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November 6, 2024

Consolidated Financial Results for the Six Months Ended September 30, 2024 (Under Japanese GAAP)

Company name:	Shin Nippon Biomedical Laboratories, Ltd.
Listing:	Prime Market, Tokyo Stock Exchange
Securities code:	2395
URL:	https://snbl.com
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Scheduled date to file semi-annual securities report:	November 6, 2024
Scheduled date to commence dividend payments:	November 29, 2024
Preparation of supplementary material on financial results:	Yes
Holding of financial results briefing:	Yes (for analysts and institutional investors)

(Yen amounts are rounded down to millions, unless otherwise noted.)

1. Consolidated financial results for the six months ended September 30, 2024 (from April 1, 2024 to September 30, 2024)

(1) Consolidated operating results (cumulative)

(Percentages indicate year-on-year changes.)

	Revenue		Operating profit		Ordinary profit		Profit attributable to owners of parent	
Six months ended	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%
September 30, 2024	12,508	5.3	80	(96.6)	1,829	(51.3)	1,331	(55.1)
September 30, 2023	11,884	14.8	2,349	1.5	3,756	(36.6)	2,966	(32.9)

Note: Comprehensive income
For the six months ended September 30, 2024: ¥3,542 million [(46.6)%]
For the six months ended September 30, 2023: ¥6,630 million [(5.7)%]

	Basic earnings per share	Diluted earnings per share
Six months ended	Yen	Yen
September 30, 2024	31.97	–
September 30, 2023	71.24	–

(2) Consolidated financial position

	Total assets	Net assets	Equity ratio	Net assets per share
As of	Millions of yen	Millions of yen	%	Yen
September 30, 2024	88,983	36,453	40.9	875.03
March 31, 2024	76,302	34,160	44.7	819.42

Reference: Equity
As of September 30, 2024: ¥36,429 million
As of March 31, 2024: ¥34,114 million

2. Cash dividends

	Annual dividends				
	First quarter-end	Second quarter-end	Third quarter-end	Fiscal year-end	Total
	Yen	Yen	Yen	Yen	Yen
Fiscal year ended March 31, 2024	–	20.00	–	30.00	50.00
Fiscal year ending March 31, 2025	–	20.00			
Fiscal year ending March 31, 2025 (Forecast)			–	30.00	50.00

Note: Revisions to the forecast of cash dividends most recently announced: None

3. Consolidated earnings forecasts for the year ending March 31, 2025 (from April 1, 2024 to March 31, 2025)

(Percentages indicate year-on-year changes.)

	Revenue		Operating profit		Ordinary profit		Profit attributable to owners of parent		Basic earnings per share
	Millions of yen	%	Millions of yen	%	Millions of yen	%	Millions of yen	%	Yen
Fiscal year ending March 31, 2025	29,835	12.8	2,350	(43.5)	5,345	(23.8)	3,920	(29.1)	94.15

Note: Revisions to the forecast of consolidated financial results most recently announced: None

* **Notes**

(1) Significant changes in the scope of consolidation during the period: None

(2) Adoption of accounting treatment specific to the preparation of semi-annual consolidated financial statements: None

(3) Changes in accounting policies, changes in accounting estimates, and restatement
- (i) Changes in accounting policies due to revisions to accounting standards and other regulations: Yes
- (ii) Changes in accounting policies due to other reasons: None
- (iii) Changes in accounting estimates: None
- (iv) Restatement: None

(4) Number of issued shares (common shares)

(i) Total number of issued shares at the end of the period (including treasury shares)

As of September 30, 2024	41,632,400 shares
As of March 31, 2024	41,632,400 shares

(ii) Number of treasury shares at the end of the period

As of September 30, 2024	469 shares
As of March 31, 2024	469 shares

(iii) Average number of shares outstanding during the period (cumulative from the beginning of the fiscal year)

Six months ended September 30, 2024	41,631,931 shares
Six months ended September 30, 2023	41,631,931 shares

* Semi-annual financial results reports are exempt from review conducted by certified public accountants or an audit corporation.

* Proper use of earnings forecasts, and other special matters
  (The forecast of financial results and forward-looking statements)

  The forward-looking statements, including earnings forecasts, contained in these materials are based on information currently available to the Company and on certain assumptions deemed to be reasonable. Consequently, any statements herein do not constitute assurances regarding actual results by the Company. Actual financial results may differ significantly from the forecasts for various reasons. For more information regarding our suppositions that form the assumptions for the earnings forecasts, please see page 9 of the attachment, "(3) Explanation of consolidated earnings forecasts and other forward-looking statements."

  (Method of obtaining financial results explanatory materials and details of financial results briefing)

  Financial results explanatory materials are posted via TDnet on the date of disclosure. The Company plans to hold a financial results briefing call for analysts and institutional investors on Wednesday, November 6, 2024. Explanatory details (audio recording in Japanese and its transcript in both Japanese and English) will be posted on the Company's website (https:/snbl.com) in a timely manner after the briefing.

Attached Material

Index

1. Qualitative information on semi-annual consolidated financial results for the six months ended September 30, 2024 2
(1) Explanation of operating results 2
(2) Explanation of financial position 8
(3) Explanation of consolidated earnings forecasts and other forward-looking statements 9
2. Semi-annual consolidated financial statements and significant notes thereto 11
(1) Semi-annual consolidated balance sheet 11
(2) Semi-annual consolidated statement of income and semi-annual consolidated statement of comprehensive income 13
Semi-annual statement of income (cumulative) 13
Semi-annual consolidated statement of comprehensive income (cumulative) 14
(3) Semi-annual consolidated statement of cash flows 15
(4) Notes to semi-annual consolidated financial statements 17
(Notes on going concern assumption) 17
(Changes in consolidated subsidiaries during the current semi-annual accounting period) 17
(Notes when there are significant changes in amounts of equity) 17
(Changes in accounting policies) 17
(Notes to semi-annual consolidated balance sheet) 18
(Notes to semi-annual consolidated statement of income) 18
(Notes to semi-annual consolidated statement of cash flows) 18
(Notes to segment information) 19

1. Qualitative information on semi-annual consolidated financial results for the six months ended September 30, 2024

(1) Explanation of operating results

In the pharmaceutical industry, companies have been increasingly turning to contract research organizations (CROs) that specialize in outsourcing, with the aim of accelerating research and development in Japan and abroad while improving cost efficiency and simplifying their correspondence with regulatory authorities. In addition, research and development involving new modalities in drug discovery (therapeutic approaches) has been in full swing, particularly with respect to nucleic acid medicine, next-generation therapeutic antibodies, peptide drugs, gene therapy, cell therapy, and regenerative medicine. With a proven track record in supporting research and development of new modalities in drug discovery, the Company has been addressing such trends by placing its focus on meeting customer needs which involves taking swift action, improving services, and persistently enhancing quality, aiming to become far and away the first name that comes to mind for clients when they consider CRO.

