

Shareholders' Newsletter

Shin Nippon Biomedical Laboratories (Securities code: 2395)

2022.4.1 — 2022.9.30



The positive effects of the facility expansion implemented from the previous fiscal year to the first half of the current fiscal year are expected to gradually emerge beginning in the second half of the current fiscal year and into the next fiscal year.

Ryoichi Nagata

Representative Chairman, President & CEO



01. Could you explain the financial results for the first half of the fiscal Year ending March 31, 2023?

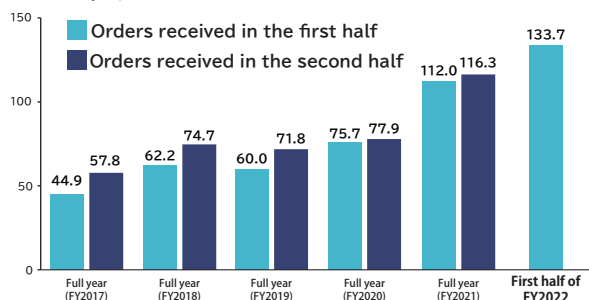
In the first half of the fiscal year ending March 31, 2023, our mainstay CRO business was the driving force behind the achievement of record high revenue for the first half, which increased ¥2,380 million (30.0%) year on year to ¥10,340 million and the record high operating profit, ordinary profit and net profit, as in the same period of the previous fiscal year.

In the pharmaceutical industry, the trend toward outsourcing operations to contract research organizations (CROs) continues to gain momentum, with the expectation that this accelerates research and development and improves cost efficiency. In addition, research and development involving new drug modalities (therapeutic tools) in drug discovery such as nucleic acid medicine and next-generation therapeutic antibodies has been in full swing. Shin Nippon Biomedical Laboratories, Ltd. ("SNBL" or "the Company") is highly valued by customers for its establishment of a stable breeding and supply system for laboratory NHPs, which are becoming increasingly important in the evaluation of new drug modalities in drug development, and its establishment of technologies and evaluation systems that are useful in evaluating the efficacy and safety of new modalities in drug development. As a result, orders received in the nonclinical business increased ¥2,160 million (19.3%) year on year, to ¥13,370 million, a record high for the first half of a fiscal year. Above all, orders received from overseas customers, where the development of new drug modalities in drug discovery is progressing, increased ¥2,970 million (107.6%) year on year, to ¥5,730 million, and the ratio of overseas orders received out of total orders received grew significantly year on year, from 24.6% to 42.9%. Beginning with this announcement, overseas orders received are converted to yen using the average exchange rate during the period, and overseas order backlogs are converted to yen using the exchange rate at the end of the period.

In the first half, we paid dividends of ¥20 per share. Interim dividends were paid for the first time since our listing.

Nonclinical CRO business orders (in yen)

(Unit: 100 million yen)



(million yen)

	10,270	13,690	13,180	15,360	22,830	13,370
Orders received						
Order backlog	7,490	10,820	11,470	13,660	20,970	33,670

Including Ina Research Inc. from the first half of FY2021.

Overseas orders received are converted to yen using the average exchange rate for the period, and overseas order backlogs are converted to yen using the year-end exchange rate for the period.

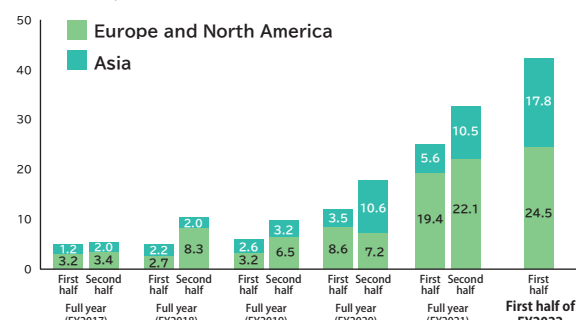
02. Could you also explain the strong financial results of equity-method affiliate PPD-SNBL K.K. ("PPD-SNBL") which operates a clinical business?

