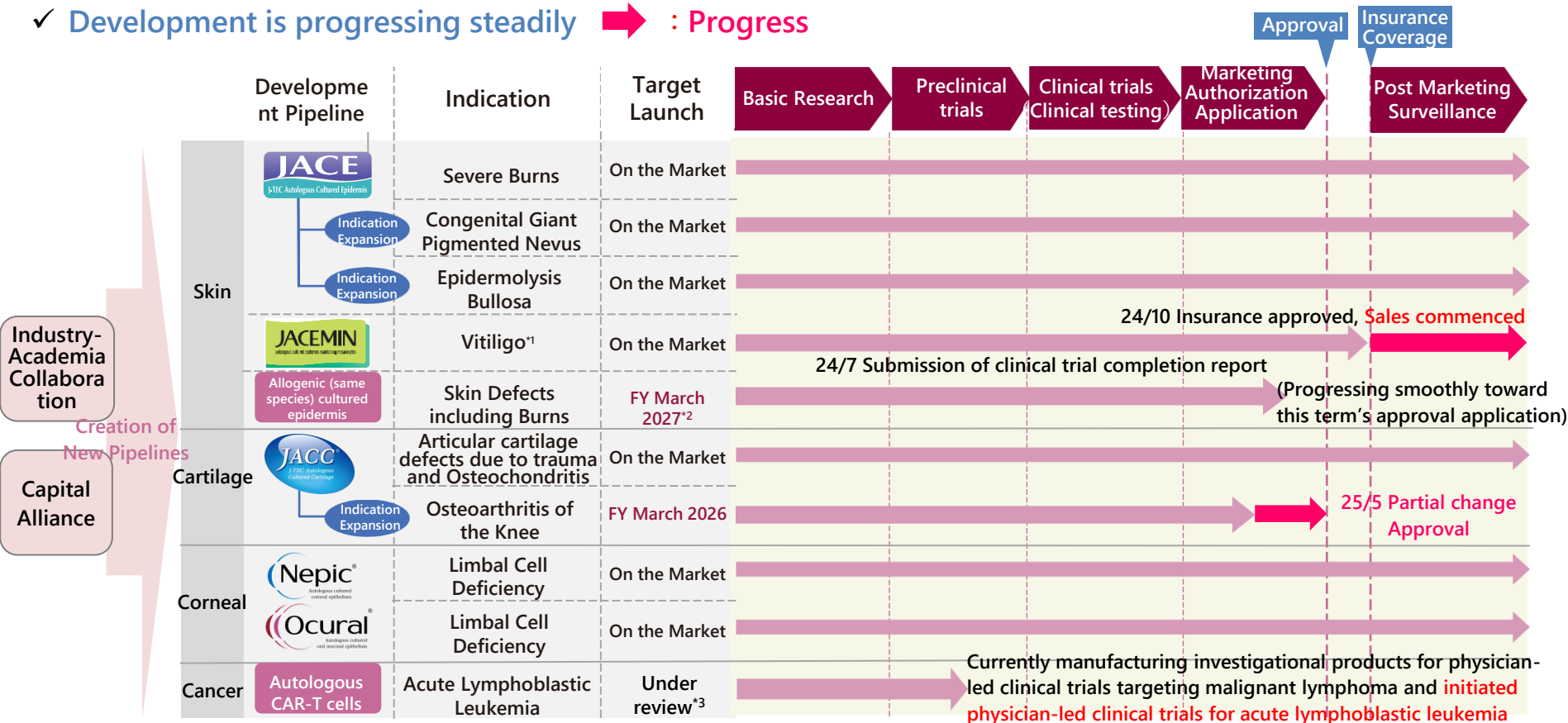
*1 An allogenic (same species) cultured epidermis under development, Japan's first allogenic product using another person's skin tissue as raw material.
*2 We concluded a patent license agreement with Nagoya University and Shinshu University to develop a low-cost, autologous CAR-T cell-derived therapeutic drug.



Regenerative Medical Product Business	Skin Line	<ul style="list-style-type: none"> ✓ JACEMIN Over 50 patients are currently waiting this term; treatment provision is in sight, and expansion of locations is progressing smoothly ✓ Allo-JaCE03*1 Approval application planned for this term; progressing smoothly ✓ Autologous cultured epidermis transplantation under free medical care at Kizu to Kizu Ato Clinic is also progressing smoothly
	Cartilage Line	<ul style="list-style-type: none"> ✓ Expansion of indication for "JACC"OA– Partial change approval obtained(5/13)、progressing toward insurance reimbursement in Q3 of this fiscal year.
	Emerging Business	<ul style="list-style-type: none"> ✓ Autologous CAR-T Cells*2 In addition to the ongoing physician-initiated clinical trial for malignant lymphoma at Nagoya University, a physician-initiated clinical trial targeting acute lymphoblastic leukemia has also commenced
Regenerative Medicine Contract Business		<ul style="list-style-type: none"> ✓ A capital and business alliance agreement with VC Cell Therapy Co., Ltd. has commenced and development is progressing smoothly ✓ Entered into a contract with Metcela Inc. for the manufacture of investigational products ✓ Contract negotiations with multiple prospective clients are underway ✓ Planning capital investment to expand GCTP-compliant facilities for future growth
R&D Support Business		<ul style="list-style-type: none"> ✓ To establish a distribution framework for EpiSensA, we launched a collaborative testing service business with Teijin Structure Analysis Center ✓ Start of provision to multiple overseas locations (EU: SenzaGen Co., US: IIVS Co. etc.) ✓ Acquired development rights for a research-use intestinal epithelium model using human iPS cells and organoid technology → Positioned as a new product, accelerating development in drug discovery market and overseas expansion (Expected to launch Q1 FY March 2027)
Building Infrastructure		<ul style="list-style-type: none"> ✓ Revamped management structure to accelerate growth ✓ Initiated joint development with Sysmex Co. to streamline quality control testing ✓ Cooperating in the dissemination of information on regenerative medicine at the Osaka-Kansai Expo

Target Market Launch of Development Pipeline

✓ Development is progressing steadily ➡ : Progress



*1 for which nonsurgical therapy is ineffective or not indicated *2 Revision of Market Launch Schedule Due to Development Delays.

*3 Since the clinical trial will be conducted under physician-led initiative rather than company-led, the overall schedule is currently under review.

Expansion of Indication for Autologous Cultured Cartilage “JACC” OA

- ✓ On May 13, 2025, **obtained partial change approval for expansion of indication for “JACC” OA**
- ✓ Although the timing of **insurance reimbursement is highly uncertain and difficult to predict**, preparations are being made for **sales assuming reimbursement will be granted** during Q3 of this fiscal year
- ✓ Initially aiming **to achieve 1000 cases, concentrating resources to cultivate this as a growth driver toward achieving 5 billion yen in sales**

Overview of “JACC” OA Indication Expansion

- ✓ Osteoarthritis of the knee affects approximately 10 million people in Japan who experience subjective symptoms in the knee joint. JACC **aims to provide the “true indication” for such patients.**
- ✓ The target osteoarthritis of the knee for JACC’s indication **includes patients whose symptoms do not improve with conservative treatments such as physical therapy and have cartilage defects of 2 cm² or more.**
- ✓ Clinical trials have show statistically significant improvement in symptoms **among patients treated with hyaluronic acid sodium preparation compared to control groups.**
- ✓ In addition, transplantation of autologous cultured cartilage has demonstrated repair of cartilage defects caused by osteoarthritis of the knee, with the formation of cartilage-like tissue at the defect site.

Strengthening Measures Under the New Sales Structure

- ✓ **Therapeutic enlightenment** for physicians
(Penetration of product value and treatment techniques)
- ✓ **Enhancing product and treatment value** through Life Cycle Management (building long-term performance evidence, standardization of surgical techniques, etc.)
- ✓ **Patient focused awareness activities**
(Strengthening publicity and PR initiatives)

Allo-JacCE03 Development Status

- ✓ In September, 2024, achieved the primary efficacy evaluation items and submitted the clinical trial completion report
- ✓ Application for approval planned within this fiscal year; targeting launch in FY March 2027 and currently advancing development.
- ✓ Maximize sales by leveraging the long self life characteristics of the product.