Under such circumstances, revenue for the six months ended September 30, 2024 (from April 1, 2024 to September 30, 2024; hereinafter, "the first half of the fiscal year ending March 31, 2025") increased by ¥624 million (up 5.3%) compared to the six months ended September 30, 2023 (hereinafter, "the first half of the previous fiscal year") to ¥12,508 million, driven by mainstay CRO business. Operating profit was ¥80 million, a deterioration of ¥2,269 million (down 96.6%) year on year. The main reason for the decrease in operating profit is the recording of ¥1,272 million in expenses for resubmission of an FDA application for STS101, an intranasal therapeutic agent for migraine from Satsuma Pharmaceuticals, Inc. (hereinafter, "Satsuma"), a consolidated subsidiary of the Company in the United States. In addition, the Company views the current business environment surrounding its mainstay CRO business as an opportunity for further growth. The increase in costs due to continuing large strategic upfront investments, such as the substantial strengthening of human resources, expansion of laboratory facilities, and establishment of a domestic breeding framework for laboratory non-human primates (NHPs), also contributed to the decrease in operating profit. Ordinary profit decreased by ¥1,927 million (down 51.3%) year on year to ¥1,829 million due to lower operating profit. The share of profit of entities accounted for using equity method from PPD-SNBL K.K., which promotes the clinical business within the CRO business, increased by ¥476 million year on year to ¥1,708 million, setting a record high for the first half of the fiscal year. As for foreign exchange losses (gains), foreign exchange losses of ¥96 million was recorded, contributing to a decrease in ordinary profit by ¥338 million compared with foreign exchange gains of ¥242 million for the first half of the previous fiscal year. Profit attributable to owners of parent decreased by ¥1,635 million (down 55.1%) year on year to ¥1,331 million.

As of September 30, 2024, the SNBL Group had 1,451 employees on a consolidated basis excluding part-time and hourly employees (an increase of 110 employees from the end of March 2024), as a result of the 100 new employees (including 59 female employees) who joined the Company in April 2024. The ratio of female employees on a consolidated basis including temporary employees was 51. 9%.

Operating results by segment and initiatives for SDGs/ESG are as follows.

(i) CRO business

The CRO business comprises the nonclinical business, which undertakes nonclinical (or preclinical) studies mainly using cells and laboratory animals, and the clinical business, which undertakes clinical studies.

The Company's nonclinical business is one of the industry's largest in Japan, and one of the industry's second-top tier nonclinical CROs globally based on the results of numerous studies using laboratory NHPs. The nonclinical business achieved steady results for the first half of the fiscal year ending March 31, 2025. The following initiatives implemented by the Company have shown positive results.

- The importance of the Company-established framework for breeding and supplying laboratory NHPs within the SNBL Group, the only such framework built by a CRO in the world, has increased due to research and development involving new modalities in drug discovery coming into full swing. In addition, the environment where it is difficult to obtain laboratory NHPs overseas has also made a positive contribution, leading to contracts received. We have also been strengthening our framework for producing NHPs in full swing in Japan since the fiscal year ended March 31, 2023 to reduce import risks and improve quality. We additionally constructed new breeding facilities and started operations in the first half of the fiscal year ending March 31, 2025.
- The concentration analysis performed on drug development candidates (test substances) and biomarkers in biological samples is called bioanalysis. The Company has introduced the cutting-edge devices required to evaluate the efficacy and safety of new modalities in drug discovery, and built a

system for evaluating test substances and biomarkers from an earlier stage. Synergies were demonstrated between this system and the above Company-established framework for breeding and supplying laboratory NHPs within the SNBL Group. This led to an increase in orders of the bioanalysis.

- These efforts were highly evaluated and led to the conclusion of preferred contracts (agreements for preferentially outsourcing to pre-selected CROs) with multiple pharmaceutical companies, leading to an increase in contracts received. In addition, the Company received contracts for the first study for due diligence in preparation for the conclusion of preferred contracts with several major pharmaceutical companies overseas in the fiscal year ended March 31, 2024. The Company has increased overseas sales personnel and strengthened sales activities in the fiscal year ending March 31, 2025. To cope with an increase in contracts received from overseas, the Company formed the Global Study Team (GST) within the laboratory.
- The Company has also achieved steady progress in terms of number of clients regarding contracts to undertake comprehensive research at the drug discovery stage with major pharmaceutical companies in Japan, and has already received orders from multiple companies for research beginning with the initial drug discovery stage.
- Construction of a new office building and research facility (eight floors above ground; two buildings) with which we had proceeded at the Kagoshima Head Office from December 2022 was completed at the end of May 2024, and the inauguration was held on June 18. The new facility plays a key role in building a system that can deal with large contracts in the nonclinical business, including expansion of the bioanalysis laboratory, and started full-scale operation from September. We are currently preparing to commence contract services for Microphysiological System (MPS), and the new office building and research facility has a dedicated laboratory for MPS contracts in place.
- On July 30, 2024, at the Gate Opening Summit for Innovative Drug Discovery convened by then-Prime Minister Kishida, President Nagata was among those invited to the Prime Minister’s Office to present case studies from the Group’s drug discovery ecosystem (Part 1 and Part 2). The presentation slides are available on the Gate Opening Summit for Innovative Drug Discovery page in the Cabinet Office website.

As a result of the aforementioned initiatives, contracts received in the nonclinical business for the first half of the fiscal year ending March 31, 2025, increased by ¥2,695 million (up 21.4%) year on year to ¥15,311 million, renewing a record high for the first half of the fiscal year. The contracts received in the second quarter (July to September) was ¥8,140 million, relative to that of ¥4,217 million in the same quarter of the previous fiscal year, renewing a record high for the second quarter. Contracts received in Japan for the first half of the fiscal year increased by ¥76 million (up 0.8%) year on year to ¥9,756 million. Contracts received from overseas increased by ¥2,619 million (up 89.2%) year on year to ¥5,555 million, and the ratio of overseas contracts received out of total contracts received was 36.3% (23.2% for the first half of the previous fiscal year). The main factor for the increase in contracts received from overseas is an increase in contracts received from customers in Europe and the U.S., and such contracts received grew by 46.7% year on year to ¥3,653 million. On the other hand, the amount of cancellations of existing contracts before studies are commenced in the first half of the fiscal year ending March 31, 2025 was ¥3,260 million, consisting of ¥2,217 million in the first quarter and ¥1,043 million in the second quarter. The order backlog as of September 30, 2024 remained high at ¥35,877 million.

