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- : Information from materials provided by the client

DIAGNOSTIC REPORT ON HIDDEN POTENTIAL

reported by  Actcell

Person in charge of Analysis:
Mr. Yasushi Azegami (Director, Actcell Corporation)

This diagnostic report on J-TEC's hidden company potential has been prepared by an analyst from Actcell Corporation, an intellectual capital consulting company. Hidden company potential is a corporate asset that is not readily apparent in financial figures. This report was prepared employing Actcell's own methods, to visualize awareness of management issues and diagnose the potential of the organization through interviews. It focuses on the long-term potential of the organization for creating value. However, no guarantees are provided as to the content, its accuracy or completeness.

Japan Tissue Engineering Co., Ltd.

Company Profile

<http://www.jppte.co.jp/>



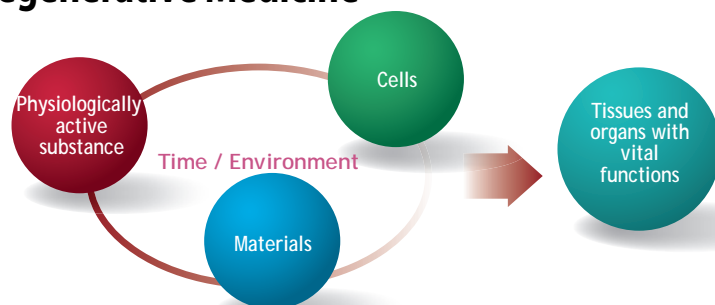
■ Corporate Information

Established: February, 1999
Initial Offering: December, 2007
Industry Sector: Precision Instruments
Listed Securities:
Exchange: JASDAQ NEO
Stock Code: 7774
Financial Year:
Ends: March
Representative: Mr. Yosuke Ozawa,
President and CEO
Headquarters: Gamagori City,
Aichi Prefecture
No. Employees: 105 / - consolidated basis
(current at March 31, 2009;
excludes external directors)

Frontrunner in Regenerative Medicine



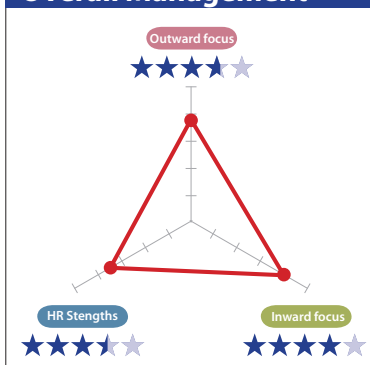
Mr. Yosuke Ozawa
President and CEO



**A 'manufacturing-style' business model
bio-venture aiming to
"industrialize regenerative medicine"**

Overall Diagnosis by ACTCELL

Overall Management



Characteristics and Strengths

Brand	★★★★★	J-TEC is the frontrunner paving the way for the regenerative medicine field, and the very first company in this field to be publicly-listed.
Technology & Know-how	★★★★★	Results and know-how in linking research findings to commercial realization.
Business Processes	★★★★★	Retaining all functions in the value chain for delivering new products to patients (R & D - Manufacturing - Sales - Post-marketing Surveillance)

Hopes and Expectations for the Future

Clients; Business Partners; Related Parties	★★★★★	Building relationships with hospitals that share an affinity with J-TEC's corporate philosophy; acquiring positive feedback from patients about their appreciation and/or high expectations of J-TEC's products.
Corporate Culture	★★★★★	Delegation of authority and affiliations that go beyond an organization's structure and hierarchy; an organizational approach focusing on collaboration, information and sharing.
Employees	★★★★★	Sustaining and further improving the excellent skills and motivational levels of J-TEC's employees, who are the driving force behind its future business expansion, and attracting new personnel.

[Business Environment and Company Position]

Regenerative medicine is a treatment method that uses the regenerative and healing abilities of cells to regenerate artificially cultured tissues. It is garnering a lot of attention as a next-generation medical treatment, as there are high expectations that it may act as a trump card for treating intractable diseases. Although the needs of patients with intractable diseases are potentially huge, a major prerequisite for the industrialization of this type of product is that it must be safe for the human body. Accordingly, close collaboration between industry and government is indispensable in this field of business. With this business environment as a backdrop, J-TEC was granted approval for coverage by National Health Insurance (NHI) for its autologous cultured epidermis as Japan's first tissue-engineered medical product (TEMP) on January 1st, 2009. J-TEC is pioneering this potential market in Japan, which is said to be worth several billion yen domestically. Having overcome various challenging hurdles to become the first manufacturer to successfully bring this type of product to commercial realization, high expectations are held that this will contribute to J-TEC's future earnings, and that both autologous cultured cartilage and corneal epithelium products will follow the trends set by cultured epidermis.

[J-TEC's Hidden Potential]

(1) The first regenerative medicine-related company in Japan to be granted manufacturing approval by MHLW and coverage under National Health Insurance (NHI). (2) As a bio-venture company, all research & development, manufacturing and sales functions are performed in-house. (3) Executive personnel and other employees demonstrate their ability to work closely together as a team to develop the business.

[Points of Interest]

The key to the company's growth lies in strengthening ties with external stakeholders and getting them involved.

★ The number of stars reflects the accumulation and usage status regarding the company's intellectual property (IP), current as at March 31, 2009, while the Notes describe the specific features and strengths of the intellectual property.

★ The number of stars reflects the accumulation and usage status regarding the company's intellectual property (IP), current as at March 31, 2009, while the Notes describe future hopes and expectations.

Description and Special Characteristics of the Company

J-TEC is a bio-venture corporation that was established with the objective of 'aiming to create a fundamental treatment through tissue regeneration. This treatment is based on tissue engineering techniques that will bring about real qualitative changes in medicine. J-TEC also aims to develop a business that will change 21st century medicine itself.' The company's principal business objectives involve the development, manufacture and sale of Tissue-Engineered Medical Products ('TEMPs') and other related products.