Autologous Cultured Epidermis (Regenerative Medical Product)



Cells taken from
another person
(allogenic)



+ Drying Process

Dried Allogenic Cultured Epidermis Allo-JaCE03 (Medical Device)



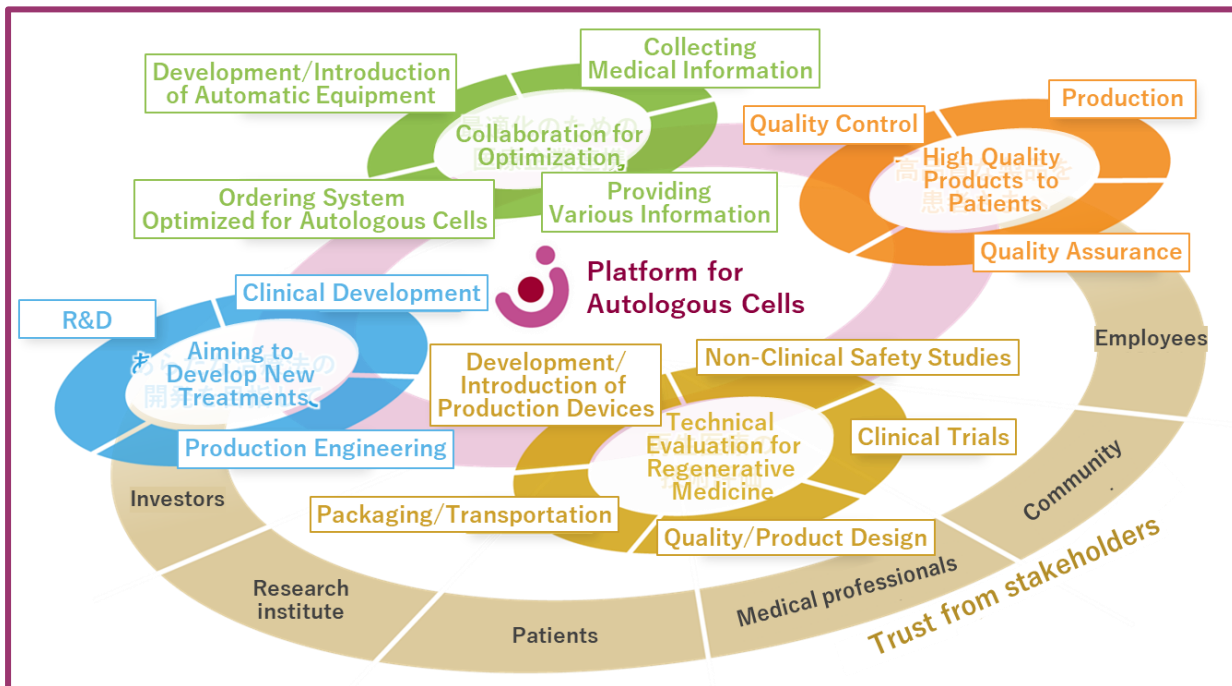
Rehydrated for use



Information at the Time of Clinical Trial

Item	Details
Classification/Class	New medical device – Class IV
Target Diseases	Skin defects including burns
Intended Uses or Effect	Promoting epithelialization of wounds, Protecting the wound surface, Preventing infection, and alleviating pain etc.
Form, Structure	A product made by drying a sheet of epidermal cells derived form skin tissue of a healthy human (same species)

Direction of the Regenerative Medicine Contract Business



Track Record of Regenerative Medical Product Launches
Proprietary Autologous Cell Platform
Initiatives Toward Manufacturing Automation

Past CDMO Order Achievements and Gained Trust

- ✓ **Shift to Pull-Based Marketing**
– Utilizing development experience, specialized personnel, ecosystems, regulatory compliance capabilities, etc., shifting from the traditional push model to a pull model to acquire customers
- ✓ **Expansion of Domestic and Overseas Clients**
- ✓ **Contract Manufacturing of Large-Scale Projects such as Clinical and Commercial Products**

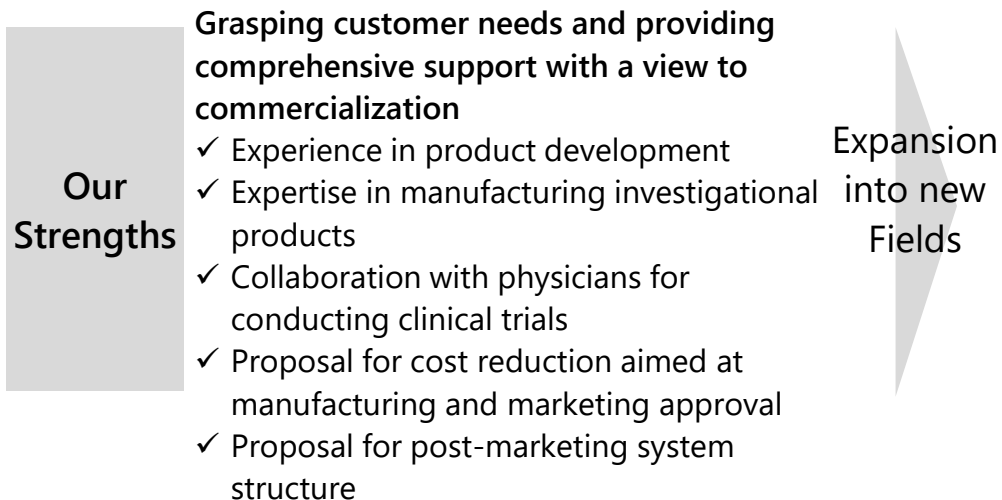
TEIJIN

- ✓ **Strengthening and Decentralizing Domestic Manufacturing Bases**
– Building a globally standardized manufacturing infrastructure (Kashiwanoha, Iwakuni)
- ✓ **Business Collaboration with Overseas CDMOs**
– Supporting overseas expansion of domestic products and domestic development of overseas products

Co-Creation

Expansion into New Areas of the Regenerative Medicine Contract Business

- ✓ 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.**



CELL THERAPY '25/1~Capital and Business Alliance

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

METCELA '25/2~Clinical trial manufacturing consignment

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

ActualEyes '22/8~Contract Development

- ✓ Contract manufacturing of regenerative medical investigational products for bullous keratopathy→Implementation of transplantation in domestic Phase II clinical trials.

Strategies to Strengthen the R&D Support Business

Current Status Recognition

- ✓ In addition to skin irritation and corrosion testing, **gained domestic presence in sensitization testing as well**
 - By inclusion in OECD guidelines, stable supply, and attentive client support, secured top market share domestically
- ✓ **Global trend toward replacing animal testing**
 - In addition to cosmetics and chemical products, there is a growing momentum to use alternatives to animal testing for safety assessments in the fields of medical devices and pharmaceuticals as well



Expansion of Business Areas

- ✓ **Toward global market entry for skin sensitization testing**
 - Already supplying our products to CROs in Europe and the U.S, actively pursuing new client development
 - Strengthening expansion in Asian countries, focusing on India
- ✓ **From cosmetics/chemicals market to medical device market**
 - Utilizing ISO inclusion of skin irritation testing for medical devices as an opportunity to strengthen sales efforts targeting new clients domestically and internationally
 - Working toward ISO inclusion for skin sensitization testing
- ✓ **From cosmetics/chemicals market to pharmaceutical market**
 - Accelerating R&D with the aim of launching a human intestinal epithelial model

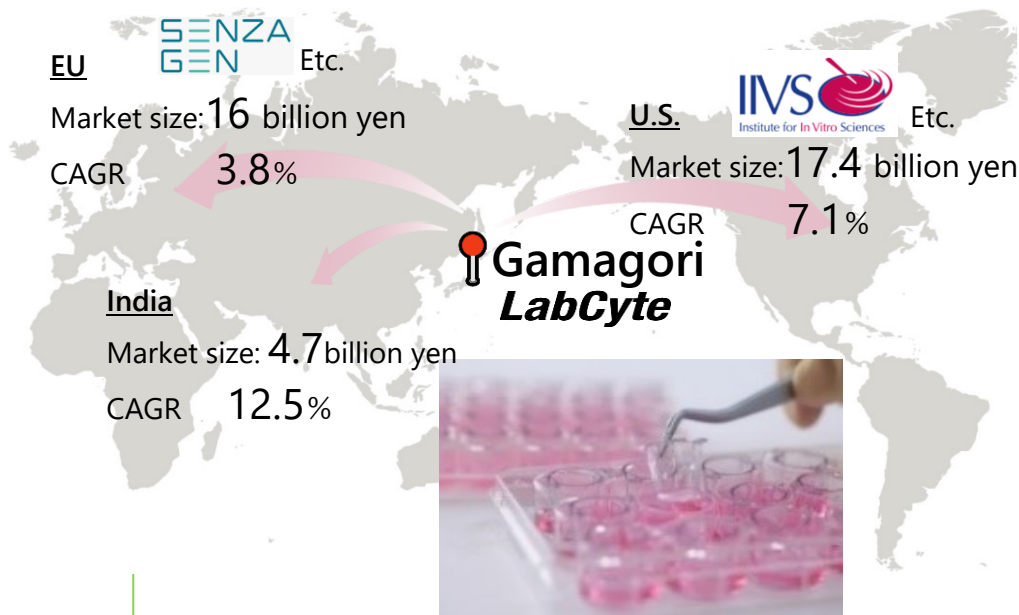
Leveraging **technology/expertise** not restricted by regenerative medicine regulations

+

Aiming for exponential growth as a sustainable business supporting alternatives to animal testing

LabCyte EPI-MODEL : Progress in Overseas Expansion for EpiSensA

- ✓ Overseas expansion activities are progressing smoothly. Expanding into the global market, with a focus on key markets in Europe and the U.S.



