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Life Sciences

Basic Policies of the 2018 Medium-term Management Plan

Cultivate future foundation of business based on materials technology and diagnostic reagent business

Strengths

- Business experiences in Life Science field (pharmaceutical 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 medical care (treatment) (including genetic diagnosis)
- Expansion of health care-related markets

Threats

- Aggressive competition among various players, including major players and venture businesses
- Policies for reduction in medical spending

M&A/Alliance strategies

Hitachi Chemical has been focusing on the establishment of infrastructure in the field of diagnostic reagent business and regenerative medicine through the acquisition of technologies and business foundations from the outside.

Kyowa Medex Co., Ltd.

Kyowa Medex has an extensive lineup of products such as diagnostic reagents used in tests for dyslipidemia, diabetes, cancer and renal diseases. In particular, the company has large shares in Japan related to dyslipidemia, and diabetes.

HCATS

Hitachi Chemical Advanced Therapeutic Solutions, LLC (formerly PCT Cell Therapy Services, LLC) is highly skilled in the development of regenerative products technologies for manufacturing and testing as well as business operations.

Fiscal Year 2017 Progress

Building our business foundation by utilizing external resources through M&A, alliances and other methods brought us a good result.

In the regenerative medicine business, we invested nearly ¥2 billion and opened a new facility for the development and contract manufacturing for regenerative cells in Yokohama. This is one of the largest facilities of its kind in Japan. We also successfully received orders from clients. Entering into agreements for contract cell manufacturing with two companies, Daiichi Sankyo Co. Ltd. and SanBio Co. Ltd., we laid the foundation for the full-scale launch of our contract cell manufacturing business. Moreover, we concluded a technical license agreement with Accellta Ltd., an Israeli company with advanced technology for making culture media.

In the diagnostic reagents business, Kyowa Medex Co., Ltd., a company that specializes in diagnostic reagents for diseases such as diabetes and dyslipidemia, has become our consolidated subsidiary through which we have a robust foundation for our diagnostic reagents. We have launched efforts including the mutual utilization of business locations and sales networks, improvement of our product lineups and addition of specialized personnel.

Key Measures for Fiscal Year 2018

Establish business foundations for regenerative medicine

The worldwide market of regenerative medicine is expected to exceed ¥3 trillion in 2025. We will strive to establish our presence in partnership with the Hitachi Group to develop technology for the mass production of regenerative products and by leveraging HCATS' fully automated cell production technology. Contract cell manufacturing from Daiichi Sankyo Co., Ltd. and SanBio Co., Ltd. will launch on a full scale. The addition of clean rooms is also planned with the aim of speedily addressing our clients' needs for contract cell manufacturing.

We will also build a system for streamlining our manufacturing practices using Accellta's latest culture media technology.

Cultivation process of cancer immunotherapy and scope of our business



(Development of manufacturing methods and contracted manufacturing of regenerative medicine products, and development and sale of consumable supplies)

Outputs and Strategies of the 2018 Medium-term Management Plan

FY2017 Progress	Initiatives for FY2018	Goals for FY2018	Goals for the 10-year Strategy
Regenerative Medicine <ul style="list-style-type: none"> Laid the business foundations and began developing manufacturing methods and contracted manufacturing of regenerative medicine products (entered contracted manufacturing agreements with SanBio Co., Ltd. and Daiichi Sankyo Co., Ltd.). Proceed with project launch in Japan (open contract manufacturing facility in Yokohama, which started business in April 2018) 	<ul style="list-style-type: none"> Fully launch contract cell manufacturing with SanBio Co., Ltd. and Daiichi Sankyo Co., Ltd. Additionally establish a contract cell manufacturing facility in Yokohama for receiving new orders 	<ul style="list-style-type: none"> Complete grand design towards global expansion Start developing manufacturing methods and contracted manufacturing of regenerative medicine products in Japan 	<p>Become a global player in the development of manufacturing methods and contracted manufacturing of regenerative medicine products</p> <p>Commercialize regenerative medicine consumables</p> <p>Develop profitable businesses in the growing markets, such as immuno-/genetic diagnostics and POCT</p>
Immuno- and Genetic Diagnostics <ul style="list-style-type: none"> Obtain a business foundation for diagnostic reagents through M&A (turning Kyowa Medex Co., Ltd. into our consolidated subsidiary) Continue the development of next-generation allergy systems Continue efforts to establish a business foundation for genetic diagnostic reagents 	<ul style="list-style-type: none"> Establish a system for immunodiagnostic and POCT diagnostic reagents Establish a PMI (Post-merger Integration) process for generating a synergy effect Continue efforts to establish a business foundation for genetic diagnostic reagents Establish a system for exploring new themes in genetic diagnostic reagents 	<ul style="list-style-type: none"> Establish the foundations for the immuno- and POCT diagnostics business and develop a system for genetic diagnostics business 	

Establish business platforms for immune, POCT and genetic diagnostics

Now that Kyowa Medex is our consolidated subsidiary, we have built a foundation for our domestic projects. In addition to mutual supplementation of product lineups, Hitachi Chemical's technological strengths and sales network in the United States will be utilized in an effort to explore markets for immune, POCT and molecular diagnosis, which concern high-value added diagnostic reagents. Kyowa Medex will function as the core of the Hitachi Chemical Group's diagnostic reagents. Also, in partnership with the HCA R&D Center, a facility characterized by its geographic advantage in the United States, we will build a system for generating a synergy effect when launching new themes in molecular diagnostics, immunodiagnosis and POCT.

POCT

Point of Care Testing
This collectively refers to tests performed near a patient, such as in a general practitioner's office.

	Hitachi Chemical	Kyowa Medex
Genetics	Cancer (under development)	
Immunology	Allergies, Infectious diseases	Heart disease, Infectious diseases, Cancer, HbA1c
Biochemical		Dyslipidemia, Diabetes, Kidney disease

Work to expand business by mutually complementing resources

HbA1c

Hemoglobin A1c
A form of hemoglobin that binds to glucose. Similar to blood glucose level, it is used in the diagnosis of diabetes.

Product examples

Diagnostics and Instruments of Kyowa Medex Co., Ltd.

Kyowa Medex Co., Ltd., which became a consolidated subsidiary in fiscal year 2017, is primarily engaged in the research and development and manufacturing and sale of in vitro diagnostics and automated analyzers used in clinical testing at medical institutions and registered clinical laboratories.



Reagents for clinical chemistry analyzers
These products are test reagents used in analyzers of biological sample material such as human serum, plasma and urine. Kyowa Medex offers a product lineup that addresses a wide range of testing needs, including measuring LDL cholesterol and neutral fat levels for diagnosing dyslipidemia and blood sugar levels and hemoglobin A1c used to diagnose diabetes.



Immunological test reagents and analyzers
These products are reagents and analyzers that utilize antibody immune responses to analyze biological materials such as human serum, plasma and urine. Measurements include tumor markers, cardiovascular risk markers, infection-related markers, hormones, markers of bone turnover, and faecal occult blood (bowel cancer screening).



Multi-allergen simultaneous test (MAST Immuno 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. The system simultaneously measures 48 IgE antibodies including antibodies to pollen and food allergens, enabling the collection of a large amount of data in a single test.



POCT (Point of Care Testing) products
These are products that enable test results to be obtained quickly and simply in a variety of healthcare settings. Products include A1cGear Quick K for glycohemoglobin, Uropisu S for urine analysis, Tear Total IgE Detection Kit for allergic conjunctivitis and Quick Chaser Flu A, B for influenza virus.