Tissue engineering is a concept that uses living cells to artificially create tissue or organs that retain their original functions to the fullest extent possible. This is based on the results of interdisciplinary studies that prove that tissue and organs with vital functions can be produced through an appropriate combination of the three elements of 'cells', 'materials' and 'physiologically active substances'.

Regenerative medicine is a discipline that focuses on restoring parts of the human body that may have been lost or damaged due to an accident or illness. Producing tissue or organs using tissue engineering techniques is one effective method for realizing regenerative medicine.

In addition to its tissue engineering techniques (from which the company's name is derived), J-TEC's fundamental business activities deal with cell culture technologies required for converting its products into commercial realities; having manufacturing plant and equipment authorized and licensed under the Pharmaceutical Affairs Law; manufacturing methods refined through research and development activities; quality control-related know-how; and sales-related organizational structure & know-how.

J-TEC's business can be classified in the two areas of Tissue-Engineered Medical Products ('TEMPs') (namely, autologous cultured epidermis, autologous cultured cartilage, and autologous cultured corneal epithelia) which are applicable under the Pharmaceutical Affairs Law, and Research & Development Support Business (cultured human tissue for research purposes), which is not applicable under the Pharmaceutical Affairs Law.

The Ministry of Health, Labor and Welfare (MHLW) granted manufacturing approval for J-TEC's autologous cultured epidermis in October 2007 as Japan's first medical product to use human cells and tissue. The product's retail name is JACE (J-TEC Autologous Cultured Epidermis), and indications include serious burns (large area burns). This product was newly approved for coverage by Japan's National Health Insurance (NHI) in January, 2009.

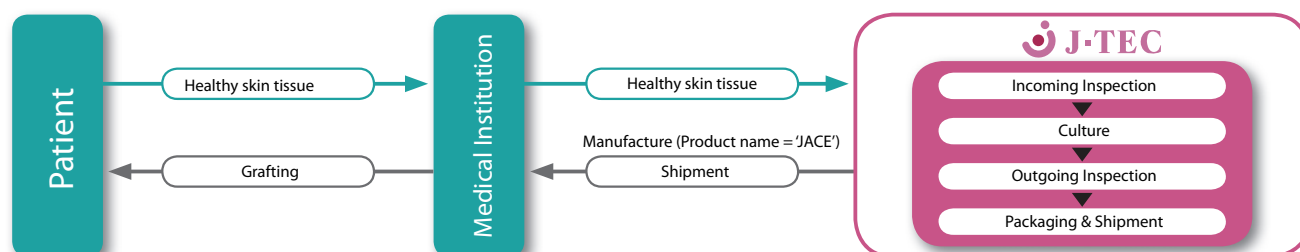


[Approval Number] 21900BZZ00039000
[Generic Name] Human autologous graft tissue
[Indications] Critical extensive burns that are second or third degree deep dermal burn wounds covering a total of 30% or more of the body surface

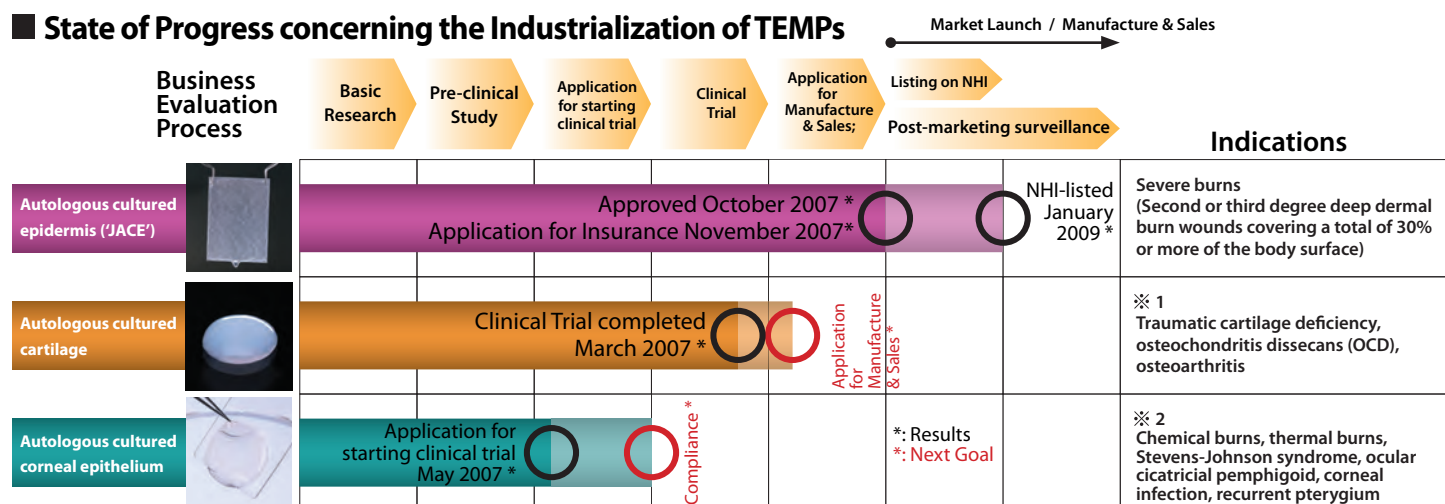
J-TEC completed its clinical trials for autologous cultured cartilage in March 2007, and is currently preparing to submit its application for manufacture and sales of this product. J-TEC also submitted its application to start a clinical trial for autologous cultured corneal epithelium in May 2007, and is working towards being granted compliance.

In April 2005, J-TEC began selling the LabCyte series of human cultured tissue for research purposes as development reagents in medical and cosmetic products, etc.

As a 'manufacturing-style' business model bio-venture corporation, J-TEC is working towards "industrializing regenerative medicine," by undertaking to perform not only all of its own research & development, but also the functional processes that range from business development through to manufacturing, sales and post-marketing practices, all in-house.



State of Progress concerning the Industrialization of TEMPs



※ 1 and ※ 2 are envisaged applications.

Strategies and Business Policies of Top Management

Please describe your business and tell us about your approach.