Market Size Forecast of the market size for skin irritation, corrosion, and sensitization testing (2025)
※For Europe, the total of five major countries is used

CAGR Growth rate for the period 2020-2025

Source MARKETSANDMARKETS 「IN VITRO TOXICITY TESTING MARKET GLOBAL FORECAST TO 2025」

Progress Report

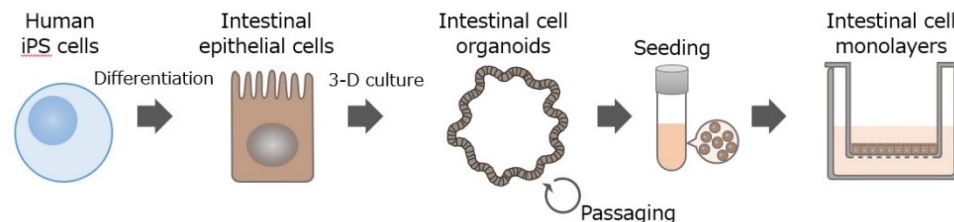
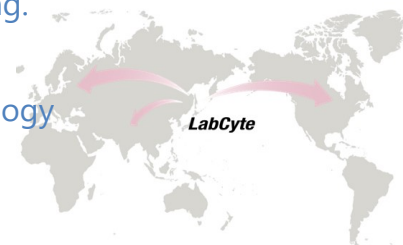
- | | |
|-------|---|
| EU/US | <ul style="list-style-type: none"> ✓ Started supplying products to several companies, mainly contract testing organizations ✓ Additionally, in discussions with multiple companies for validation ✓ Aiming to foster these relationships into stable, revenue-generating business partnerships |
| India | <ul style="list-style-type: none"> ✓ Through Shiven Biotech, inquiries from local contract testing organizations and cosmetic development companies are increasing ✓ Working to expand sales in the next fiscal year |

Regulatory Status on Animal Testing

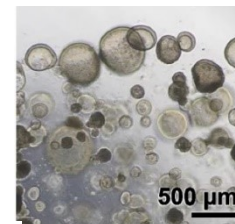
India	Animal testing for cosmetic development is prohibited
EU	Animal testing for cosmetic development is completely banned
U.S.	Legal bans are in place in 12 states, and major industry groups support federal legislation (as of 2023)

LabCyte New Product : Research-use Intestinal Epithelium Model

- ✓ 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



Process of creating an intestinal epithelial model using human iPS cells and organoid technology

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](#).

Strategic Direction for Growth Infrastructure

✓ New Export Strategy

- Building overseas sales routes for LabCyte (EU/US/India)
- Utilization of the Technology in the Field of Private Medical Practice (Kizu to kizu ato no Clinic)
- **Response to overseas inbound medical needs (Participation in MEJ*1)**

✓ Enhancement of Business and Production Functions

- **Planned expansion investment for GCPT-complaint facilities**
- Expansion of CMO capacity (Teijin joint venture)
- Automation of manufacturing and quality control functions (Sysmex Co.)

✓ Realization of new Technologies

- Exploration of new pipelines
- Development of new LabCyte products
- Support for realization of Japanese iPS cell technology

Human Resources

- ### ✓ Human Resource Development
- Developing of a nurturing environment for specialized talent
 - Activation of employee potential
 - Collaboration with educational institutions

Technology

✓ Information Dissemination to Society and the World

- Strengthening of PR and media outreach
- Sustainable development of regional collaboration
- **Cooperation with Osaka/Kansai Expo**

Society

Promote the rapid development of regenerative medicine and cell technology

*1 Medical Excellence JAPAN : Established in 2013 as a general incorporated association. Promotes Japan's inbound and outbound business in cooperation with the government, medical institutions, and companies. As of May 2025, has 43 member institutions

Promoting Open Innovation for Building a Growth Foundation

- ✓ To promote transformation towards growth under the new structure, **open innovation in each field will be advanced**



《Main Examples》

Capital and business alliance with VC Cell Therapy Co. for the commercialization of iPS cell products
(2025.1.14)

Basic agreement with Sysmex Co. for the advancement of manufacturing functions
(2024.12.5)

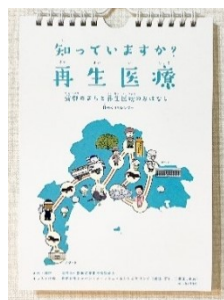
Contract with Shiven Biotech Co. for LabCyte
(2024.12.16)

Collaboration agreements with educational intuitions
2024.6.2 Ritsumeikan University,
2024.10.5 Kaiyo Academy
2025.4.15 Toyohashi University of Technology

Initiatives for Regional and Social Contribution

- ✓ Our company, in cooperation with Gamagori City, promotes **various activities** aimed at the development and spread of regenerative medicine, targeting everyone from elementary school students to adults.
- ✓ To support next-generation education, **promote industry-academia collaboration**, and **revitalize human resources**, we are advancing partnerships with educational institutions.

Involvement with the Local Community and Next-Generation Education through “Regenerative Medicine”



Easy-to-understand introduction to
“Regenerative Medicine”

(Regenerative Medicine town exhibit)



Agreement with Gamagori
City and Kaiyo Academy

(started October 5, 2024)

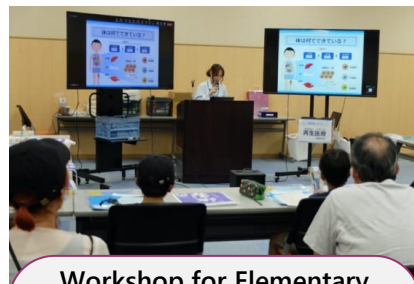


Agreement with
Ritsumeikan University
College of Pharmaceutical
Sciences (June 12, 2024)



Lecture on Regenerative
Medicine for Local Residents

(co-hosted with Gamagori city)



Workshop for Elementary
School Students

(co-hosted with Gamagori City)



Dispatch of students to the
Japan Society for
Regenerative Medicine

(For Junior and Senior High School Students)





Company tour for Junior
and High School Students

(Super Science High School Program)

Co-creation with Teijin

✓ Accelerating value co-creation across businesses and functions



	Regenerative Medical Product Business	Regenerative Medicine Contract Business	R&D Support Business
R&D	<ul style="list-style-type: none"> Joint exploration and research of new products 	<ul style="list-style-type: none"> Launch of operations at Kashiwanoha development outsourcing base Launch of operations at manufacturing outsourcing base "Iwakuni Factory" 	<ul style="list-style-type: none"> Development of Next-Gen LabCyte products
Production	<ul style="list-style-type: none"> Utilization of Teijin's engineering for Allo-JaCE03 production →Mechanization and automation 	<p>A Regenerative Medicine Platform that Delivers "One-Stop Services"</p> <div>  <p>Technical foundation for product design and stable manufacturing of regenerative medicine and related products</p>  <p>Technical expertise in R&D development, and manufacturing of pharmaceuticals and medical devices</p>  </div> <div> <p><u>National Cancer Center</u> Research cooperation and support based on the latest cancer treatment and research</p> <p><u>Mitsui Fudosan</u> Creation of spaces and communities for innovation promotion</p> </div>	<ul style="list-style-type: none"> Launch of contract testing services in collaboration with Teijin Structural Analysis Center Consideration of mechanization and automation
Sales	<ul style="list-style-type: none"> Strengthening of sales planning leveraging experienced personnel from Teijin Pharma Joint exploration of overseas expansion 	<ul style="list-style-type: none"> Launch of joint sales activities by J-TEC and Teijin Acceleration of partnerships with overseas entities <ul style="list-style-type: none"> ➢ Partnership with U.S. biotech CDMO company "National Resilience" (April, 2023) ➢ Business alliance with Singapore-based Hillman Laboratories regarding CDMO (October 2024) 	<ul style="list-style-type: none"> Collaboration for overseas expansion based at India location

3. Market Environment and Risks

Regenerative Medical Products Approved in Japan

- ✓ Our company successfully commercialized Japan's first regenerative medical product and continues to advance its development pipeline, holding the largest number of such products in the country

Approved regenerative medical products in Japan

In total **20**

J-TEC's Products **5**

(As of June 2025)



...Transplant-based



...Drug-administration-base

Approval Year	Product Name		Approval Year	Product Name	
2007	JACE ①	Autologous	2021	Ocural ④	Autologous
2012	JACC ②	Autologous	2021	Delytact Injection	Gene Therapy
2015	TEMCELL HS Injection	Allogenic	2021	Alofisel Injection	Allogenic
2018	Stemirac Injection	Autologous	2022	Sakracy	Autologous
2019	Kymriah Intravenous Infusion	Autologous	2022	Abecma Intravenous Infusion	Autologous
2020	Zolgensma Intravenous Infusion	Gene Therapy	2022	Carvykti Intravenous Infusion	Autologous
2020	Nepic ③	Autologous	2023	JACEMIN ⑤	Autologous
2021	YESCARTA Intravenous Infusion	Autologous	2023	Vyznova	Allogenic
2021	Breyanzi Injection	Autologous	2023	LUXTURN A Injection	Gene Therapy
			2024	AkuuGo Injection	Autologous
			2025	Elevidys intravenous infusion	Gene Therapy

Markets and Features of Our Products

- ✓ Our products target patients with diseases that lack effective treatments, including rare diseases, contributing to the **provision of new therapies and the improvement of patients' quality of life (QOL)**