The clinical business has been engaged mainly in contract operations of global studies (studies conducted simultaneously in multiple countries and regions) at PPD-SNBL K.K. (“PPD-SNBL”), a joint venture with PPD International Holdings, LLC (“PPD”), an international clinical CRO based in the United States. In December 2021, PPD became a member of the corporate group of Thermo Fisher Scientific Inc., a major global player in medical devices, with the objective of enhancing contract synergies. PPD-SNBL’s mainstay business is that of the implementation in Japan of studies, outsourced to PPD, that are conducted simultaneously in multiple countries. While it is a global company, PPD-SNBL has established a working environment with high retention rates by incorporating the management and training know-how that the Company has developed over many years, and it has achieved high rates of growth ever since it was founded, against the background of high order backlogs.

When promoting clinical trials, it seeks to take advantage of the spread of online conferencing systems and compatible devices to improve efficiency through the use of remote monitoring, which it uses to gather data without visiting medical institutions. In terms of personnel recruitment, when PPD-SNBL was originally founded we introduced a system, running parallel to that for new graduates joining in April, that enables new graduates wishing to join the company in October to benefit from a six-month scholarship for language study overseas, thus facilitating their ability to deal with global situations and enhancing their experience of society. Accordingly, more than 200 new graduates have joined the company after the language study overseas, ever since it was founded. At the same time, in addition to actively recruiting from the group interested in a global career and that already have some experience and the group of bilingual graduates from overseas universities, this has enabled us to maintain a flexible hiring strategy that achieves a good balance with the system for new graduates joining PPD-SNBL in spring and fall. We have been striving to develop world-class global human resources for many years by providing opportunities for new graduates to study at the business English school located within the Company for two years after joining, and then to learn about clinical trial systems in Europe and the U.S. through short-term study abroad programs utilizing PPD's international network. As a result, headcount has exceeded 1,000 employees as of the end of April 2024, roughly three times the number with which we started in April 2015.

The share of profit of entities accounted for using equity method from PPD-SNBL's contribution for the first half of the fiscal year ending March 31, 2025 increased significantly to ¥1,617 million (¥1,232 million in the first half of the previous fiscal year), a record high for the first half of the fiscal year. While the nonclinical business using laboratory NHPs are a growth engine at SNBL, the clinical business conducted by PPD-SNBL is the second growth engine of the Company.

The CRO business posted revenue for the first half of the fiscal year ending March 31, 2025 of ¥12,199 million, which was an increase of ¥708 million (up 6.2%) relative to the first half of the previous fiscal year, renewing a record high for the first half of the fiscal year. Operating profit of the CRO business decreased by ¥736 million (down 25.0%) year on year to ¥2,205 million, and ratio of operating profit to revenue was 18.1%.

(ii) Translational Research business (TR business)

Translational Research business (hereinafter, "TR business") is a research and development business that discovers promising seeds and new technologies generated through in-house research and development as well as fundamental research performed at Japanese and overseas universities, biotech ventures, and research institutes, and develops them for commercialization, stock listing, or M&A, by increasing their added value.

The Company's proprietary development intranasal drug delivery platform technology, which has been a focus of inquiry as the core of the TR business since 1997, is a platform technology that combines a powdered formulation technology using a carrier composition as the base with a drug delivery device (medical device). It is characterized by rapid onset of action based on sufficient retention and drug absorption through the nasal mucosa. It has the advantage of being easier to administer than injections and allowing the formulation to be stored at room temperature.

Regarding the commercialization of intranasal administration, Satsuma has completed clinical trials for an intranasal therapeutic agent for migraine (development code: STS101) and resubmitted a New Drug Application (NDA) to the US Food and Drug Administration (FDA) on October 30, 2024. Additionally, SNLD, Ltd., a consolidated subsidiary of the Company, is developing a nasal on-demand therapy for the treatment of off symptoms of Parkinson's Disease (development code: TR-012001).

STS101, which Satsuma in the United States is working to develop, is an easy-to-use and portable intranasal formulation with dihydroergotamine as the active ingredient, which has a proven track record of efficacy against migraines. It has been confirmed in clinical trials to have rapid and sustained absorption and a high level of safety. The paper detailing the results of the Phase III long-term safety and tolerability study of STS101 (study name: ASCEND), conducted by Satsuma, was published on October 8, 2024 in CNS Drugs, an international medical journal with authority on drug therapy for central nervous system diseases. The first author of the paper is Dr. Stewart J. Tepper, MD, a Fellow of the American Headache Society (AHS) and an internationally prominent figure in the field of headaches. Dr. Stewart J. Tepper provided the following comments in a press release from Satsuma: "I am pleased that the data demonstrates that STS101 was safe, well tolerated, and easy for patients to use over the long term. This is exciting and important information for people living with migraine who have experienced inadequate relief with existing therapies and the practitioners who treat them who are in need of new options." "Even with the introduction of new treatment options in the past few years, there is a critical need for novel non-oral treatment options for patients who are often unable to achieve rapid relief with oral routes of administration."

Regarding the development of a nasal on-demand therapy for the treatment of off symptoms of Parkinson's Disease (development code: TR-012001), the dosing of patients in the Phase II clinical trial thereof was completed in January 2024. The Company is currently working to confirm the safety, tolerability, and rapid absorption and to fix and analyze the data leading to the acquisition of a Proof-of-Concept (POC), and conformation of the final report is imminent. An academic conference presentation is planned for next fiscal year. The Company also completed the dosing of healthy Japanese adults in the Phase I clinical trials in August 2024 for an improved development product of TR-012001 (TRN501) that aims to achieve even greater convenience, and is proceeding with that study's data analysis.