As a 'manufacturing-style' business model bio-venture, J-TEC is committed to "industrializing regenerative medicine," which is something that no other organization has ever attempted. Regenerative medicine endeavors to be a curative technique by restoring tissue and/or organs, that have been lost as a result of accident or illness, to their former state. J-TEC will provide this new treatment method known as regenerative medicine to patients, in addition to existing treatments incorporating pharmaceuticals or surgery, in order to contribute to improving their Quality Of Life (QOL). In October 2007, autologous cultured epidermis (offered under the name 'JACE') became Japan's first medical product using human cells and tissue to be granted manufacturing approval by the Ministry of Health, Labor and Welfare (MHLW), and in January 2009, JACE was further approved to be listed as covered under National Health Insurance (NHI). Development of an additional two products, namely, autologous cultured cartilage and autologous cultured corneal epithelium, is also progressing smoothly. As a manufacturer, J-TEC pursues quality and safety in its Tissue-Engineered Medical Products (abbreviated as 'TEMPs') so as to deliver products that excel in both these qualities to its customers.

Please describe any special characteristics or know-how involved in your company's technology.

The tissue-engineered medical products ('TEMPs') currently being developed by J-TEC are cultivated in our factory using tissue and/or cells harvested from the actual patient. These are then used in 'autologous transplantations' whereby the cultured tissue is grafted back onto the same patient. Autologous transplantations generally pose a minimal risk of immunological rejection and are said to have a high survival rate after grafting on the body. To manufacture and sell this type of TEMP, official permission and authorization must be granted by MHLW in accordance with the Pharmaceutical Affairs Law. As part of the process for obtaining approval to manufacture 'JACE' autologous cultured epidermis, J-TEC had to acquire the necessary cell culture technology for making the product a commercial reality, as well as accumulating know-how with regard to manufacturing methods and quality control refined through research and development activities. This is all in addition to our tissue engineering technology (from which our company name is derived). J-TEC's production facility has been granted GMP (Good Manufacturing Practice) accreditation by MHLW, making it the only plant in Japan capable of producing TEMPs on a commercial basis.



Aiming to Industrialize Regenerative Medicine

Mr. Yosuke Ozawa
President and CEO,
Japan Tissue Engineering Co., Ltd. ('J-TEC')

Please describe the qualities J-TEC demands from its employees.

As I mentioned previously, J-TEC is committed to "industrializing regenerative medicine," which is something that no other organization has ever attempted, so we look for personnel that can work together with us, just as a soccer player would do for his/her team. In other words, we look for people who are capable of flexibly but actively 'playing' outside of their fields of expertise, rather than sticking to a single, specific area of business. We don't believe it is sufficient for an employee to simply possess specialist knowledge in medicine and biology. Regardless of whether a person works within our Research & Development, Manufacturing, Pharmaceutical or Quality Control Departments, they are also expected to become involved in the business activities of other divisions, and to strengthen these inter-department bonds. In addition to the smooth implementation of the aforementioned activities, the field of regenerative medicine also requires a multitude of other skills such as expression, negotiation and analysis. Consequently, we have developed our own "Employee Education & Training Program" in an effort to improve the skills and capabilities of all our employees. I hope that J-TEC can serve as a place where we can accomplish the goal of "striving to live better," in accordance with our corporate philosophy.

Please tell us about the company's future business policies and outlook.

To begin with, we will concentrate J-TEC's management resources on launching 'JACE' autologous cultured epidermis. As Japan's first tissue-engineered medical product, the efficacy and safety of JACE needs to be thoroughly demonstrated and firmly grounded, with a view to industrializing regenerative medicine. Following this, we will proceed with ensuring we can bring J-TEC's next pipeline products, autologous cultured cartilage and autologous cultured corneal epithelium, to market. In the medium- to long-term, we foresee an increase in the number of people we employ, business tie-ups with many other companies, and formation of a complicated regenerative medicine industry. When this takes place, J-TEC will be bolstered by the professionalism of its personnel. In addition to creating 'tissue-engineered medical products (TEMPs)' and a 'regenerative medicine industry,' it can be said that J-TEC also educates and nurtures its 'people.' As a corporation involved in healthcare, we hope to steadily develop our business activities and become the type of company that society really needs. As a result, we aim to continue to grow as a company for as long as the human race exists.

What are the main aspects of running a bio-venture company?

Generally speaking, venture companies tend to lack management resources, namely people, materials, and money. However, J-TEC is blessed with stakeholders including stockholders, and has gathered together more than 100 very talented employees from all over Japan. We have our own manufacturing facility and have raised capital worth approximately JPY 9 billion so far (comprising just over JPY 6 billion before going public, and just under JPY 3 billion at the time of public offering). We believe that the main aspects to be conscious of when running a bio-venture company in this bioindustry-specific environment are as follows:

1. Producing results in the main businesses.
2. Resolving managerial mistakes promptly.
3. Always preparing for the 'worst-case scenario' when running the business.

Regenerative medicine has virtually no precedents within the bioindustry. Accordingly, Points #2 and #3 above will fall under the responsibility of management. Conversely, teamwork is required to achieve Point #1. J-TEC is driven by its people, and I believe that it is vital for our employees to have the backbone and tenacity to enable our company to progress as much as it can, and that we must create an environment in which these feats can be accomplished.

Visualizing Hidden Potential

**Autologous cultured epidermis - 'JACE'**

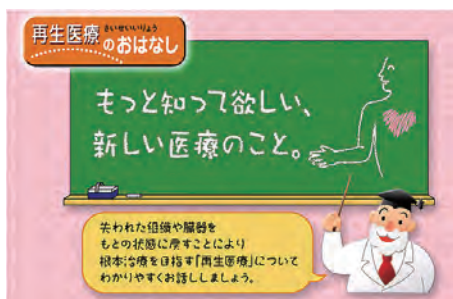
■ In October, 2007, this product became the very first tissue-engineered medical product (TEMP) in Japan to be granted manufacturing approval by the Ministry of Health, Labor and Welfare (MHLW). Indications are for severe burns. This product was newly approved for insurance coverage, being listed on Japan's National Health Insurance (NHI) in January, 2009.