Area	Disease	Number of patients	Positioning of Our Products	Competing Products
Skin	Severe Burns	Approx. 450 people/year ^{※1}	"JACE" enables treatment of severe burns over wide areas using a patient's own skin, contributing as a standard treatment for saving lives	"RECELL Autologous Cell Harvesting and non-cultured Cell Suspension Preparation Kit"
	Congenital giant pigmented nevus	Approx. 50 people/year ^{※2}	For small congenital pigmented nevi, excision and grafting with the patient's own skin is used, but not suitable for large areas. "JACE" allows one-time treatment from small to extensive nevus excision	none
	Epidermolysis bullosa	Approx. 20 people/year ^{※3}	Blisters and ulcers occurring on the skin were previously treated only by protection with wound dressings and natural healing. "JACE" promotes healing and can suppress the occurrence of blisters and ulcers	none
	Vitiligo	Approx. 2,000 people/year ^{※4}	Vitiligo is typically treated with phototherapy, oral, or topical drugs, but these are often ineffective or unsuitable. "JACEMIN" provides a new treatment option for such difficult cases.	none
Cartilage	Traumatic cartilage defects Osteochondritis dissecans	Approx. 1,300 people/year ^{※5}	For joint pain relief, hyaluronic acid injections are used, but "JACC" treats traumatic cartilage defects or osteochondritis dissecans of 4cm ² or more	none
Cornea	Limbal stem cell deficiency(LSCD)	Approx. 200 people/year ^{※6}	Nepic and Ocural can treat severe limbal stem cell deficiency for which no effective treatment existed. "Sakracy", used to alleviate symptoms on the ocular surface in LSCD, is also sold in Japan	Human amniotic membrane-based epithelial cell sheet derived from autologous oral mucosa- "Sakracy"

※1 Estimate based on the "Burn Treatment Manual, Revised 2nd Edition" and the "Population Estimates by the Statistics Bureau of the Ministry of Internal Affairs and Communications"

※2 Quoted from "Treatment of Congenital Giant Pigmented Nevus- Limitations of Current Therapies and Toward Expanding Indications for Autologous Cultured Epidermis"

※3 Quoted from "Guidelines for the Treatment of Rare and Intractable Diseases. III Epidermolysis Bullosa Part 2. Research on Rare and Intractable Diseases under the Ministry of Health, Labour and Welfare's Scientific Research Grant Program for Overcoming Intractable Diseases.

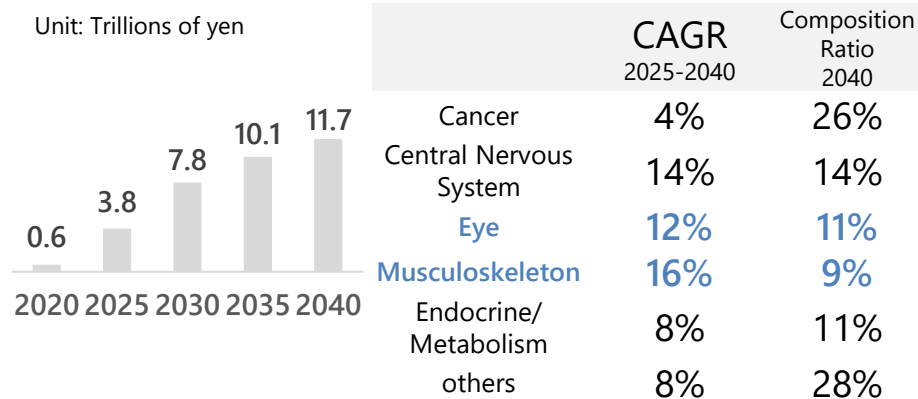
※4 Estimate based on "Intractable Congenital and Acquired Leukoderma and Albinism in the Field of Dermatological Diseases (FY 2011)" and the "Overview of the 2011 Abridged Life Tables" by the Ministry of Health, Labour and Welfare.

※5 Estimate based on the usage status of autologous chondrocyte transplantation overseas and the population ratio between Japan and the United States.

※6 Estimate based on performance data from a specialized hospital (Tokyo Dental College Ichikawa General Hospital) and the Ministry of Health, Labour and Welfare's statistics on medical practices by type.

Market Forecast for Regenerative Medical Product Business/Regenerative Medicine Contract Business

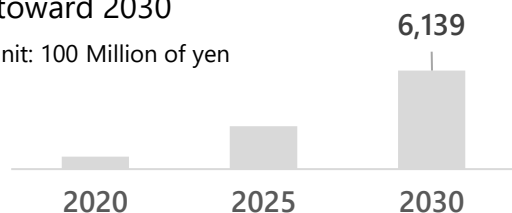
Global Market Forecast for Regenerative Medicine and Gene therapy



Domestic Market Forecast for Regenerative Medicine / Gene Therapy-Related Industries

Mainly expanding services such as contract manufacturing toward 2030

Unit: 100 Million of yen



Source: "analysis of Domestic and International Development Trends and Market Size Forecasts: Government Investment Trends" (Sep. 2 2020)

1st Regenerative and Cellular Medicine/Gene Therapy Development Council Material 4-Lecture Materials (conducted by Arthur D. Little

Our Market Perspective

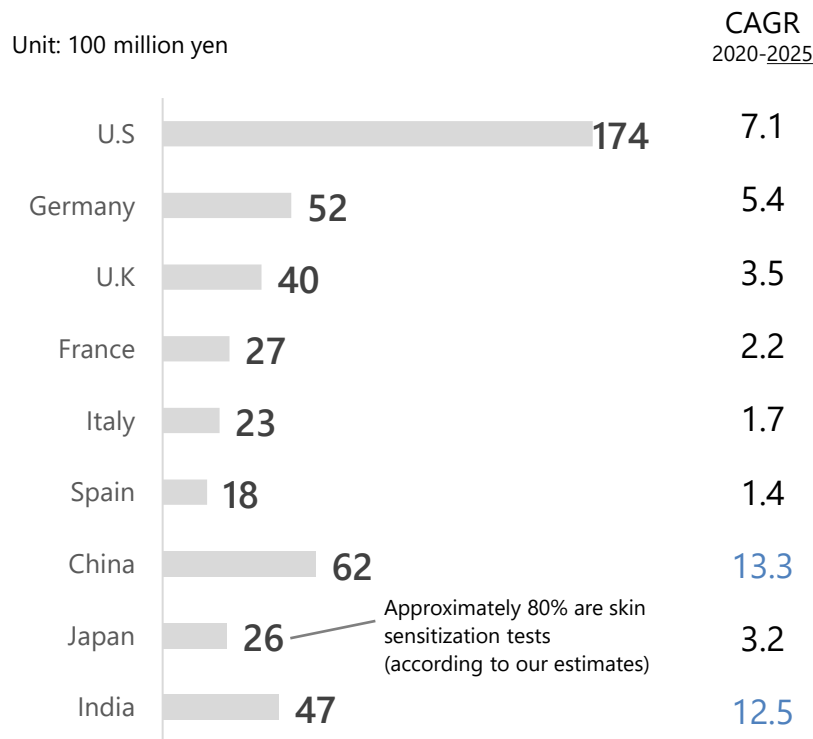
- ✓ The market for **products aimed at tissue regeneration**, an area in which our company excels, is showing a trend where **Japan takes the lead**, and **market growth is expected**.
- ✓ Including areas our company is working on, such as the eye and musculoskeletal system (cartilage), **global market expansion is anticipated**.

Our Direction

- ✓ **Technological innovation** including the expertise related to manufacturing and transportation of products with a three-dimensional structure aimed at tissue regeneration
- ✓ **Building an ecosystem with medical institutions**, etc., for reliable medical service including the optimization of surgical techniques
- ✓ Expansion of contract service business in line with the growth of the CDMO market related to regenerative medicine

Market Forecast for R&D Support business

Skin Irritation, Corrosion, and Sensitization Test Market Forecast (2025)



Source : MARKETSANDMARKETS 「IN VITRO TOXICITY TESTING MARKET
GLOBAL FORECAST TO 2025」

Our Market Perspective

- ✓ With the trend of replacing animal testing, **growth is expected globally, centered on skin sensitization tests.**
- ✓ **Even in the fields of medical devices and pharmaceuticals,** there is increasing activity in using alternatives to animal testing for safety evaluations