As another intranasal drug development project, the Company's TR business has conducted research on an intranasal vaccine that is expected to act as an intranasal mucosal immunizing agent. While the goal of most vaccines is to prevent the onset or increase in severity of disease, the intranasal vaccine we are developing aims to prevent infection itself from occurring (this is called "immune barricade"). For the "FY2023 Program on R&D of New Generation Vaccine Including New Modality Application" solicited by the Strategic Center of Biomedical Advanced Vaccine Research and Development for Preparedness and Response (SCARDA), which is an organization established within the Japan Agency for Medical Research and Development (AMED) to promote rapid vaccine development as a national policy by the Japanese government, the "Development of a TR's nasal vaccine powder delivery system which generates IgA" supervised by the Company's Nasal Vaccine Research and Development Center was selected as one of developments to be supported. We have gained ¥100 million as an initial research grant to assess a non-clinical POC of the system, and are now in full-scale development of a powder-type intranasal vaccine that provides capability of immune barricade to multiple respiratory viruses in the upper respiratory tract with the aim of establishing pharmaceutical formulation research and nonclinical experimental system.

Gemseki Inc. ("Gemseki"), a consolidated subsidiary of the Company, was established in October 2017 with the corporate philosophy of "Striving to support the best development of drug candidates and technologies for society." The company operated a licensing brokerage business for drug discovery seeds and technologies on a global basis, and formed a fund setting itself as an unlimited liability partner to conduct investment business in venture companies. However, upon considering the effective utilization and optimization of the Group's management resources as well as the efficiency of management, a decision was made that integrating Gemseki's activities into the Company as one of its divisions would be the reasonable thing to do, and a company split and absorption-type merger of Gemseki were executed on October 1, 2024. Specifically, the Company has absorbed and merged with the license brokering business of Gemseki, and a newly established company, Gemseki Investment Inc., has succeed to its investment business. This move aims to implement flexible and adaptable business strategies while enhancing management efficiency. In the license brokering business, as in the past, Gemseki used biotechnology-related exhibitions and partnering events to search for and conclude contracts with new clients such as academic institutions and companies with promising drug discovery seeds and technologies, and also focused on introducing drug discovery seeds and technologies of existing clients. Going forward, the license brokering business will engage in activities in collaboration with other sectors as one of the SNBL's divisions, aiming to enhance brokerage performance and generate synergies within the Group.

As for the investment business, PRISM BioLab Co., Ltd, an investee company of the fund, was newly listed on the Growth Market of the Tokyo Stock Exchange on July 2, 2024. We have also continued to provide support to other investee companies, being committed to their further growth. Moreover, in conjunction with our continual search for potential investee companies in Japan and overseas, we are also engaging in discussions about startup investments with academic institutions that possess promising seeds and technologies. We will provide the comprehensive support needed for the creation and development of pharmaceuticals and medical devices aimed at overseas expansion.

Amid these circumstances, the TR business posted revenue of ¥15 million for the first half of the fiscal year ending March 31, 2025, relative to revenue of ¥6 million for the first half of the previous fiscal year. Higher costs of ¥1,272 million associated with the incorporation of Satsuma in consolidated results resulted in operating loss of ¥1,775 million, relative to operating loss of ¥498 million for the first half of the previous fiscal year.

(iii) Medipolis business (Social Benefits Generation business)

The Company owns a large tract of land of 340 hectares (840 acres) in the highlands of Ibusuki City, Kagoshima Prefecture called Medipolis Ibusuki. The Company leverages this natural asset (approximately 90% forest) to operate the Medipolis business and generate benefits for society. This business is the embodiment of the Company's corporate principle: "Committed to the environment, life and people." We are committed to creating benefits for society in an integrated fashion, not only from the perspective of economic gains, but also in terms of the issues in society and the environment. Specifically, we operate a power generation business using renewable energy sources, as well as a hospitality business centering on the operation of hotels based on the concept of well-being, or in other words, holistic health.

In the power generation business, we have operated a 1,500 kW binary geothermal power plant since February 2015. Geothermal power generation produces hardly any CO2 emissions, is not affected by the weather during the day or night, and has the potential to be a baseload power source capable of stable power generation all year round. Our geothermal power plant is capable of generating approximately 10 million kWh of electricity throughout the year. This is equivalent to roughly half of the Company's annual power consumption. In addition, we generate steady electricity sale income from the produced electricity, using the feed-in tariff (FIT) system. Nine years have passed since the start of operation, so we conducted open inspections and repairs of the generator from the fourth quarter of the fiscal year ended March 31, 2024 to ensure stable long-term operation, and suspended operation at the geothermal power plant. However, power generation was resumed in the middle of May 2024. As a new power generation project, progress has been made on a hot spring power generation plant (annual output of 4 million kWh) that utilizes residual steam from the hot spring sources supplied to hotel bathing facilities and floor heating. Hot spring power generation also produces hardly any CO2 emissions, contributing significantly to reduction of greenhouse gases. We also plan to sell electricity produced from hot spring power generation under the FIT system, and electricity sales are scheduled to be started from January 2025.

In the hospitality business, two facilities, namely the Amafuru Oka as a healing resort hotel and the HOTEL Freesia as an accommodation facility for patients of the Medipolis Proton Therapy and Research Center, are each operated to meet the needs of guests. The Medipolis Proton Therapy and Research Center has treated more than 6,700 cancer patients with proton therapy since it began treatments in January 2011. There are two main reasons why we operate our hospitality business. The first one is that, from the perspective of enhancing corporate value, we are a company which contributes to people's well-being. The second one is to contribute to fostering a stronger customer-oriented hospitality mindset at SNBL. We believe that further strengthening the hospitality mindset of the SNBL Group through the hospitality business and plowing the benefits back into the mainstay CRO business will play a key role in our efforts to compete on the world stage.

The Medipolis business posted revenue of ¥225 million for the first half of the fiscal year ending March 31, 2025, which was a decrease of ¥123 million (down 35.3%) relative to the first half of the previous fiscal year. The decrease in revenue is largely due to the suspension of sales of electricity from geothermal power generation until the restart of the operation in mid-May. However, electricity sales were resumed nearly six months earlier than expected at the beginning of the period. Effects of the suspension of sales of electricity from geothermal power generation resulted in operating loss of ¥221 million, relative to operating loss of ¥57 million for the first half of the previous fiscal year.

(iv) Initiatives for SDGs/ESG

In September 2015, the UN General Assembly adopted the "Sustainable Development Goals (SDGs)" as globally shared targets to be met by 2030 that were established so that the people of the world can live in happiness. The SDGs are actually the same as the Company's all-time corporate philosophy of "We are a company that values the environment, life, and people" and the Company's slogan "I'm happy, you are happy, and everyone is happy," and the Company accordingly has an awareness of being an industry leader in initiatives for SDGs/ESG.