**Manufacturing Facilities**

■ Japan Tissue Engineering Co., Ltd.'s production facility is the only manufacturing facility in Japan capable of producing TEMPs on a commercial basis that has been approved by the MHLW for GMP (Good Manufacturing Practice).

**Employee Award System**

■ Since 2006, we have incorporated a system for recognizing major contributions made throughout the year by individuals or teams towards our company's business development. We display the historical achievements of our award recipients on a wall of honor to remember these contributions long into the future.

**Discussing the Basics of Regenerative Medicine**

■ We have created a website and booklet full of easy-to-understand information, to encourage as many people as possible to learn more about regenerative medicine.

URL: <http://www.jp-te.co.jp/stories/index.html>

**Our employees are thoroughly versed in cell cultivation**

■ Every one of our employees involved in producing TEMPs has expert knowledge in cell cultivation, and has undertaken adequate educational training in specific information and cultivation techniques pertaining to TEMPs. Only those employees actively engaged in thoroughly mastering their craft are allowed to be involved in the manufacturing process.

**Education within the company**

■ Lecture sessions are held every month as part of our 'Employee Education & Training Program.' We make efforts to improve all of our employees' skills by engaging external lecturers as well as asking our own employees to give presentations.

Company History

- 1999** • Japan Tissue Engineering Co., Ltd was founded in Gamagori City, Aichi Prefecture, through joint capital investment funded by Nidek Co., Ltd., INAX Corporation, Toyama Chemical Co., Ltd. (now a group company of Fuji Film Holding Corporation) and Central Capital K.K. (now Mitsubishi UFJ Capital Co., Ltd.). Company headquarters were relocated to Miyakitadoori, Gamagori City, Aichi Prefecture.
- 2000** • Submission of pre-clinical trial application for confirmation of autologous cultured epidermis ('JACE') to the Ministry of Health and Welfare [MHW] (now the Ministry of Health, Labor and Welfare [MHLW]).
- 2001** • Submission of application for starting clinical trial of autologous cultured cartilage to MHLW.
- 2002** • Approval obtained from the Pharmaceutical Affairs Biotechnology Subcommittee of the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) for application to start clinical trial of autologous cultured epidermis ('JACE'); Notice of compliance received from MHLW.
- 2003** • Research and development on cultured corneal epithelia begins with technology introduced from The Veneto Eye Bank Foundation, which conducts stem cell research in Italy's Cornea Banks.
• Institutional Review Board (IRB) gives approval for clinical trials on autologous cultured epidermis ('JACE') to commence at facilities including those at Tokyo Women's Medical University Hospital.
- 2004** • Approval obtained from the Bio-based Technology Subcommittee of the Pharmaceutical Affairs and Food Sanitation Council (PAFSC) for application to start clinical trial of autologous cultured cartilage; Notice of compliance received from MHLW.
• Institutional Review Board (IRB) gives approval for clinical trials on autologous cultured cartilage to commence at facilities including those at Hiroshima University Hospital.
• Submission of application for manufacture and sales of autologous cultured epidermis ('JACE').
• Completion of, and relocation to, new company premises in Miyakitadoori, Gamagori City, Aichi Prefecture.
- 2005** • Approval received from MHLW for priority review on autologous cultured epidermis ('JACE').
• Sales of LabCyte EPI-MODEL cultured human tissue for research purposes begin.
- 2007** • Submission of notification of completion of clinical trials for autologous cultured cartilage to the Pharmaceutical and Medical Devices Agency, Japan (PDMA).
• Submission of application for starting clinical trial of autologous cultured corneal epithelium to MHLW.
• Approval obtained from MHLW to manufacture and sell autologous cultured epidermis ('JACE') as Japan's first medical product using human cells and tissues
• Submission to MHLW of official documents requesting insurance coverage, with the objective of securing a listing for autologous cultured epidermis ('JACE') to be approved for coverage under National Health Insurance (NHI).
• Became a NEO-listed company on the JASDAQ securities exchange.
- 2008** • Advisory contract concluded with Professor Howard Green of Harvard University.
- 2009** • Approval granted for listing of autologous cultured epidermis ('JACE') as covered under National Health Insurance (NHI).

Hopes & Expectations for J-TEC



Dr. Norio KUMAGAI

Professor, Department of Plastic and Reconstructive Surgery

St. Marianna University School of Medicine

University Website:
<http://www.marianna-u.ac.jp>

I have been conducting research on autologous cultured epidermis, which was developed by Professor Howard Green of Harvard Medical School, since the 1980s. In 1985, I reported the first case of treating severe burns in Japan using Dr. Green's autologous cultured epidermis technique. In the past 25 years, we have treated almost 600 cases of severe burns, scarring, vitiligo and nevi (birthmarks) in clinical practice using both autologous and allogeneic cultured epidermis.

A key feature of autologous cultured epidermis is that a large volume can be cultivated from a small sample of the patient's skin tissue. Furthermore, there is an extremely low risk of rejection response following grafting of the cultured epidermis to the patient, as the patient's own cells are used for cultivation. Conversely, there are individual differences in the propagating ability of cells when cultivating a patient's own cells. Dr. Green's autologous cultured epidermis uses a superb technique for propagating cells with 3T3-J2 cells as the feeder layer to supplement these individual differences.

The number of physicians in Japan with practical experience in the use of tissue engineered medical products (abbreviated as 'TEPs') is extremely limited. Therefore, I have high expectations that J-TEC will fulfill its mission of providing information and research materials to physicians and healthcare facilities, as well as educating them and proactively supporting educational activities, to ensure that physicians can provide appropriate treatment for cell harvesting and grafting as well as in post-graft patient care. Through these efforts, I feel sure that J-TEC will be able to establish a mechanism for popularizing regenerative medicine.



Dr. Kohichiro YOSHINO

President and CEO,
Carna Biosciences Inc.