While our main business is nonclinical, which involves contracted nonclinical (or preclinical) studies to investigate the efficacy and safety of drug candidate compounds, we are also engaged in the clinical business, which is contracted human clinical studies (therapeutic trials), through PPD-SNBL, a joint venture with PPD International Holdings, LLC ("PPD"), an international clinical CRO based in the United States. PPD-SNBL's mainstay business is the implementation of global studies (studies conducted simultaneously in multiple countries and regions) that are outsourced to PPD in Japan, which has bases in approximately 50 countries around the world. Although it is a global company, by incorporating Japanese-style management elements under which a harmonious working environment that we have cultivated is valued, PPD-SNBL has achieved a high employee retention rate and is steadily increasing its business performance. As PPD-SNBL is an equity-method affiliate (currently SNBL owns 40% of its equity), it is included in our results of operations as "share of profit of entities accounted for using equity method" under non-operating income.

Last year, PPD was acquired by Thermo Fisher Scientific, Inc. in the United States, a leading global medical device company, and the foundation of PPD's business has been strengthened by its becoming a member of the Thermo Fisher Scientific Group. Backed by more and bigger orders, equity in earnings from PPD-SNBL totaled ¥980 million for the first half of the current fiscal year, a record high for the first half of a fiscal year and a ¥580 million increase over the same period last year. This is well above our initial forecast and it is one of the driving forces behind our performance.

Nonclinical CRO business international orders (in US\$)

(Unit: Million dollars)



	10.5%	12.3%	12.9%	20.6%	28.6%	42.9%
Percentage of orders received from overseas customers						
Order backlog	\$10.0M	\$19.9M	\$18.9M	\$36.0M	\$65.6M	\$117.9M

03. Could you explain the construction of the new building and research building announced in March 2022?

As we have continued to enjoy high utilization rates of our facilities due to strong orders received in recent years, there have been instances where we have been unable to respond to orders received from our clients. For this reason, we have been renovating existing facilities and increasing our business processing capacity by introducing robots and IT-based process management. However, it became difficult to address this situation, so we decided to build a new building and a new research building on the premises of the Kagoshima Main Branch. The new buildings are two eight-story reinforced concrete (RC) buildings with a total floor area of 13,022 m². They will house the bioanalysis research department, the analytical research department, the IT department, staff office area, conference rooms, and executive offices. The total construction cost is expected to be approximately ¥5,400 million, and completion is targeted for June 2024.

Once the series of renovations and new construction projects is completed, our contract capacity will increase by around 50% compared to the end of the fiscal year ended March 31, 2022, and we will be able to handle larger orders. We will hire about 150 new employees next spring and focus on strengthening their core skills. The construction costs are expected to be funded by cash on hand and borrowings from financial institutions.

04. Could you explain the forecasts for the second half of the fiscal year ending March 31, 2023 and future direction of the Company?

We expect that the environment surrounding our mainstay nonclinical CRO business will continue to be favorable, with orders received from international markets recognized as a growth driver. In the first half of the fiscal year ending March 31, 2023, the expansion of the European standard test facility requested by some of our customers in Europe and the United States was completed in the second quarter and is already available for testing. In addition, new employees hired this spring will join our team in the second half. Therefore, we believe that our ability to handle business will steadily improve in the future. We will continue to expand our facilities and increase the number of research staff, as well as focus on robotization and DX to maximize customer profit and provide “time value” to customers by shortening the lead time from order receipt to the submission of the final report. In this way, we will work from a global perspective to become the first choice of our clients as a CRO second to none.