Regarding our initiatives for SDGs/ESG, the SDGs Committee (chaired by independent External Director, Dr. Keiko Toya), which the Company established as an advisory body to the Board of Directors, and the Environmental Committee (chaired by the director in charge of sustainability), which the Company established as a subordinate organization of the SDGs Committee conduct lively discussions on a monthly basis. The Company discloses a ESG data book that is produced based on these achievements regarding initiatives for SDGs/ESG, each of the Company's policies, information based on TCFD Recommendations, and such on a dedicated page of the Company's website (https://snbl.com/esg/).

In the Integrated Report, we have provided our 2028 Vision "promoting people's happiness in close involvement with stakeholders" as the future we aim to create. The management strategy specifies FY2028 financial KPIs (targets) of ¥50 billion in revenue, ¥20 billion in ordinary profit, ordinary profit margin of 40%, and payout ratio of 30–40%. The cost of capital has been set at 5.1%, estimated based on the earnings results for the fiscal year ended March 31, 2024. In our analysis of capital return indicators, we put emphasis on ROE and ROIC, which are presented during the Board of Directors meetings held monthly. It calls for ROE and ROIC of at least 10%, and calculated based on operating results for the fiscal year ended March 31, 2024, ROE is 18.3%, and ROIC is 10.3%. In addition, the Company updated its Corporate Governance Report in June 2024, and has implemented all the principles of the Corporate Governance Code following the revisions in June 2021, including those for the TSE Prime Market. The ratio of female Directors as of September 30, 2024 was 22.2% (two out of nine Directors).

The Company has been highly evaluated by various rating agencies for its continuous efforts for SDGs/ESG. In July 2024, the Company was again selected as a component of the FTSE Blossom Japan Sector Relative Index, constructed by global index provider FTSE Russell in the UK. In the MSCI ESG ratings, the Company received an "A" rating in March 2024 as a company in the Health Care Equipment & Supplies sector again this year. In August 2024, the Company was again selected as a component of the JPX-Nikkei Mid and Small Cap Index, jointly provided by JPX Market Innovation & Research, Inc. and Nikkei Inc. In March 2024, the Company was recognized by the Ministry of Economy, Trade and Industry as one of the "White 500" Certified Health & Productivity Management Outstanding Organizations for the eighth consecutive year. As for women's participation and advancement in the workplace, in October 2023, the Company received "Platinum Eruboshi" certification from the Ministry of Health, Labour and Welfare in accordance with the Act on the Promotion of Women's Active Engagement in Professional Life. In September 2024, the Company was awarded "Platinum Kurumin Plus" certification by the same ministry, recognizing its support for balancing work with both childcare and infertility treatments (first time in Kagoshima Prefecture).

As for the results of dialogue with shareholders and investors during the first half of the fiscal year ending March 31, 2025, the Company conducted 104 meetings with institutional investors and analysts. In the General Meeting of Shareholders held in June, the Company held a briefing session on its intranasal drug delivery platform technology for shareholders, who attended such shareholder's meeting, after the conclusion of the meeting.

For efforts to conserve biodiversity and regional contribution (Kagoshima Prefecture is the No. 1 supplier of Japanese eels in Japan), the Company has been pursuing research into the production of Japanese eels in their juvenile stage (glass eels), which are listed as endangered in the IUCN Red List, in artificial habitats. In 2019, we moved our research facility to Wadomari-cho, Okinoerabujima, Kagoshima Prefecture, to produce farm-raised glass eels using natural seawater. We have already achieved a high survival rate of 50% or more in small-scale rearing in the laboratory, from the onset of feeding to the large larva stage prior to glass eel metamorphosis. In May 2024, we held a tasting event of farm-raised eels for the first time in Tokyo.

In the first half of the fiscal year ending March 31, 2025, we worked on developing a new large-scale water tank and resolving issues to realize the expansion of the scale toward achieving volume production.

(2) Explanation of financial position

(Analysis of assets, liabilities and net assets)

Changes in financial position for the six months ended September 30, 2024 from the end of the previous fiscal year were as follows:

Total assets as of September 30, 2024 increased by ¥12,681 million compared to the balance as of the end of the previous fiscal year, to ¥88,983 million (up 16.6%). Current assets increased by ¥3,124 million compared to the balance as of the end of the previous fiscal year, to ¥33,961 million (up 10.1%) due mainly to increases in inventories of ¥1,840 million (up 14.9%), cash and deposits of ¥810 million (up 7.9%), and notes and accounts receivable - trade, and contract assets of ¥544 million (up 9.4%). Non-current assets increased by ¥9,556 million compared to the balance as of the end of the previous fiscal year, to ¥55,021 million (up 21.0%) due mainly to an increase in property, plant and equipment of ¥5,946 million (up 22.6%) as a result of capital expenditures, etc., as well as increases in investment securities of ¥3,088 million (up 20.3%) and deferred tax assets of ¥343 million (up 34.7%).

Liabilities increased by ¥10,388 million compared to the balance as of the end of the previous fiscal year, to ¥52,529 million (up 24.7%). Current liabilities increased by ¥5,249 million compared to the balance as of the end of the previous fiscal year, to ¥28,816 million (up 22.3%) due mainly to increases in short-term borrowings of ¥4,277 million (up 54.7%) and advances received of ¥3,088 million (up 32.4%). Non-current liabilities increased by ¥5,138 million compared to the balance as of the end of the previous fiscal year, to ¥23,712 million (up 27.7%) due mainly to an increase in long-term borrowings of ¥4,708 million (up 25.9%).

Net assets increased by ¥2,293 million compared to the balance as of the end of the previous fiscal year, to ¥36,453 million (up 6.7%) due mainly to the posting of ¥1,331 million in profit attributable to owners of parent, despite an increase in valuation difference on available-for-sale securities of ¥2,786 million, dividends paid of ¥1,248 million, and a decrease in foreign currency translation adjustment of ¥553 million.

(Analysis of cash flows)

The outstanding balance of cash and cash equivalents (“cash”) as of September 30, 2024 was ¥11,085 million, up ¥810 million (7.9%) compared to the balance as of the end of the previous fiscal year.

Status of each cash flow during the six months ended September 30, 2024 and main contributing factors thereof are as follows.