Our Direction

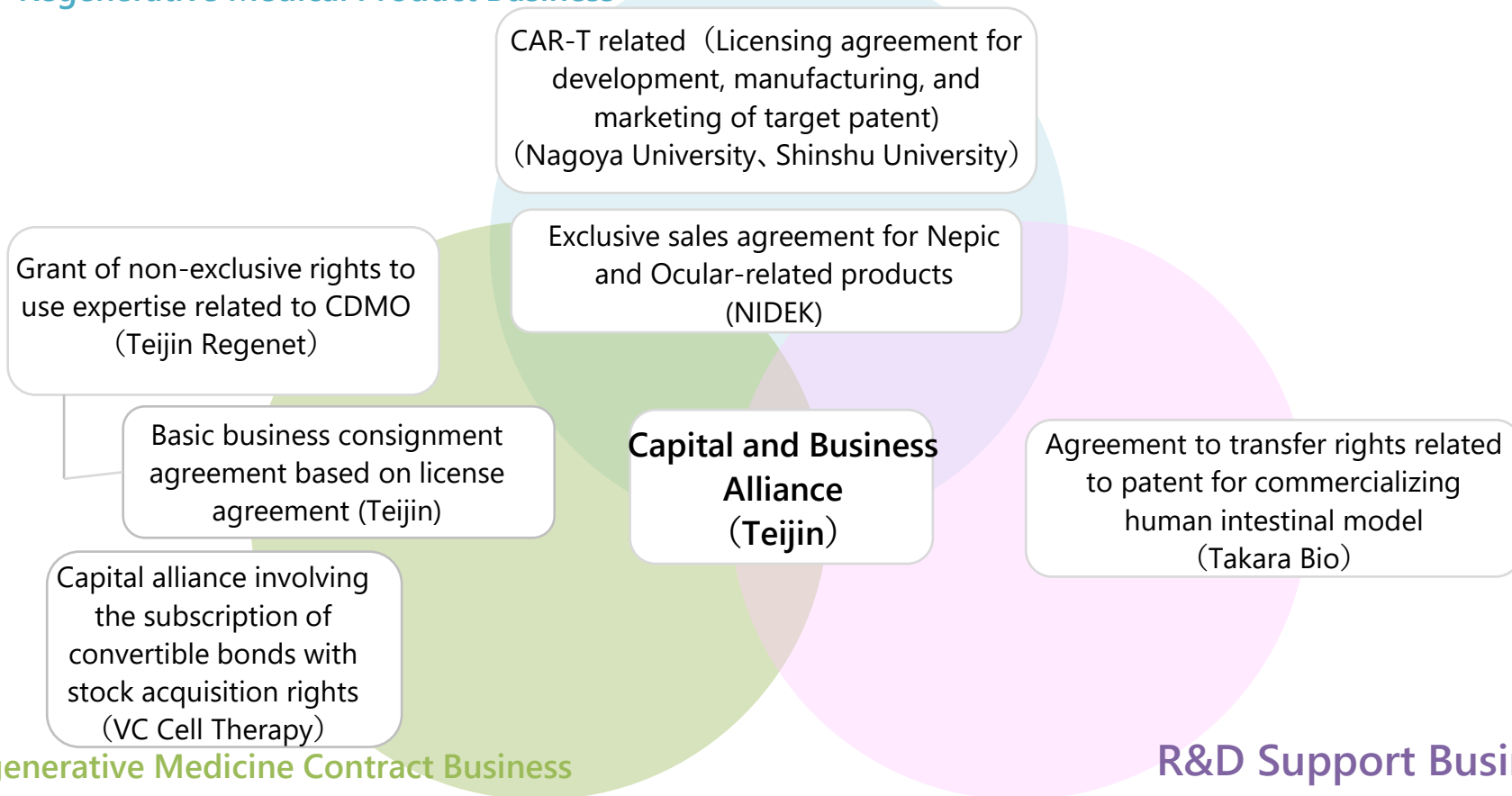
- ✓ **Strengthen overseas expansion of skin sensitization tests**
- ✓ **Promote guideline formulation (ISO inclusion) in the medical device field,** where market expansion is expected
- ✓ **Develop human intestinal epithelial models and aim to enter the pharmaceutical field**

Company		J-TEC	MatTek	EPISKIN
Headquarters		Japan	U.S	France
Guideline	Skin Corrosion Test (OECD TG431)	○	○	○
	Skin Irritation Test (OECD TG439) (ISO10993-023)	○	○	○
	Skin Sensitization Test (ISO 10993-10)	○	-	-
		Under development	-	-
Cost (Epidermal Model) ※Price for purchase in Japan		130,900yen (12/24well)	260,000yen (24well)	N/A

Important Contracts

Regenerative Medical Product Business

※For all contracts and their details, please refer to the securities report.



Risks Related to our Business

Major Risks	Overview of Major Risks	chance	Impact	Risk Mitigation Measures
Market size	<ul style="list-style-type: none"> Since the market size for our products is limited, even if we secure a certain market share, sales may fluctuate significantly due to factors such as changes in the occurrence of target conditions or the entry of other companies 	M	H	<ul style="list-style-type: none"> Collaborating closely with medical institutions and conducting outreach activities to appropriately identify target patients and minimize impact
	<ul style="list-style-type: none"> There is a possibility of contract termination or downsizing of consigned work depending on development progress or policy changes by consignor 			<ul style="list-style-type: none"> Working closely with contractors to understand their intentions and plans, and responding or making proposals in a timely manner to minimize impact
Regulations	<ul style="list-style-type: none"> If unpredictable legal revisions or drastic changes in the environment due to policy changes in healthcare administration occur, there is a possibility that our business strategy and performance may be affected 	M	M	<ul style="list-style-type: none"> Enhancing experience and expertise related to drug approval and engaging in close consultations with regulatory authorities to minimize impact
Stable product manufacturing	<ul style="list-style-type: none"> We use several essential raw materials and resources with no viable substitutes. If these cannot be procured, there is a possibility of suspension of in-house or outsourced product manufacturing 	M	H	<ul style="list-style-type: none"> Entering into stable supply contracts with suppliers Investigating, reviewing, and selecting substitutes for important raw materials and resources Establishing alternative technologies through the development of new manufacturing and testing methods
Loss of Human Resources	<ul style="list-style-type: none"> Possibility of increased employee turnover due to more competitors and demand for specialized personnel Possibility of resignation among employees desiring remote work due to the rise in companies adopting telework Loss of highly specialized employees may temporarily affect operations due to the time required for recruitment and training 	H	M	<ul style="list-style-type: none"> Recognizing and revising internal systems as needed to accommodate diverse working styles and internal/external conditions Aiming to improve employee satisfaction through initiatives such as meaningful job design and reward systems that enhance brand value and workplace engagement
Information Leaks	<ul style="list-style-type: none"> Possibility that employees may unintentionally provide confidential information to third parties Possibility of data leaks or losses caused by cyberattacks such as computer virus intrusions 	M	M	<ul style="list-style-type: none"> Thoroughly raise employee awareness regarding confidential information management through employment rules, pledges and training Strengthen network security and enforce employee education
Large-Scale Disasters/Pandemics	<ul style="list-style-type: none"> Possibility of business disruption as both headquarters and production bases are concentrated in one location Possibility of sales decline or development schedule delays due to postponement of surgeries and treatments in case of strain on the medical system Possibility of negative impact on business performance due to changes in research and development progress of clients and contractors (research institutions, etc.) 	L	H	<ul style="list-style-type: none"> Prepare infrastructure and operational systems assuming large-scale disasters Minimize business impact by understanding the actual situation and trends through close relationships with medical institutions and promoting new sales activities Investigate, examine, and select alternatives for raw materials and resources; build relationships with suppliers to prepare for emergencies

Reference) Company Overview

Business Area

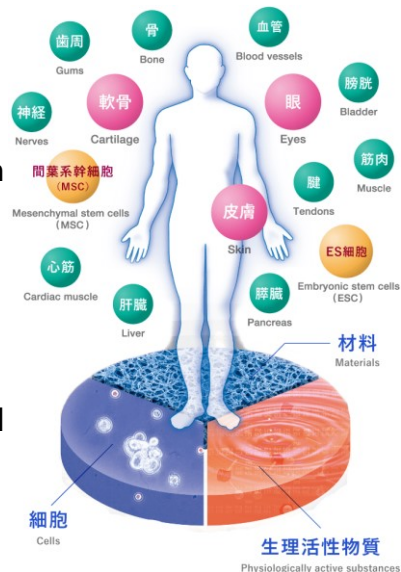
- ✓ Our company has been working on **building a system aimed at the industrialization of regenerative medicine** by developing and promoting “**autologous**” regenerative medicine, based on **cell culture technology through tissue engineering**

What is Tissue Engineering?

