Bioscience Business

Nichirei Biosciences Inc.
https://nichireibiosciences.com/

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Transformation of the Bioscience Business

Nichirei started its bioscience business in the 1980s as part of a drive to create new businesses. In addition to the import and sale of fetal bovine serum used in cell culture, we expanded our business through the manufacture and sale of placenta extract, which is a raw material for cosmetics.

Since the 1990s, we have also been conducting a raw materials for biologics manufacturing business (involving the import and sale of cell culture media[1]), a functional materials business[2] (involving the sale of acerola powder and other products), a molecular diagnostics business (involving the development, manufacture and sale of diagnostic agents using antibodies), and a rapid diagnostics business (currently the immunochromatographic assay business).

In 2006, we began sales of automated immunostaining devices in our molecular diagnostics business, and in 2019 we established the Global Innovation Center as a new R&D and production facility. We also acquired Pathcom Systems Corporation (Pathcom), an automated immunostaining device manufacturer in the United States, and took other steps to provide high-quality products and services that leverage our technological capabilities globally.

Progress of Medium-term Business Plan Compass Rose 2024

In FY2023 (the fiscal year ended March 31, 2023), the first year of Compass Rose 2024, although Japan made progress in establishing a medical system to deal with COVID-19, the virus continued to spread. Consequently, both net sales and operating profit of the bioscience business increased significantly compared with FY2022, driven by the immunochromatographic assay business.

In the immunochromatographic assay business, the difficulty of predicting the number of infections, unlike with previous seasonal infectious diseases, made it necessary to establish a system for rapidly supplying antigen test kits to respond to repeated, large-scale outbreaks of COVID-19. We struggled to keep up with demand until FY2022, when we reconfigured our supply system by collaborating with a manufacturer of diagnostic agents in China in addition to producing antigen test kits in-house. This enabled us to adequately meet testing demand in FY2023, when the number of infections rose significantly, leading to business opportunities. We intend to shorten the lead time for supplying antigen test kits by further ramping up collaboration and will promote alliances with new sales partners. Moreover, the start of over-the-counter sales of COVID-19 antigen test kits represents a new opportunity, which we will address by dealing with pharmaceutical affairs requirements, establishing sales routes and strengthening our organizational structure to respond flexibly to changes in the market environment. We will also continue developing products that reflect market needs for simultaneous testing for multiple infectious diseases and less invasive specimen collection methods.

In the molecular diagnostics business, which we have positioned as a growth area, FY2023 sales increased compared with the previous fiscal year as a result of significant achievements including the launch of new immunostaining antibody reagents, increased sales of fully automated immunostaining devices and growth in sales of bulk reagent products for overseas markets. We will continue to promote sales of fully automated immunostaining devices in the pathological diagnosis market to maintain our share of the device market and improve profitability by expanding sales of reagents for fully automated immunostaining devices. In addition, a specialized diagnostic agent for a genetic testing device in-licensed from Biocartis Group NV of Belgium has received regulatory approval as a companion diagnostic agent[3] for colorectal cancer. We will therefore promote sales of the companion diagnostic agent along with the testing device. In our overseas business, we will continue addressing pharmaceutical affairs and quality system regulations in the United States in preparation for the start of sales of reagents. We will also build a stable supply system for bulk products for overseas markets. To improve profitability, Pathcom will adjust the selling price of its fully automated immunostaining devices to cover rising component procurement costs.

In the raw materials for biologics manufacturing business, FY2023 sales and operating profit were on par with the previous fiscal year. In FY2024, we aim to improve capital efficiency by working to optimize inventories through expedited sales of serum in stock based on purchase reservations and by controlling the volume of new purchases. We will also work to increase new business transactions, backed by the growing market for serum and cell culture media used in the development and manufacture of biopharmaceuticals, regenerative medicine products and vaccines.

One characteristic of Nichirei Biosciences is an earnings structure with a higher gross profit margin than other businesses in the Nichirei Group. Over the past three years, however, the timing of establishing our new R&D and production base coincided with worsening business performance due to the impact of COVID-19, resulting in a significant drop in the ratio of operating profit to net sales. We have been returning to our previous earnings structure due to the recovery in business results in FY2023. We will continue to reduce capital used and shift to a business model with a competitive advantage to continue enhancing the overall profitability of the bioscience business.

Progress of Material Matters for the Group

Having set forth our vision to continue to support people's health by creating new value, we are focusing on the material matter of creating new value in food and health. Needs are expected to continue rising for pathological diagnosis of cancer patients, who are increasing in number as Japan's population ages, and for rapid diagnosis of infectious diseases such as influenza and COVID-19. We believe that our business, which is directly involved in resolving such social issues, is highly valuable, and we will continue striving to provide unique added value through our high-quality, technology-based products and services.

In FY2023, we received a silver rating[4] in an assessment by the global sustainability platform EcoVadis for the second consecutive year. We will step up our efforts even further in FY2024.

Regarding the active participation of diverse human resources, approximately half of our regular employees are women, and the ratio of women employees in management positions exceeds 20%. We will raise this level further by creating an environment that facilitates women's participation.

1. Liquids or powders containing ingredients for mammalian cell culture. Powders are used in solution.
2. The functional materials business was transferred to Nichirei Foods Inc. in June 2021.
3. In-vitro diagnostics for testing one's biomarkers or genes, enabling patients to receive appropriate drugs or therapies. Uses include improving the efficacy and safety of certain drugs and assessing whether patients are eligible for molecular targeted cancer therapies.
4. A global authority for assessment of sustainability and supply chains, this organization has rated more than 100,000 organizations and companies in 200 industries in 175 countries, in the areas of the environment, labor and human rights, ethics and sustainable procurement. The silver rating is awarded to only the top 25% of all companies that undergo the assessment.

Material Matter 1 Creating New Value in Food and Health

Specialized Diagnostic Agent for a Genetic Testing Device Receives Regulatory Approval as a Companion Diagnostic Agent for Colorectal Cancer

Nichirei Biosciences is promoting the uptake in Japan of a specialized diagnostic agent for a genetic testing device developed by its partner Biocartis Group NV. In 2022 and 2023, we obtained approval to manufacture and sell two in-vitro diagnostics that use this specialized agent as companion diagnostic agents for molecular targeted therapies for colorectal cancer. This groundbreaking technology allows the medical institution where a patient is examined to conduct genetic testing for cancer, which was largely outsourced in the past. By shortening turnaround time on test results, we will provide new value in cancer treatment.