(Cash flows from operating activities)

Net cash provided by operating activities was ¥231 million, down ¥455 million (66.2%) relative to the six months ended September 30, 2023.

The main contributing factors included profit before income taxes of ¥1,755 million, depreciation of ¥1,079 million, share of profit of entities accounted for using equity method of ¥1,834 million, an increase in inventories of ¥1,709 million, an increase in advances received of ¥3,088 million, income taxes paid of ¥1,746 million, and interest and dividends received of ¥1,113 million.

(Cash flows from investing activities)

Net cash used by investing activities was ¥7,522 million, up ¥3,850 million (104.9%) relative to the six months ended September 30, 2023.

The main contributing factors included purchase of property, plant and equipment of ¥7,640 million, and proceeds from redemption of securities of ¥211 million.

(Cash flows from financing activities)

Net cash provided in financing activities was ¥7,658 million, up ¥5,534 million (260.5%) relative to the six months ended September 30, 2023.

The main contributing factors included proceeds from long-term borrowings of ¥10,000 million, repayments of long-term borrowings of ¥4,595 million, an increase in short-term borrowings of ¥3,580 million, and dividends paid of ¥1,247 million.

(3) Explanation of consolidated earnings forecasts and other forward-looking statements

Both revenue and profit for the first half of the fiscal year ending March 31, 2025 came in higher than our forecasts announced on May 8, 2024. Our full-year forecasts remain unchanged. The assumed exchange rate is US$1 = ¥145.00, established at the beginning of the period.

In the second half of the fiscal year ending March 31, 2025, we are committed to enhancing our operations in our mainstay CRO business. Ina Research Inc., which became part of the SNBL Group in July 2022, changed its name to SNBL INA Ltd. effective October 1, 2024. We believe that aligning our brand with SNBL in the new company name is a crucial step in enhancing our unity as a member of the Group and in effectively accelerating our business development Additionally, as of October 1, 2024, the Company has begun offering nonclinical study services at an animal facility adjacent to SakuLab™-Tsukuba, an open innovation laboratory within the Astellas Tsukuba Research Center. This marks the first service provision in the facility that houses startups, academic institutions, and venture companies. Drawing on its experience gained and achievements secured in nonclinical studies across various modalities in drug discovery, the Company is poised to assist startups, academic institutions, pharmaceutical companies, and other entities in operating within the drug discovery ecosystem.

The Company announced a business alliance with SBI Holdings Inc. on July 31. The SNBL Group and the SBI Group will jointly establish and manage a company that operates the incubation facility of a startup company owned by the SNBL Group in Washington, the U.S. Furthermore, these two groups established a joint fund in the U.S. on September 24. Forming the fund with the function of operating the incubation facility and the incubation function in the U.S., which is a global center for biotechnology and drug discovery, and providing investment and support for business expansion to promising startup companies has great significance from a perspective of contribution to a drug discovery ecosystem. In addition, the Company can expect to receive contract studies from investee companies as well, and thinks that these efforts will also contribute to revenue in its mainstay CRO business.

Please refer to the following for principal management benchmarks (capital expenditures, depreciation, R&D expenses, and number of employees), assumptions on which the forecast is based.

[Contracts received in the nonclinical business]

(Millions of yen)

	Results for the six months ended September 30, 2021	Full-year results for the fiscal year ended March 31, 2022	Results for the six months ended September 30, 2022	Full-year results for the fiscal year ended March 31, 2023	Results for the six months ended September 30, 2023	Full-year results for the fiscal year ended March 31, 2024	Results for the six months ended September 30, 2024	Full-year plan for the fiscal year ending March 31, 2025
Contracts received	11,208	22,839	13,373	24,920	12,615	27,411	15,311	34,284
Of which, Japan	8,448	16,318	7,642	16,339	9,679	20,359	9,756	21,829
Of which, overseas	2,760	6,521	5,731	8,581	2,935	7,052	5,555	12,455
Order backlog	17,671	20,966	33,672	29,248	32,210	33,212	35,877	

(Notes) 1. Results of Ina Research (currently SNBL INA Ltd.) are included from July 1, 2022.

2. For calculation of contracts received (overseas), an average USD/JPY exchange rate of each fiscal year is applied.

3. For calculation of order backlog (overseas), a year-end exchange rate of each fiscal year is applied.

[Trends in principal management benchmarks]

(Millions of yen, unless otherwise noted)

	Results for the six months ended September 30, 2021	Full-year results for the fiscal year ended March 31, 2022	Results for the six months ended September 30, 2022	Full-year results for the fiscal year ended March 31, 2023	Results for the six months ended September 30, 2023	Full-year results for the fiscal year ended March 31, 2024	Results for the six months ended September 30, 2024	Full-year plan for the fiscal year ending March 31, 2025
	From April 2021 to September 2021	From April 2021 to March 2022	From April 2022 to September 2022	From April 2022 to March 2023	From April 2023 to September 2023	From April 2023 to March 2024	From April 2024 to September 2024	From April 2024 to March 2025
Capital expenditures	734	1,703	1,971	5,614	2,174	8,525	7,639	10,559
Depreciation	560	1,177	741	1,544	830	1,774	1,079	2,751
R&D expenses	180	425	265	683	482	1,741	1,276	3,121
Number of employees at period-end (people)	1,005	994	1,219	1,208	1,358	1,341	1,451	1,465

(Note) Results of Ina Research (currently SNBL INA Ltd.) are included from July 1, 2022.

2. Semi-annual consolidated financial statements and significant notes thereto

(1) Semi-annual consolidated balance sheet

(Thousands of yen)

	As of March 31, 2024	As of September 30, 2024
Assets		
Current assets		
Cash and deposits	10,274,773	11,085,459
Notes and accounts receivable - trade, and contract assets	5,778,872	6,323,812
Securities	336,724	120,991
Inventories	12,373,178	14,213,473
Other	2,130,226	2,331,571
Allowance for doubtful accounts	(56,062)	(113,353)
Total current assets	30,837,713	33,961,955
Non-current assets		
Property, plant and equipment		
Buildings and structures, net	10,686,940	15,761,676
Land	3,959,041	3,929,597
Other, net	11,711,684	12,612,422
Total property, plant and equipment	26,357,666	32,303,697
Intangible assets		
Goodwill	1,934,419	1,953,324
Other	224,879	248,296
Total intangible assets	2,159,298	2,201,621
Investments and other assets		
Investment securities	15,235,711	18,324,153
Other	1,725,904	2,206,083
Allowance for doubtful accounts	(13,947)	(13,947)
Total investments and other assets	16,947,667	20,516,289
Total non-current assets	45,464,633	55,021,607
Total assets	76,302,347	88,983,563