- ✓ Living cells
- ✓ Artificially created matrix (materials / scaffolds)
- ✓ Various bioactive substances that affect cells and the human body

Artificially creating tissues and organs using living cells while retaining as much of their original function as possible

Using the cultured cells themselves for the treatment of patients



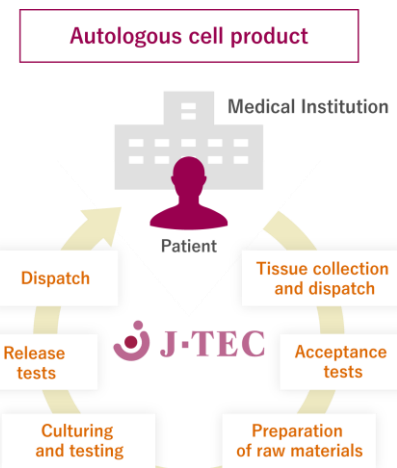
Autologous Regenerative Medicine

Characteristics of Autologous Cell-Based Products

- ✓ Risk of **rejection is extremely low, and safety is high**
- ✓ Takes time until treatment is available

Our Achievements

- ✓ **Building a system that includes all functions** to realize autologous regenerative medicine
- ✓ **Obtained approval for 5 products**



Basic Information and Company History

(as of March 31, 2025)

Basic Information

Company name	Japan Tissue Engineering Co., Ltd. Abbreviation : J-TEC
Head office Address	6-209-1 Miyakitadori, Gamagori, Aichi 443-0022, Japan
Representative	President and CEO: Kazuto Yamada
Established	February 1 st , 1999
Capital	4,958,760,000 yen
Employees	204
Business Areas	1. Regenerative Medical Product Business 2. Regenerative Medicine Contract Business 3. Research and Development Support Business
Listed Market	Tokyo Stock Exchange (listed Dec. 2007)
Major Shareholders	Teijin Limited (57.7%) NIDEK Co., Ltd. (10.4%)

History

1999	Company Founded
2009	Insurance coverage approved for autologous cultured epidermis "JACE" (for severe burns)
2013	Insurance coverage approved for autologous cultured cartilage "JACC"
2014	Became a subsidiary of FUJIFILM Corporation
2016	Insurance coverage approved for autologous cultured epidermis "JACE" (for Congenital Giant Nevus)
2019	Insurance coverage approved for autologous cultured epidermis "JACE" (for Epidermolysis Bullosa)
2020	Insurance coverage approved for autologous cultured corneal epithelium "Nepic" -Became a subsidiary of Teijin Limited
2021	-Insurance coverage approved for autologous cultured oral mucosal epithelium "Ocural"
2024	Insurance coverage approved for autologous cultured epidermis containing melanocytes "JACEMIN"
2025	Indication expansion approval obtained for autologous cultured cartilage "JACC" (for osteoarthritis of the knee)

Business Segments and Financial Results

- ✓ Position **all three businesses as growth businesses**

Business 1

Regenerative Medical Products

Providing "Regenerative Medicine" in the form of products



- ✓ Offering regenerative medical products by culturing and transplanting the patient's own cells
- ✓ Holding five products in areas such as skin, knee cartilage, and cornea
- ✓ Contributing to the healing of severe burn patients and fundamental treatment for intractable diseases

Business 2

Contract Services

Supporting the commercialization of "Regenerative Medicine"



- ✓ Offering comprehensive contract services from basic research to practical application, utilizing existing product development and manufacturing expertise
- ✓ Supporting the commercialization efforts of academia and industry, contributing to the overall expansion and growth of industry

Business 3

R&D Support

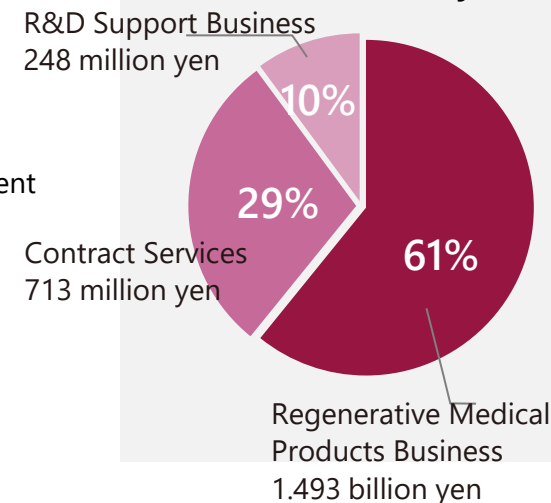
Providing "cultured human tissue" for research use



- ✓ Utilizing advanced culturing technology to provide research-use human cultured tissue (LabCyte Series)
- ✓ Used in basic research for the development of external-use pharmaceuticals and cosmetics, using skin and corneal tissues
- ✓ In line with the global trend toward banning animal testing, being widely adopted as an alternative to animal testing

Net Sales FY March, 2025

2.455 billion yen








Regenerative Medical Products Business Breakdown

(Unit: Millions of yen)

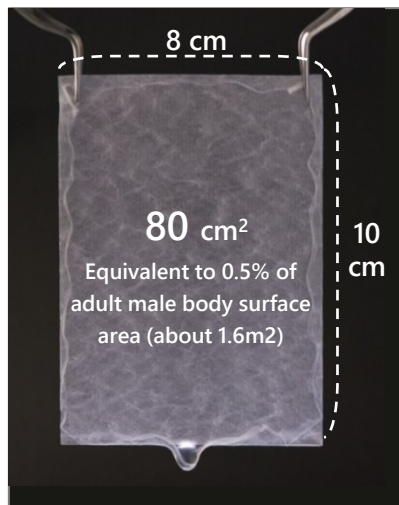
Skin	985
Cartilage	382
Corneal	125

Our Products

- ✓ All of our regenerative medical products have obtained manufacturing and marketing approval from the government and are provided under health insurance coverage

Product	Autologous Cultured Epidermis 	Autologous Cultured Cartilage 	Autologous Cultured corneal epithelium 	Autologous Cultured Oral Mucosal Epithelium 	Autologous Cultured Epidermis Containing Melanocytes 
	Japan's first approved regenerative medical product	Japan's second approved regenerative medical product developed using Japanese technology	First regenerative medical product in Japan for the corneal field	Second regenerative medical product in the ophthalmology field	Regenerative medical product for vitiligo, which affects many patients
Approval Insurance Listing	Oct. 2007 Jan. 2009	July 2012 Apr. 2013	Mar. 2020 June 2020	June 2021 Dec. 2021	Mar. 2023 Oct. 2024
Indications	① Severe burns ② Congenital giant pigmented nevus ③ Epidermolysis bullosa	① Cartilage defects or osteochondritis dissecans of the knee ② Osteoarthritis of the knee with cartilage defects	Limbal stem cell deficiency	Limbal stem cell deficiency	Intractable vitiligo unresponsive to non-surgical treatment
Insurance Price	✓ Harvesting/Culturing Kit 4,460,000 yen ✓ Processing/Transplant Kit 154,000 yen/ per sheet	✓ Harvesting/Culturing Kit 1,000,000 yen ✓ Processing/Transplant Kit 1,890,000 yen	✓ Harvesting/Culturing Kit 4,280,000 yen ✓ Processing/Transplant Kit 5,470,000 yen	✓ Harvesting/Culturing Kit 4,280,000 yen ✓ Processing/Transplant Kit 5,470,000 yen	✓ Harvesting/Culturing Kit 4,460,000 yen ✓ Processing/Transplant Kit 154,000 yen / per sheet
Technology Origin	Harvard University Professor Howard Green	Hiroshima University Professor Mitsuo Ochi	University of Modena Professor G Pellegrini· Professor M De Luca	Osaka University Professor Koji Nishida	University of Modena Professor G Pellegrini· Professor M De Luca

Autologous Cultured Epidermis "JACE"



Indications

① Severe Burns

Applicable for burns covering 30% or more of the body surface area, involving a combination of deep second-degree and third-degree burns

② Congenital Melanocytic Nevus

Applicable in cases where standard treatments cannot address the removal of the nevus, especially when it covers 5% or more of the body surface

③ Dystrophic Epidermolysis Bullosa and Junctional Epidermolysis Bullosa

Applicable to erosions and ulcers that have persisted for approximately four weeks, as well as recurring erosions and ulcers undergoing repeated ulceration and re-epithelialization

Insurance Reimbursement Price

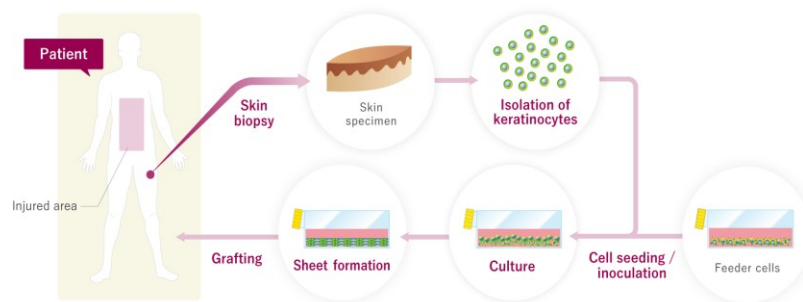
① Harvesting/Culturing Kit : 4,460,000 yen

② Processing/Transplant Kit : 154,000 yen/ per sheet

Limits: 40 sheets (for burns). However, if medically necessary, up to 50 sheets may be approved, provided the reason is stated in the appropriate section of the medical report. 30 sheets (for giant nevus), 50 sheets (for epidermolysis bullosa)

Technology Origin

Professor Howard Green of Harvard University



Autologous Cultured Cartilage "JACC"



Indications

① Relief of clinical symptoms of traumatic cartilage defects or osteochondritis dissecans of the knee joint.

However, it is limited to cases where no other treatment options are available, and the cartilage defect area is 4cm² or larger.

