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Life Sciences

Basic Policies of the 2018 Medium-term Management Plan
Cultivate future foundation business based on materials technology and diagnostic medicine business

Strengths

- Business experiences in Life Science field (medicine and diagnostics business)
- Accumulation of applicable technologies to the life science field (wiring board technologies and material technologies)
- Collaboration with other companies, other businesses and the Hitachi group

Weaknesses

- Inadequate interaction between R&D and building business models

Opportunities

- Rapid growth in the regenerative medicine markets
- Expansion of personalized medicine (including genetic diagnosis)
- Expansion of health care-related markets

Threats

- Aggressive competition among various players, including major players and start-ups
- Reduction in medical spending by governments

Outcomes and Strategies of the 2018 Medium-term Management Plan

FY2016 Progress	Initiatives for FY2017	Goals for FY2018	Goals for the 10-year Strategy
Regenerative Medicine <ul style="list-style-type: none"> • Decided to acquire 100% stake in U.S. company PCT • Began to construct the facility for the production and development of the cells for regenerative medicine (Japan). 	<ul style="list-style-type: none"> • Establish the foundations and launch contract cell manufacturing services • Proceed with the establishment of Japan business (complete production facility) 	<ul style="list-style-type: none"> • Complete grand design towards global expansion • Launch contract cell manufacturing services in Japan 	<ul style="list-style-type: none"> • Expand contract cell manufacturing services for regenerative medicine globally • Commercialize regenerative medicine consumables • Develop profitable businesses in the growing markets, such as immuno-/molecular diagnostics and POCT
Immuno- and Molecular Diagnostics <ul style="list-style-type: none"> • Delays in the development of a fully automated immunodiagnostic instrument • Started large-scale clinical studies with The University of Texas MD Anderson Cancer Center, focusing on the molecular analysis of CTC 	<ul style="list-style-type: none"> • Strengthen fundamental business through M&As and other means, and develop next-generation allergy systems • Establish foundations for molecular diagnostics business 	<ul style="list-style-type: none"> • Establish the foundations for the immuno- and POCT diagnostics business and develop a system for molecular diagnostics business 	
M&A/Alliance strategies <p>Hitachi Chemical has been focusing on the establishment of infrastructure to enter the business in molecular diagnostics and regenerative medicine through the acquisition of technologies and business foundations from the outside.</p>			

■ Fiscal Year 2016 Progress

The fiscal year 2016 was a year for establishing business foundations for the Life Sciences through the utilization of external resources. In order to gain a foothold in the regenerative medicine business, we made a decision to wholly own the Company, PCT, LLC, located in the U.S., and their global marketing rights of its contract cell manufacturing services. In addition, we decided to invest ¥2 billion to build a new facility for the development and contract cell manufacturing of regenerative medicine cells in Yokohama, Japan.

In parallel, Hitachi Chemical entered into a strategic alliance agreement with The University of Texas MD Anderson Cancer Center in the U.S. for the evaluation of our CTC capturing system and large-scale clinical studies towards molecular diagnostics. Moreover, we have just begun to find new partners in order to build our business foundations in diagnostics.

■ Key Measures for Fiscal Year 2017

Establish business foundations for regenerative medicine

The worldwide market of regenerative medicine is expected to exceed ¥3 trillion in 2025. We have been eager to establish our presence in contract cell manufacturing for regenerative medicine, through collaboration with the Hitachi Group's expertise in the latest production technologies and the application of effective mass production technologies developed by PCT, LLC for regenerative medicine cells. The new facility is expected to initiate trial operations in December 2017. We will focus on the commer-

PCT

PCT Cell Therapy Services, LLC
(formerly PCT, LLC, a Caladrius Company)

The University of Texas MD Anderson Cancer Center

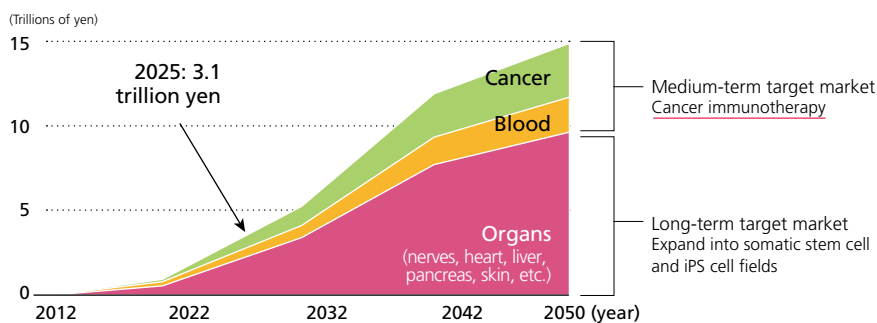
A large-scale cancer center specializing in cancer treatment, prevention, research, and education in Texas Medical Center in Houston, Texas.