Website:
<http://www.carnabio.com>

My company, Carna Biosciences Inc., aims to create medical products targeting an enzyme known as kinase, a type of protein. Like J-TEC, Carna Biosciences is also listed publicly on the JASDAQ NEO. During my regular discussions with Mr. Ozawa, we often speak of promoting NEO (New Entrepreneurs' Opportunity) through our efforts, and encourage each other with our dreams of further growing the biotechnology industry to become one that can support the nation.

Under Mr. Ozawa's energetic leadership, J-TEC has succeeded in industrializing regenerative medical products in the brand-new medical field of tissue engineering. In January this year, autologous cultured epidermis ('JACE') was listed as an item covered by Japan's National Health Insurance (NHI). Healthcare industry insiders viewed this as a landmark breakthrough, signifying that a new era in healthcare was beginning. It is necessary to demonstrate both 'safety' and 'effectiveness' in order to successfully industrialize this new field of healthcare known as regenerative medicine. As there are no precedents in this new field, every progressive step needs to be taken in close consultation with the Ministry of Health, Labor and Welfare (MHLW), and thus it became clear that bringing the product to commercial realization was an even more difficult task than had been imagined. Mr. Ozawa is optimistic, tenacious and full of ideas, which is exactly why he has succeeded with these great achievements.

In the future, we hope that Japan's NHI will agree to cover autologous cultured cartilage and autologous cultured corneal epithelium as promptly as possible, to facilitate the supply of these vital products to the many patients eagerly awaiting their industrialization.

Company Financial Performance

Year Ending	2005/March	2006/March	2007/March	2008/March	2009/March	2010/March (Est.)
Sales (million JPY)	40	68	103	111	114	361
Operating income (million JPY)	-712	-810	-973	-1,071	-1,102	-1,150
Ordinary income (million JPY)	-681	-793	-912	-1,049	-1,113	-1,173
Net income (million JPY)	-578	-690	-916	-1,086	-1,133	-1,177
Net income per share (JPY)	-9,719	-10,035	-13,269	-13,074	-11,218	-11,626
Dividend per share (JPY)	0	0	0	0	0	0

[Business Risk]

The following issues are some of the potential risk factors our company foresees might occur as our business develops. Please refer to our company's financial reports for further details.

- | | | |
|---|---|--|
| (1) Main Focus of Japan Tissue Engineering's Business | (5) Competition | (9) The Company's Organizational Structure |
| (2) Being a completely new field of business | (6) Intellectual Property Rights | (10) Product Liability Risks |
| (3) Changes in management performance | (7) Relationships with Universities and other Research Institutions | (11) Stakeholders, Key Players and Related Parties |
| (4) Research and Development Activities | (8) Company Premises | |

Actcell's Analysis of the Value Creation Process

The value creation process is a series of processes that incorporate a combination of "human resource strengths," "inward focus" and "outward focus" to create value.

Objective

To become the type of company that society truly needs by industrializing regenerative medicine. To continue to grow as a company for as long as the human race exists by contributing to improvements in our patients' Quality of Life (QOL) in compliance with ethics. As a result of these efforts, we hope to enable all of our stakeholders to live a better life.

Outward Focus

Item	Benchmark Figures	Remarks and Notes
Accomplishments at Academic Conference Presentations and Lecture Presentations	Number of lecture presentations given: 27	Between April 2008 and March, 2009 (Example of actual presentation) 'The 8th AGM of The Japanese Society for Regenerative Medicine,' 'Venture 2008 Kansai' and so on.
Notable Award Achievements	Received the 'Japan Bio-venture Grand Prize' at the 'Fourth Japan Bio-venture Grand Prix'	October, 2005 Held by 'Fuji Sankei Business i'
	Received the 'Highest Award' at the '2006 Chubu Economic Federation New Business Awards'	November, 2006 Held by Chubu Economic Federation
Patent Acquisition Status	Under examination: 60 cases (of which, 14 overseas) Registration of rights: 24 cases (of which, 13 overseas)	Current as at March 31, 2009
Qualification Acquisition Status	One dental practitioner / 6 Pharmacists / 8 Doctors of Philosophy / 3 clinical laboratory technicians	Current as at March 31, 2009
Business fields considered as national strategies	'Millennium Genome Project'	July, 2005. Prime Minister's Final Report
	'Vision of Medicine Industry,' 'New Vision of Medicine Industry'	August 2002, August 2007 MHLW
	'Broad Outline of Biotechnology Strategy'	December 2002, Biotechnology Strategy Meeting held by the Prime Minister's Office
	Cutting-edge medical development districts (Super special districts)	November 2008, Cabinet Office

(Documentation provided by J-TEC)

Inward Focus

<Research & Development>	Basic Research / Pre-clinical Studies / Clinical Trials / GLP		
<Pharmaceutical Development>	Application for starting Clinical Trials / Clinical Trials / Application for Manufacture & Sales / Listing on NHI / GCP		
<Reliability Assurance / Quality Assurance>	QMS / ISO9001 / ISO13485 / GQP / GMP / GVP / GPSP		
<Research & Development>	<ul style="list-style-type: none"> ● Sales core facility / selection of consultant physicians ● Educating and promoting to physicians, surgery and hospital staff ● Optimal logistics structure 	<ul style="list-style-type: none"> ● Determining Price of Product ● Promote understanding by patients and their families ● Advertising & Promoting TEMPs 	Margin
<<Acceptance of Patient Tissue>> <ul style="list-style-type: none"> ● Sterile, closed devices with temperature control ● Transport system ● Educating about tissue harvesting and transport procedures 	<<Manufacture>> <ul style="list-style-type: none"> ● Made-to-order system ● Cell cultivation procedures ● System for reporting progress status of cultures ● Outgoing inspection 	<<Product Supply>> <ul style="list-style-type: none"> ● Sterile devices with temperature control ● Transport system ● Procedural education at time of customer receipt 	
		<<Post-marketing Surveillance>> <ul style="list-style-type: none"> ● Post-marketing clinical trials ● Actual use studies ● Safety management system ● Records storage 	