② Osteoarthritis of the Knee

Relief of clinical symptoms. However, this is limited to cases where clinical symptoms do not improve through conservative treatments such as exercise therapy, and cartilage defect area is 2cm² or larger

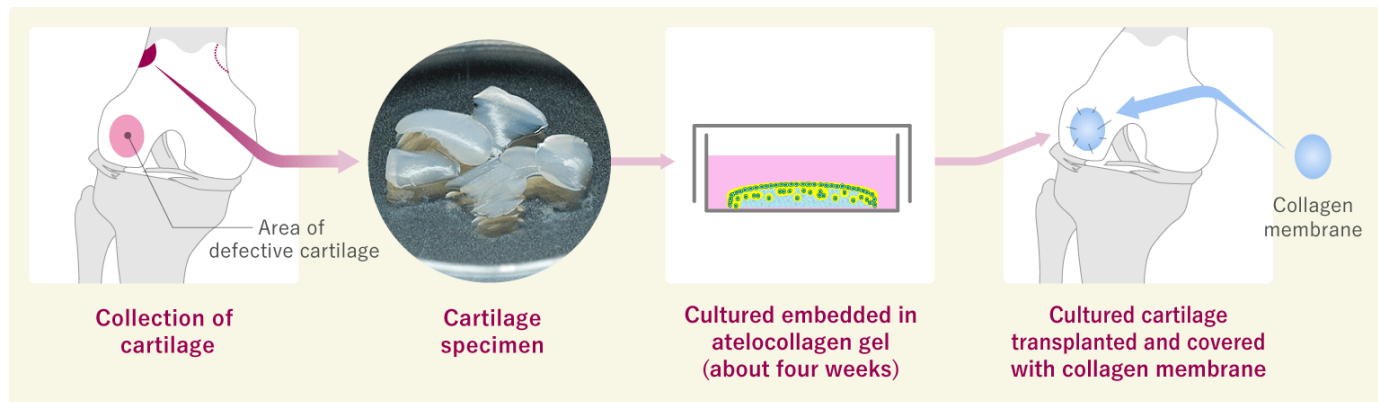
Insurance Reimbursement Price

① Harvesting/Culturing Kit : 1,000,000 yen

② Processing/Transplant Kit : 1,890,000 yen (number used not limited)

Technology Origin

Professor Mitsuo Ochi of Hiroshima University



Autologous Cultured Corneal Epithelium (Nepic)



Seller : NIDEK Co., Ltd.



Indications

Limbal Stem Cell Deficiency (LSCD)

However, the following patients are excluded:

- Patients with Steven-Johnson syndrome
- Patients with ocular pemphigoid
- Patients with graft-versus-host disease
- Patients with aniridia or other congenital corneal epithelial stem cell dysplasia
- Patients with recurrent pterygium
- Patients with idiopathic corneal epithelial stem cell deficiency

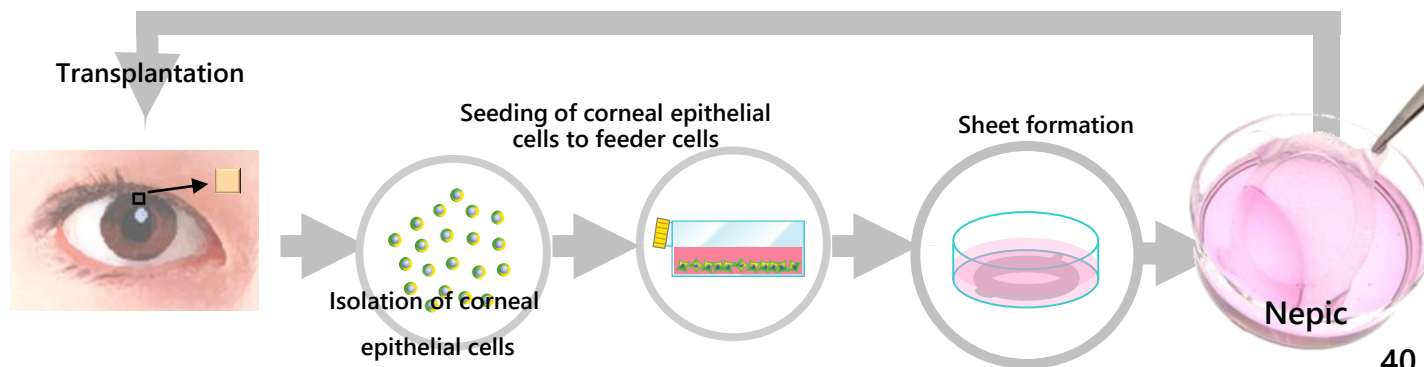
Insurance
Reimbursement
Price

① **Harvesting/Culturing Kit : 4,280,000 yen**

② **Cultured Corneal Epithelium Package : 5,470,000 yen**

Technology
Origin

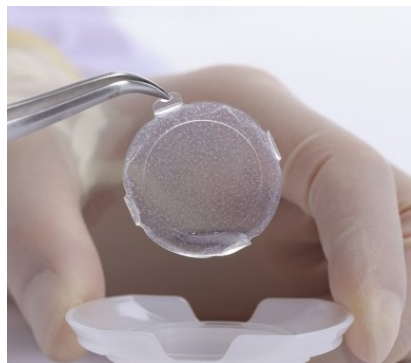
Professors G Pellegrini and M De Luca of the University of Modena (Italy)



Autologous Cultured Oral Mucosal Epithelium "Ocural"



Seller : NIDEK Co., Ltd.



Indications

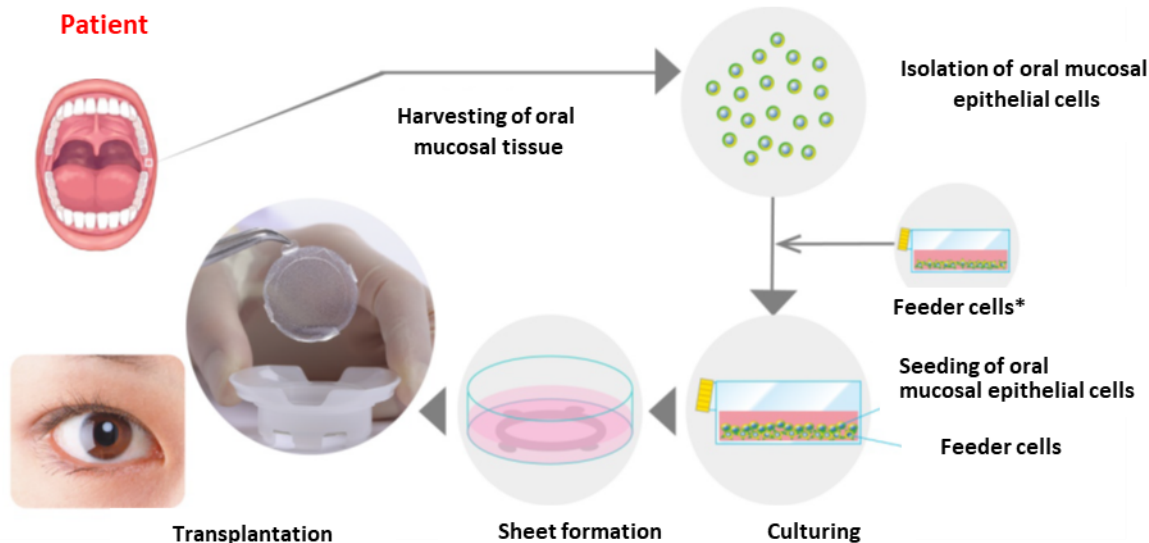
Limbal Stem Cell Deficiency (LSCD)

Insurance Reimbursement Price

- ① Harvesting/Culturing Kit : 4,280,000 yen
- ② Cultured Corneal Epithelium Package : 5,470,000 yen

Technology Origin

Professor Koji Nishida of Osaka University



Autologous Cultured Epidermis Containing Melanocytes (JACEMIN)



Indications

Vitiligo for which nonsurgical therapy is ineffective or not indicated

Vitiligo vulgaris which symptoms have been stable for approximately 12 months, Vogt-Koyanagi-Harada disease, complete depigmentation by chemical substance, and complete depigmentation due to congenital abnormalities such as piebaldism

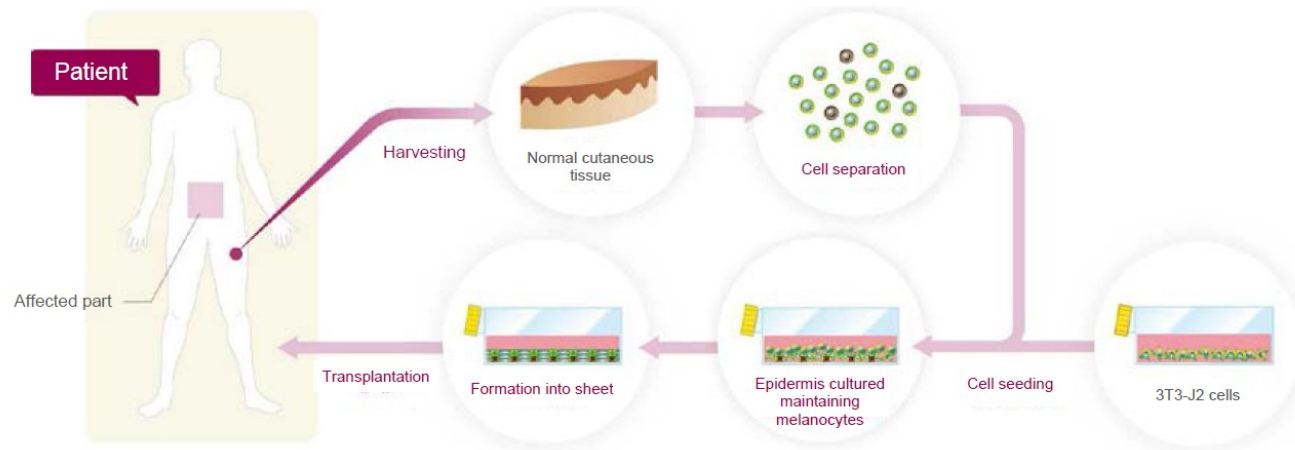
Insurance Reimbursement Price

① **Harvesting/Culturing Kit : 4,460,000 yen**

② **Cultured Corneal Epithelium Package : 154,000 yen/per sheet**

Technology Origin

Professors G Pellegrini and M De Luca of the University of Modena (Italy)