CTC

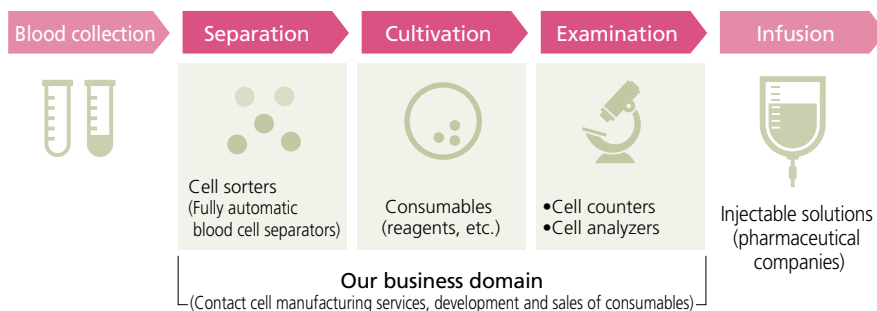
Circulating Tumor Cells (CTC) are cells that are carried around the body in circulation shed into the vasculature or lymphatics from a primary tumor. CTC is considered to be associated with metastases, forming additional tumors in vital distant organs. Recently, CTC has been receiving attention as an alternative and low-invasive method to biopsies for cancer diagnosing.

cialization of contract cell manufacturing services as well as the development of fully-automated cell production technology.

Global market forecast for regenerative medicine cells by application
(Source: compiled from Ministry of Economy, Trade and Industry data in 2013)



Cancer immunotherapy cell culture process and target domain



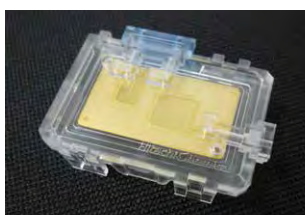
Establish business platforms for immune, POCT and molecular diagnostics

We will explore new markets including overseas, due to the saturation of the domestic diagnostics market. The new diagnostics should cover not only conventional diagnostics for diseases but also personalized diagnostics, including the prediction of efficacy of therapy or individual differences of side effects. We will develop a molecular diagnostics business which can be applied to personalized diagnostics, profitable businesses with high growth rates, such as immunodiagnostics, and POCT, in the fields of oncology and allergy. Especially for molecular diagnostics business, we will determine a business model, which enables us to create the synergy between our material and process technologies through developing the CTC diagnostics technologies and clinical test items.

Product examples: CTC Capture System

CTC has been receiving attention as an alternative method to conventional biopsies in cancer diagnosis, which cause pain and bleeding. A clinical test utilizing CTC has already been approved in the United States as a method for prognosis of patients with metastatic breast, colorectal or prostate cancer.

The CTC Capture System developed by Hitachi Chemical comprises of a filter with micro-pores and a fully automated blood processing instrument. The filter, which applies Hitachi Chemical's unique micro-fabrication technology, enables us to capture cancer cells in blood with high recovery rate.



Fine filter for CTC Capture System



Fully automated blood processing instrument

POCT

Point of Care Testing. Defined as a medical diagnostic test at or near the patients.

Cancer immunotherapy

A treatment that purifies immune cells in withdrawn blood that is activated by gene transduction, expanded and injected back to patient so that activated immune cells will drive out cancer cells.

Main products

Allergy Diagnostic Systems

This product measures the levels of allergen-specific IgE antibodies in human serum, which helps physicians identify the allergens responsible for the patients' symptoms. 36 major allergens can be measured with a single serum sample by this product.



In-Vitro Diagnostic Kit for Anti-Chlamydia Pneumoniae IgA, IgG and IgM Antibodies

This product is a test kit for the diagnosis of C. pneumoniae infection, which causes respiratory diseases such as pneumonia and acute upper respiratory tract infection, etc.



Hitachi Chemical's Strength

At a Glance

Our Strategy

Our Initiatives