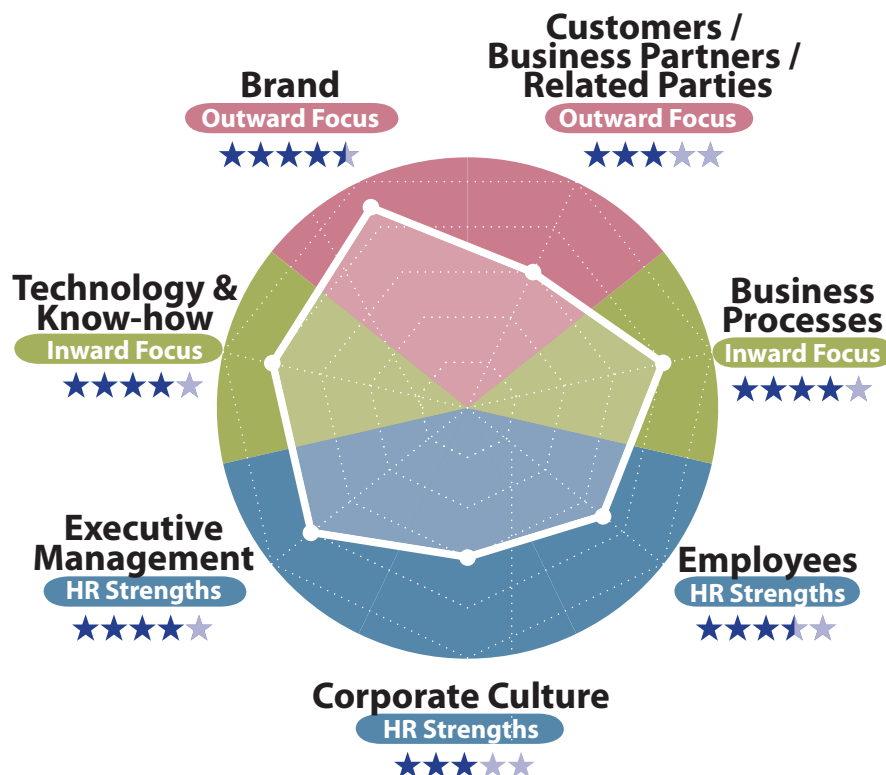
HR Strengths

Management Strategy	Carry around cards inscribed with the 'Objectives of founding the company,' 'Corporate philosophy,' and 'Behavioral Policies'
	A policy of always coming back to the corporate philosophy to make decisions whenever unsure
Education & Training	J-TEC's own 'Employee Education & Training Program'
	Support for improving skills such as expression, negotiation and analysis (for all employees)

No. of Employees (excluding external directors)	Good balanced ratio of male and female personnel
105 (54 male, 51 female) (current at March 31, 2009)	

: Category
 : Explanation of Category
 : Specific benchmarks for category

Actcell's Diagnosis of Hidden Potential



Outward Focus

The Brand and Innovative Capabilities as 'Frontrunners in Regenerative Medicine.'

J-TEC has boldly taken up the challenge to 'industrialize regenerative medicine,' a feat that no one else has succeeded in as yet. Already, the company has broken through numerous barriers on its way to achieving this goal. As a pioneering company with an ability to accomplish its innovations that is unmatched by any other company, J-TEC continues to formulate the No. 1 Brand in Japan's domestic regenerative medicine field.

As Japan's aging population continues to increase, so too does the national healthcare expenditure, reaching as much as JPY 33.4 trillion in 2007, equivalent to 8% or more of the country's GDP (Gross Domestic Product). The fact that healthcare costs are rising at a faster rate than the economy's rate of growth is cause for apprehension about the nation's future financial burden. The government is attempting to implement various measures to curb healthcare costs, such as revising medical treatment fee schedules, shortening hospital stays, and promoting generic drugs.

Despite these grim circumstances, J-TEC was granted coverage by National Health Insurance (NHI) for its JACE product (J-TEC Autologous Cultured Epidermis) as Japan's first Tissue-Engineered Medical Product (TEMP) on January 1st, 2009. However, the product's Points To Consider (PTC) specify that there are currently only a few more than twenty facilities that comply with the requirements for supplying JACE under insurance, and the coverage limit is set at a maximum of 20 JACE sheets per patient. Therefore, it remains very difficult for this product to become profitable. However, the achievement of being listed as covered by NHI has contributed to an environment in which both patients and medical institutions can now use this product with confidence. It could be said that J-TEC, as a 'manufacturing-style' business model bio-venture involved in much more than just research, has acted as a bridgehead in working towards making regenerative medicine more widely-known, as there had previously been some apprehension in the field regarding practical application of this product.

The addition of regenerative medicine as a new option, available together with existing treatment methods, may enable patients to select the best treatment method for

themselves in the future, as they will be able to consider treatment expenses and duration, efficacy & effects, and any risks of side-effects. In this case, the range of healthcare services would be expanded, and it has been predicted that this would result in a shift towards user-oriented services, where the patient makes a proactive choice about their treatment method, rather than a one-way decision made by the service provider. It is hoped that patients will consider and choose JACE as a suitable treatment option, and that gradually, a wide range of related parties will steadily come to acknowledge the value of autologous cultured epidermis. An expansion of sales channels will also be vital, and it is anticipated that J-TEC will build relationships based on mutual trust with various medical institutions in the future.

In contrast to the negative elements of healthcare financing's current predicament, there are actually high expectations for regenerative medicine to become the 'healthcare mode that will support the next generation.' In light of its acknowledgement of the problems being faced by the regenerative medicine system, the government established an Investigative Commission into Regenerative Medicine in March 2009, to discuss matters such as whether it should be made possible to commission external outsourcing of cell cultivation. Debate is scheduled to take place between relevant persons from industry, academia and government. J-TEC has already succeeded in overcoming numerous hurdles in its dealings with the Ministry of Health Labor and Welfare (MHLW) and regulatory authorities. These include being the first company to submit applications for starting clinical trials, implementing clinical trials, application for Manufacture & Sales of JACE, and managing to get autologous cultured epidermis listed for coverage under NHI. It could be said that J-TEC has built up special relationships that no other company can claim to have. Fees for medical treatments are scheduled to be revised in April 2010, at which time a number of aspects will be reviewed, including calculation limits, facility compliance requirements, and insurance reimbursement amounts. By continuing to steadily accumulate these various achievements, it is hoped that JACE will truly be able to begin making a profit.