Business Model of Autologous Regenerative Medical Products

Product Supply Flow

- ✓ Cultivating cells received from the patient and manufacturing **autologous regenerative medical products**, then supplying them back to the patient
- ✓ Through **proprietary supply mechanisms and strong collaboration with medical institutions**, a stable system for manufacturing and supplying viable cell-based products is achieved



Value-chain

- ✓ Overcoming the unique difficulties of regenerative medical product development through experienced and capable personnel, **constructing a full value chain** from R&D to manufacturing, sales, and post-marketing support
- ✓ Realizing **reverse translational research** by feeding back clinical performance into product improvement and new product development

R&D	Conducting a unified process from basic research to product development research	Return
Clinical Development & Drug Development	Establishing joint development specific to regenerative medical products	
Quality Assurance & Safety Management	Ensuring quality and safety of cell-based products even after commercialization	
Sales & Marketing	Creating surgical technologies with physicians to improve treatment outcomes, and building logistics reliably supply autologous cell-based products	

Patient tissue
collection

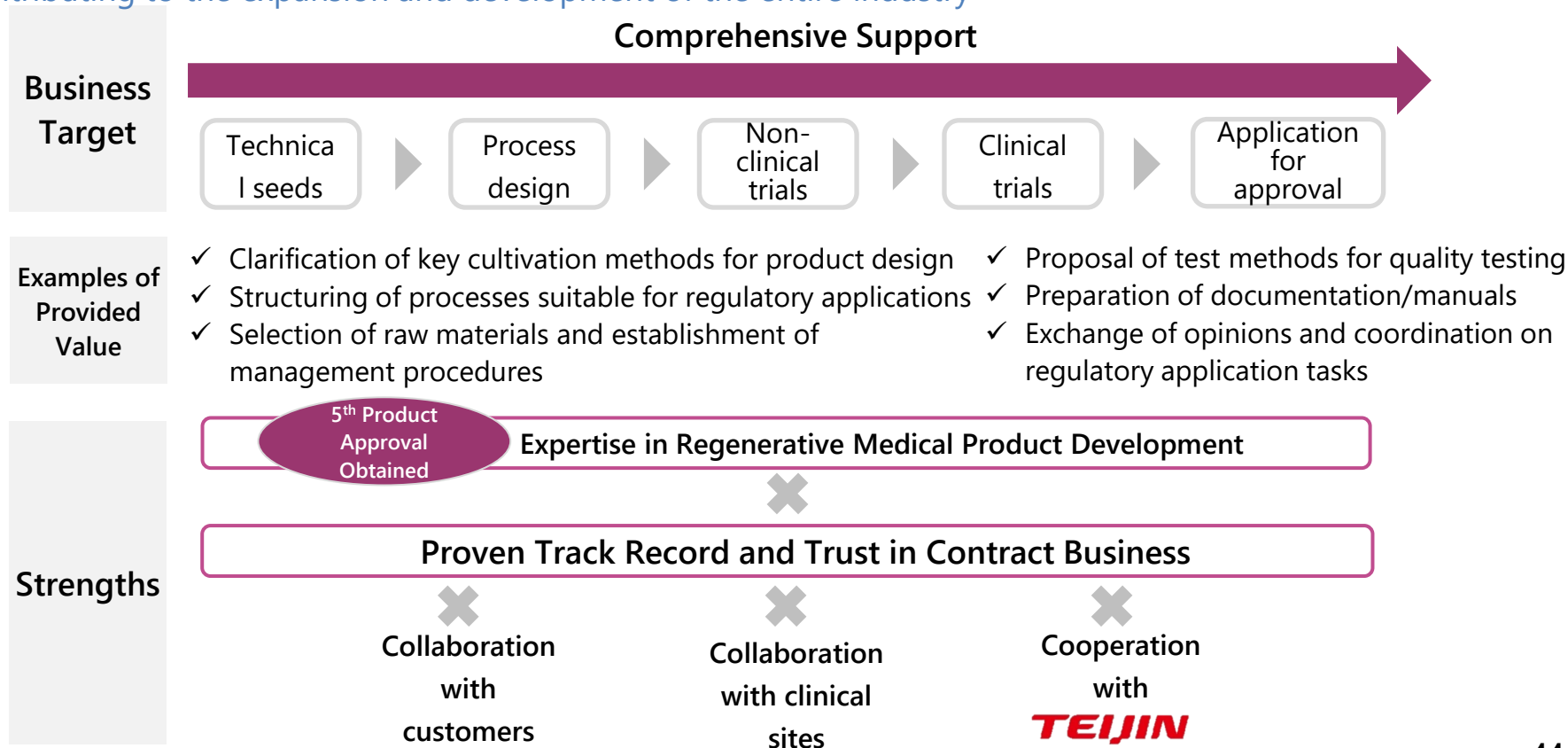
manufacturing

Product
Supply

Post-Marketing
Support

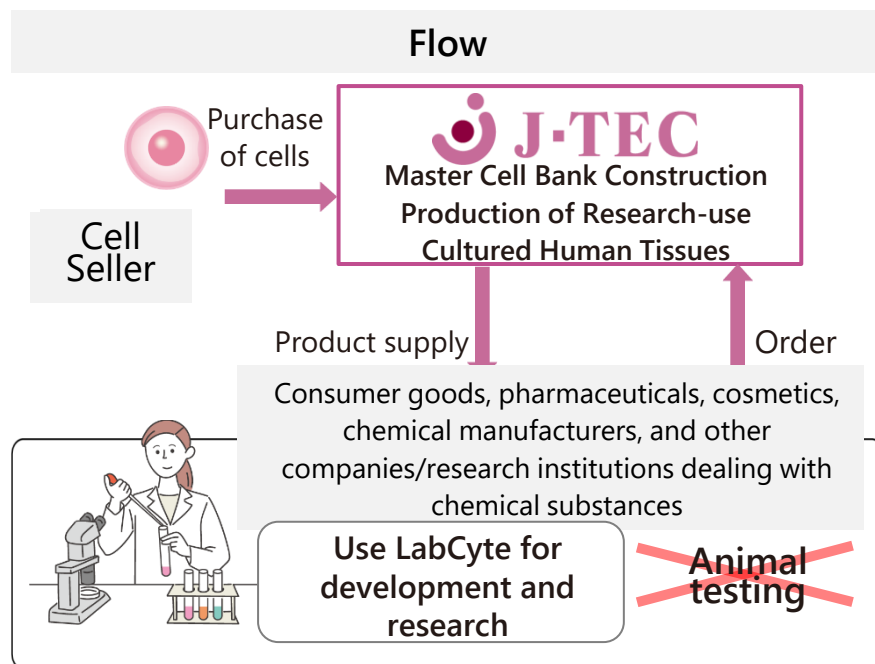
Business Model of Regenerative Medicine Contract Business




- ✓ Using the expertise we've accumulated, we provide **comprehensive support** through contract services, **contributing to the expansion and development of the entire industry**



Business Model of Research & Development Support

- ✓ Utilizing advanced cultivation technologies accumulated through the development of regenerative medical products, we sell research-use human cultured tissues under the “LabCyte Series”
- ✓ These human cultured tissues have 3-D structures and are used for basic research involving the development of topical pharmaceuticals and cosmetics, as well as studies involving skin and corneal tissues
- ✓ The world’s first “Skin Sensitization Test” included in the OECD Guidelines
- ✓ Aligned with the global trend of replacing animal testing from the perspective of animal welfare



	LabCyte EPI-MODEL	LabCyte EPI-KIT	LabCyte Corneal-Model
Product	3D Cultured Human Epidermis 	Epidermis Model Kit 	3D Cultured human Corneal Epithelium 
OECD Test Guidelines	Skin Irritation Test (TG439) Skin Corrosion Test (TG431) Skin Sensitization Test (TG442D)	—	Eye Irritation Test (TG492)
Product Launch	March 2005	April 2013	July 2010

Regarding the Information in this Presentation

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 from the content described in this presentation.

- ✓ The next disclosure of this information, “Business Plan and Growth Potential,” is scheduled for May 2026