(Thousands of yen)

	As of March 31, 2024	As of September 30, 2024
Liabilities		
Current liabilities		
Notes and accounts payable - trade	460,527	664,988
Short-term borrowings	7,826,167	12,103,313
Income taxes payable	1,701,128	600,430
Advances received	9,542,361	12,631,225
Other	4,037,708	2,817,022
Total current liabilities	23,567,894	28,816,980
Non-current liabilities		
Long-term borrowings	18,147,876	22,856,311
Lease liabilities	212,815	167,580
Other	213,125	688,881
Total non-current liabilities	18,573,818	23,712,773
Total liabilities	42,141,712	52,529,753
Net assets		
Shareholders' equity		
Share capital	9,679,070	9,679,070
Capital surplus	2,358,493	2,358,493
Retained earnings	17,215,849	17,297,927
Treasury shares	(420)	(420)
Total shareholders' equity	29,252,993	29,335,071
Accumulated other comprehensive income		
Valuation difference on available-for-sale securities	3,644,434	6,430,699
Foreign currency translation adjustment	1,216,991	663,461
Total accumulated other comprehensive income	4,861,426	7,094,160
Non-controlling interests	46,215	24,577
Total net assets	34,160,635	36,453,809
Total liabilities and net assets	76,302,347	88,983,563

(2) Semi-annual consolidated statement of income and semi-annual consolidated statement of comprehensive income

Semi-annual statement of income (cumulative)

(Thousands of yen)

	Six months ended September 30, 2023	Six months ended September 30, 2024
Revenue	11,884,047	12,508,481
Cost of revenue	5,530,749	5,985,140
Gross profit	6,353,298	6,523,340
Selling, general and administrative expenses	4,003,818	6,443,312
Operating profit	2,349,479	80,028
Non-operating income		
Interest income	85,389	34,913
Dividend income	1,525	850
Share of profit of entities accounted for using equity method	1,239,850	1,834,943
Foreign exchange gains	242,380	–
Other	161,238	73,263
Total non-operating income	1,730,384	1,943,971
Non-operating expenses		
Interest expenses	62,692	93,994
Foreign exchange losses	–	96,392
Commission expenses	252,327	2,066
Other	8,388	2,409
Total non-operating expenses	323,408	194,863
Ordinary profit	3,756,455	1,829,136
Extraordinary income		
Gain on sale of non-current assets	3,655	–
Gain on sale of investment securities	–	21,919
Gain on step acquisitions	82,164	–
Total extraordinary income	85,819	21,919
Extraordinary losses		
Loss on retirement of non-current assets	22,705	85,138
Loss on sale of non-current assets	2,581	–
Impairment losses	3,165	9,921
Total extraordinary losses	28,453	95,060
Profit before income taxes	3,813,821	1,755,995
Income taxes - current	1,178,999	582,136
Income taxes - deferred	(338,627)	(138,684)
Total income taxes	840,371	443,451
Profit	2,973,450	1,312,543
Profit (loss) attributable to non-controlling interests	7,281	(18,492)
Profit attributable to owners of parent	2,966,169	1,331,035

Semi-annual consolidated statement of comprehensive income (cumulative)

(Thousands of yen)

	Six months ended September 30, 2023	Six months ended September 30, 2024
Profit	2,973,450	1,312,543
Other comprehensive income		
Valuation difference on available-for-sale securities	563,398	2,786,264
Foreign currency translation adjustment	3,030,544	(688,974)
Share of other comprehensive income of entities accounted for using equity method	63,255	132,298
Total other comprehensive income	3,657,198	2,229,588
Comprehensive income	6,630,648	3,542,132
Comprehensive income attributable to		
Comprehensive income attributable to owners of parent	6,625,402	3,563,770
Comprehensive income attributable to non-controlling interests	5,246	(21,637)

(3) Semi-annual consolidated statement of cash flows

(Thousands of yen)

	Six months ended September 30, 2023	Six months ended September 30, 2024
Cash flows from operating activities		
Profit before income taxes	3,813,821	1,755,995
Depreciation	830,652	1,079,298
Impairment losses	3,165	9,921
Amortization of goodwill	37,370	57,354
Increase (decrease) in allowance for doubtful accounts	(8,307)	57,291
Interest and dividend income	(86,914)	(35,764)
Interest expenses	62,692	93,994
Foreign exchange losses (gains)	(444,312)	(61,687)
Share of loss (profit) of entities accounted for using equity method	(1,239,850)	(1,834,943)
Loss (gain) on sale of non-current assets	(1,073)	–
Loss on retirement of non-current assets	22,705	85,138
Loss (gain) on step acquisitions	(82,164)	–
Loss (gain) on sale of investment securities	–	(21,919)
Decrease (increase) in trade receivables	(369,925)	(575,601)
Decrease (increase) in inventories	(2,637,341)	(1,709,111)
Increase (decrease) in advances received	1,735,499	3,088,864
Increase (decrease) in trade payables	(163,020)	189,385
Other	(1,092,589)	(1,213,632)
Subtotal	380,408	964,583
Interest and dividends received	1,092,278	1,113,700
Interest paid	(58,714)	(100,264)
Income taxes paid	(726,041)	(1,746,065)
Net cash provided by (used in) operating activities	687,931	231,954
Cash flows from investing activities		
Proceeds from redemption of securities	–	211,945
Purchase of property, plant and equipment	(2,931,345)	(7,640,488)
Purchase of intangible assets	(4,511)	(64,878)
Proceeds from sale of property, plant and equipment	4,619	–
Purchase of investment securities	(139,979)	(61,956)
Proceeds from sale of investment securities	274,988	24,000
Purchase of shares of subsidiaries resulting in change in scope of consolidation	(850,364)	–
Payments from changes in ownership interests in subsidiaries that do not result in change in scope of consolidation	(15,457)	–
Other	(9,882)	9,317
Net cash provided by (used in) investing activities	(3,671,934)	(7,522,061)

(Thousands of yen)

	Six months ended September 30, 2022	Six months ended September 30, 2023
Cash flows from financing activities		
Increase (decrease) in short-term borrowings	(2,850,028)	3,580,000
Proceeds from long-term borrowings	9,000,000	10,000,000
Repayments of long-term borrowings	(2,689,035)	(4,595,667)
Repayments of finance lease liabilities	(89,919)	(78,728)
Dividends paid	(1,243,832)	(1,247,180)
Dividends paid to non-controlling interests	(2,950)	–
Net cash provided by (used in) financing activities	2,124,234	7,658,424
Effect of exchange rate change on cash and cash equivalents	887,759	442,369
Net increase (decrease) in cash and cash equivalents	27,990	810,685
Cash and cash equivalents at beginning of period	9,197,694	10,274,773
Cash and cash equivalents at end of period	9,225,685	11,085,459

(4) Notes to semi-annual consolidated financial statements

(Notes on going concern assumption)

Not applicable.