In addition, the achievement of securing government backup in the form of National Health Insurance (NHI) coverage for autologous cultured epidermis in the field of regenerative medicine heightens the probability that insurance coverage may also be applied to the manufacture and sale of cartilage and corneal epithelia, and future movements will undoubtedly be watched with interest.

Inward Focus

Establishing a coherent value chain, from Research & Development through to Manufacturing, Sales and After-care Support

Although it is anticipated that the market for regenerative medicine will expand in the future, there are various hurdles to overcome before a product can become a commercial reality, such as the issues of safety and quality. Therefore, research findings do not necessarily translate immediately into the development of a business in this field. To successfully achieve industrialization, a manufacturer must have vital operational technology in order to facilitate a stable supply of the product.

J-TEC has a value chain function in place for delivering new products to patients (Research & Development, Manufacturing, Sales, Post-marketing surveillance). These are different 'strengths' to those found conventionally in 'research & development-style' business model bio-ventures. J-TEC is contributing to building a new business structure as a frontrunner, despite regenerative medicine's currently inadequate social infrastructure.

Furthermore, J-TEC has built up GMP (Good Manufacturing Practices) and QMS (Quality Management Systems) to ensure safety through its stringent quality control, while the company's strengths in production technology contribute to improving efficiency and risk reduction. Continuous improvements aimed at establishing unassailable business processes, such as more refined operating procedures and compilation of manuals, will also be vital in the future.

Major barriers for other companies wishing to participate in this market include the lengthy duration and expense required to perform clinical trials, and the extremely strict conditions that must be met in order for authorization and/or licensing to be granted. Despite this, it is anticipated that J-TEC will further demonstrate its strengths by accumulating know-how as it chalks up new milestones with each individual accomplishment and case example.

HR Strengths

It is vital to have a corporate environment that encourages employees to be independent, and a structure that will draw out their abilities and ideas

Effective leadership in management ensures that everyone in the company is thoroughly familiar with J-TEC's values (such as its corporate philosophy and behavioral policies), and the workforce itself comprises a talented group of highly-skilled and motivated people. However, a possible personnel shortage has been predicted as the company expands and grows from its current business development stage. Although appropriate training and education are not easy matters when it comes to a person's specific aptitude for research, plant and sales, education and training are necessary for the division leaders. Simultaneously, employee shortages need to be supplemented and/or internal capacity expanded through utilization of external skills and professionals.

In particular, it is not possible for products in the medical field to become well-known unless they are being used properly by the relevant professionals. Accordingly, education and training needs to be provided to middle-management employees so that they will be able to lead the field of regenerative medicine, as it will be vital for these employees to have a high degree of expertise in their business dealings with physicians or medical institutions.

In addition, decisions need to be flexible and dynamic in order to cope with uncertain elements and changes so that the company can develop further. Accordingly, other aspects that will become even more important include the progressive delegation of authority, getting each individual employee to become more conscious of actively participating in the company's management, together with business relationships and information-sharing that extend beyond organizations and hierarchy. J-TEC uses a soccer team analogy to describe what the company looks for in its employees, noting that the company educates and trains "personnel capable of flexibly but actively 'playing' across a wide range of disciplines." In order to continue to make the most of employee autonomy whilst demonstrating organizational abilities, Actcell believes that other possible strategies that could be pursued might include a personnel rotation system, an internal recruitment system (to assign suitable employees that are interested in participating in a particular task or project), or policies to further strengthen human resources as a venture corporation.

ABOUT THIS REPORT

Reading the Report

This Report was compiled by Actcell Corporation from analysis based on our own research of hidden potential (known as Intellectual Capital), which can be difficult to detect in a company's financial statements. We believe that it is crucial for a company to accumulate individual strengths, such as technological skills, human resources, and a strong client base, in order to create long-term corporate value, and to have "hidden potential" that effectively utilizes those resources. This Report is intended to provide information for reference purposes on the hidden potential (or Intellectual Capital) of the organization, and represents our understanding of characteristics and strengths of the organization. Accordingly, the information contained in this report is not intended for investment activities nor to attract investment. No analysis has been made of financial information such as stock prices or financial performance. This Report in no way intends to offer either investment or any other type of advice. Furthermore, any costs incurred in issuing this Report were borne by the organization that is the subject of the actual Report.

The ratings for Intellectual Capital range from 5 (★★★★★) representing the optimum state in which sufficient intellectual capital has been accumulated and is being properly utilized, to 1 (★☆☆☆☆) representing the state in which sufficient Intellectual Capital has not been accumulated and is not being properly utilized.

- ★★★★★...Initial level (minimal accumulated Intellectual Capital; management is haphazard; a confused state)
- ★★★★★...Replicable level (accumulation of foundation-level experience in Intellectual Capital through self-refinement)
- ★★★★★...Definite level (unique Intellectual Capital is defined; management processes to enhance Intellectual Capital are clearly set)
- ★★★★★...Under control level (possesses adequate Intellectual Capital and its maintenance and enhancement is managed quantitatively as a structure)
- ★★★★★...Optimum level (possesses optimum Intellectual Capital and is enhanced systematically and continually in the organization as a whole)

This Report has been compiled from scores that visualize management's recognition of issues, with analysis based on interviews. Therefore, the factors indicated below need to be taken into consideration with regard to high and low scores. Please use this Report as a material for assessing the company together with financial statements, including performance trends.

High score: Has reached management's satisfactory level = Score may be slightly higher when management's recognition of issues is low

Low score: Has not reached management's satisfactory level = Score may be slightly lower when management's recognition of issues is high

Terminology

● Outward focus

"Outward focus" describes the extent of awareness by the external parties of the company – clients, business partners, society, stockholders, etc. – and of establishment of relationships with them. This consists of Clients, Brand, and Business Partners, and stakeholders' strengths.