(Changes in consolidated subsidiaries during the current semi-annual accounting period)

In the second quarter of the fiscal year ending March 31, 2025, three subsidiaries were included in the scope of consolidation as it was newly established.

(Notes when there are significant changes in amounts of equity)

Not applicable.

(Changes in accounting policies)

(Application of the “Accounting Standard for Current Income Taxes,” Etc.)

The Company has applied the “Accounting Standard for Current Income Taxes” (Accounting Standards Board of Japan (ASBJ) Statement No. 27, October 28, 2022; hereinafter, the “2022 Revised Accounting Standard”) and other relevant ASBJ regulations from the beginning of the six months ended September 30, 2024.

With regard to revisions to the classification of current income taxes (taxation on other comprehensive income), the Company conforms to the transitional treatment stipulated in the proviso of paragraph 20-3 of the 2022 Revised Accounting Standard, and the transitional treatment stipulated in the proviso of paragraph 65-2 (2) of the “Guidance on Accounting Standard for Tax Effect Accounting” (ASBJ Guidance No. 28, October 28, 2022; hereinafter, the “2022 Revised Guidance”). This change in accounting policies has no impact on the semi-annual consolidated financial statements.

In addition, the Company has applied the 2022 Revised Guidance from the beginning of the six months ended September 30, 2024 as for the revisions related to the revised treatment in consolidated financial statements when gain or loss on sale arising from the sale of shares of subsidiaries, etc. among consolidated companies is deferred for tax purposes. This change in accounting policies has no impact on the semi-annual consolidated financial statements for the same period of the previous fiscal year and the consolidated financial statements for the previous fiscal year.

(Notes to semi-annual consolidated balance sheet)

* The composition of inventories is as follows.

(Thousands of yen)

	As of March 31, 2024	As of September 30, 2024
Merchandise and finished goods	5,583,121	5,776,072
Work in process	6,436,226	7,731,819
Raw materials and supplies	353,830	705,581
Total	12,373,178	14,213,473

(Notes to semi-annual consolidated statement of income)

* The major item of selling, general and administrative expenses is as follows.

(Thousands of yen)

	Six months ended September 30, 2023	Six months ended September 30, 2024
Salaries and allowance	964,300	1,491,424
Provision of allowance for doubtful accounts	–	57,291

(Notes to semi-annual consolidated statement of cash flows)

* The reconciliation of cash and cash equivalents at the end of the period with the account balances in the semi-annual consolidated balance sheets is as follows.

(Thousands of yen)

	Six months ended September 30, 2023	Six months ended September 30, 2024
Cash and deposits	10,721,485	11,085,459
Time deposits with maturity over 3 months	(1,495,800)	–
Cash and cash equivalents	9,225,685	11,085,459

(Notes to segment information)

(Segment information)

I. Six months ended September 30, 2023 (from April 1, 2023 to September 30, 2023)

1. Disclosure of revenue and profit (loss) for each reportable segment

(Thousands of yen)

	Reportable segments				Other (Note 1)	Total	Adjustments (Note 2)	Amount recorded on the semi-annual consolidated statement of income (Note 3)
	CRO business	TR business	Medipolis business	Subtotal				
Revenue								
Revenues from external customers	11,421,226	6,457	293,384	11,721,068	162,979	11,884,047	–	11,884,047
Transactions with other segments	69,736	–	55,352	125,088	579,069	704,157	(704,157)	–
Total	11,490,962	6,457	348,736	11,846,156	742,048	12,588,205	(704,157)	11,884,047
Segment profit (loss)	2,942,714	(498,673)	(57,265)	2,386,776	69,010	2,455,787	(106,308)	2,349,479

(Notes) 1. The “Other” classification serves as a business segment not included in the reportable segments, and accordingly includes the real estate business and other such businesses.

2. Segment profit (loss) adjustments amounting to negative ¥106,308 thousand consist of negative ¥42,086 thousand in elimination of intersegment transactions and negative ¥64,221 thousand in corporate expenses not allocated to a reportable segment. Corporate expenses are mainly general and administrative expenses, which are not attributable to the reportable segments.

3. Segment profit (loss) has been calculated upon adjusting operating profit in the semi-annual consolidated statement of income.

II. Six months ended September 30, 2024 (from April 1, 2024 to September 30, 2024)

1. Disclosure of revenue and profit (loss) for each reportable segment

(Thousands of yen)

	Reportable segments				Other (Note 1)	Total	Adjustments (Note 2)	Amount recorded on the semi-annual consolidated statement of income (Note 3)
	CRO business	TR business	Medipolis business	Subtotal				
Revenue								
Revenues from external customers	12,169,500	15,393	175,902	12,360,797	147,684	12,508,481	–	12,508,481
Transactions with other segments	30,020	–	49,621	79,642	1,091,338	1,170,981	(1,170,981)	–
Total	12,199,521	15,393	225,524	12,440,439	1,239,022	13,679,462	(1,170,981)	12,508,481
Segment profit (loss)	2,205,960	(1,775,490)	(221,186)	209,283	60,339	269,623	(189,594)	80,028

(Notes) 1. The “Other” classification serves as a business segment not included in the reportable segments, and accordingly includes the real estate business and other such businesses.

2. Segment profit (loss) adjustments amounting to negative ¥189,594 thousand consist of negative ¥131,597 thousand in elimination of intersegment transactions and negative ¥57,996 thousand in corporate expenses not allocated to a reportable segment. Corporate expenses are mainly general and administrative expenses, which are not attributable to the reportable segments.

3. Segment profit (loss) has been calculated upon adjusting operating profit in the semi-annual consolidated statement of income.

2. Information about impairment loss for non-current assets or goodwill, etc., by reportable segment

The information is omitted since there is no significant change occurred.