● Inward focus

"Inward focus" describes the extent of structure within the company to ensure the business runs smoothly. This consists of Business processes, and Technology and know-how strengths.

● Human resource (HR) strengths

"Human resource strengths" describe whether the "people" working for the organization do what needs to be done correctly and with satisfaction, and whether the environment is set up for them to do so. This consists of Management, Employees and Corporate Culture strengths.

● Clients' score

The analysis is a synthesis of the following:

- ① Does the company have many clients willing to consume and use its products, services, business, etc. on an ongoing basis, and is it maintaining them?
- ② Does the client base improve the credibility and reputation of the organization, and is the company acquiring and maintaining clients willing to nurture an ongoing relationship?
- ③ Is the company continually increasing sales from a highly loyal client base?
- ④ Is the company avoiding competing with its rivals, and maintaining sales consistently with minimal costs?

- ⑤ Is the company acting consciously to achieve these things?

● Brand score

The analysis is a synthesis of the following:

- ① To what extent do brand recognition, differentiation from the competitors, and credibility contribute?
- ② How capable is the brand of acquiring and maintaining clients?
- ③ Can the company connect abilities such as maintaining competitive pricing in negotiations to its performance?
- ④ Can the brand effect be extended to join together products and services?
- ⑤ Is the company building and using brands strategically?

● Business partners and stakeholders score

The analysis is a synthesis of the following:

- ① Does the strength of relationships with other interested parties go beyond individual transactions?
- ② How do transactions with and support from other stakeholders contribute to performance, competitive advantage and risk aversion?
- ③ What is the power balance between the company and the sales/marketing channels, and funding sources, such as suppliers, financial institutions and stockholders, that may have significant impact on the business?

● Organization / Corporate culture score

The analysis is a synthesis of the following:

- ① Are common values and objectives shared within the company, and is the company spontaneously and functionally operating consistent activities?
- ② Are action policies decided by management, along with

authorities and responsibilities, relayed promptly to the appropriate organization, and are they implemented in the same way?

- ③ Does the management carefully monitor and evaluate the result, and make changes where necessary?

● Technology and know-how score

The analysis is a synthesis of the following:

- ① What is the originality, difficulty of imitation and durability of value of the intellectual capital?
- ② Can the company maintain and improve the durability of this value?
- ③ Can the company convert its Intellectual Capital to apply it to products, services and businesses?
- ④ To what extent does the company's Intellectual Capital contribute directly or indirectly to enhancing the business value?
- ⑤ Is the company engaging in internal activities to improve and increase its Intellectual Capital, and in activities to form assets specific to the company by documentation and information-sharing?

● Business process score

The analysis is a synthesis of the following relating to the company's process of providing value to its clients, that is, the areas of the products and services development function, the operational function including procurement, production and distribution, the product planning and marketing function, the sales, marketing and services function and the financial and business administration functions:

- ① Is the company operating with high productivity and cost efficiency, and is its productivity standardized?

- ② Is the company enjoying advantages in terms of productivity and quality when compared with its competitors and within the industry?

- ③ Does the company have controls and strategies in place to improve the efficiency and functionality of the overall process?

● Management score

The analysis is a synthesis of the following:

- ① Is management equipped with such qualities as innovative leadership and comprehension of and insight to industry and markets that are indispensable for leading the company to sustainable growth?
- ② Is management proactively encouraging the creation of new value and improving organizational capacity beyond the current corporate scheme?
- ③ Is management taking the initiative itself?

● Employee score

The analysis is a synthesis of the following:

- ① Do the employees have the ability to undertake their tasks and the expertise to contribute to the company's business activities, and do they have a sense of belonging and motivation?
- ② Does the company have a clear picture of the employees it requires for sustainable growth?
- ③ Is the company properly evaluating, recruiting, developing, placing and retaining employees?

Guidelines followed by this Report

The structure of this Report corresponds to the Guidelines for Statements of Intellectual Capital Management issued by the Ministry of Economy, Trade and Industry (METI), which is a report on non-financial information, and the content of EBRC Framework Version 2.1. However, it may not necessarily cover all items outlined therein.

[Guidelines for Statements of Intellectual Capital Management] ※ From Page 4, '4. Representative examples of reporting on Intellectual Capital' of METI's Guidelines for Statements of Intellectual Capital Management.

Item / Content		Corresponding part of this report	
【Body of Statement】	(General) Outline of basic management philosophy/nature of business	Description and Special Characteristics of the Company Strategies and Business of Top Management	P2 P3
	(Past to Present) A. Past management policies / B. Investment (based on A) (including figures on performance) / C. Inherent Intellectual Capital accumulated by the organization (based on A and B), strengths and method of value creation founded on this Intellectual Capital (including supporting Intellectual Capital indicators) / D. Performance, such as profit (including figures) (resulting from the value creation in C)	Strategies and Business of Top Management Actcell Analysis of the Value Creation Process Company History Company Financial Performance	P3 P6 P4 P5
	(Present to Future) (based on C and diagnosis relating from Past to Present) E. Intellectual Capital firmly established in the organization that will continue to be valid in the future, and method of value creation based on this IC (including supporting intellectual capital indicators) / F. Recognition of future uncertainty and risk, responses to it, and management policies for the future that include these / G. New and additional investment required to maintain and develop Intellectual Capital (in alignment with management policies in F)(including figures) / H. Anticipated future earnings, etc. (based on these)(including numerical targets)		
【Appendices】	Other indicators of Intellectual Capital (Optional)	Actcell Diagnostic of Hidden Potential	P7

※ The Intellectual Capital indicators are likened to the "Seven Aspects for increasing Corporate Value" (see below)

- ① Management stance/Leadership, ② Selection and focus, ③ External negotiation power/Relationships, ④ Knowledge creation/Innovation/Speed, ⑤ Teamwork/Organizational knowledge, ⑥ Risk management/Governance, ⑦ Coexistence with society.

※ Please refer to ACTCELL's website (www.actcell.com) for the EBRC Framework.

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