05. Is there any progress in the Translational Research (TR) business?

We think that the second half will be the touchstone for the future commercialization of the TR business. We are promoting formulation technology, which we have been working on since 1997, by making excellent use of the intranasal drug delivery technology that we have developed on our own. In the United States, we plan to announce the top-line results of a large-scale Phase III clinical efficacy trial of an intranasal migraine drug (STS101) conducted by Satsuma Pharmaceuticals, a NASDAQ-listed drug discovery venture that has been licensed with the underlying technology, by the end of the year. In addition, the Company’s consolidated subsidiary SNLD, Ltd. also plans to announce, by the end of the year, the results of the Phase I clinical trial of an intranasal drug (TR-012001) for the treatment of off-symptoms of Parkinson’s disease in Japan. If SNBL was an airplane, currently, its profit engine would mainly consist of a single engine, our CRO business, but I expect the TR business to become the second engine in the future.

06. Could you explain your initiatives for the SDGs/ESG toward the enhancement of corporate value?

In October 2022, we published our first integrated report. In the integrated report, we laid out our 2028 Vision, “Be close to our stakeholders and promote people’s happiness.” By promoting sustainability initiatives and creating economic and social value in an integrated manner through our business activities, we will promote people’s happiness with our stakeholders around the world. We are also focused on the happiness of our employees and have provided all employees with special bonuses to cover rising prices.

During the first half under review, our ongoing initiatives for the SDGs/ESG have been highly evaluated by various evaluation agencies, and we were selected to be a constituent of the FTSE Blossom Japan Sector Relative Index created by global index provider FTSE Russell in June. In August we were also selected to be a constituent of the JPX Nikkei Small- and Mid-cap Index, which is jointly calculated by JPX Research Institute, Inc. and Nikkei Inc. We will continue to enhance our information disclosure going forward.

07. Could you share a message for the shareholders?

In September 2022, SNBL celebrated the 65th anniversary of its founding. For the past 30 years since I became the President in 1991, I have been independently developing and implementing horizontal and vertical business expansion as a growth strategy, and I am confident that each of the various tactics I have implemented during this period is bearing fruit. I would like to continue to promote people’s happiness with all of you. We would like to ask our shareholders to watch over our sustainable growth and continue to support us.

Results for the first half of FY2022 (100 million yen)

	Results for the first half of FY2021	FY2022		
		Results for the first half	YoY	
Revenue	79.6	103.4	+23.8	30.0%
Operating profit	19.6	23.1	+3.5	17.5%
Ordinary profit	25.2	59.2	+34.0	134.4%
Ordinary profit (Excluding the impact of foreign exchange losses [gains])	23.7	33.4	+9.7	40.6%
Profit attributable to owners of the parent	35.0	44.1	+9.1	26.1%

Full-year earnings forecasts for FY2022

	Full-year results for FY2021	FY2022		
		Revised forecasts	YoY	
Revenue	177.4	240.0	+62.6	35.2%
Operating profit	41.9	52.6	+10.7	25.4%
Ordinary profit	70.7	98.0	+27.3	38.5%
Ordinary profit (Excluding the impact of foreign exchange losses [gains])	57.0	72.1	+15.1	26.4%
Profit attributable to owners of the parent	71.2	70.0	-1.2	-1.8%

Ina Research, a Company in the Same Industry, Became a Wholly Owned Subsidiary Through a TOB



On July 20, 2022, we conducted a tender offer ("takeover bid" or "TOB") for shares of Ina Research Inc. ("Ina Research"), the core business of which is the CRO business (nonclinical business), which conducts nonclinical studies commissioned by pharmaceutical companies and others.

Ina Research became a wholly owned subsidiary of the Company, and its financial results were consolidated into the SNBL Group in July 2022. Ina Research is headquartered in Ina City, Nagano, rich in nature surrounded by the Japanese Chuo and Minami Alps. Since its establishment in July 1974, Ina Research has been refining its technology and expertise with a commitment to quality and reliability. It provides full services in the nonclinical stage of drug development support, and is known worldwide as a CRO capable of conducting special studies, such as dependency studies for psychotropic drugs, which require advanced knowledge and technology and can only be conducted in a few places in the world. In recent years, the company has acquired customers globally, with overseas sales expanding at a rate approaching 50% of total sales, and has demonstrated its strength in East Asia, particularly in the South Korean market.



In terms of contributions to the community and society, it provides part of its headquarters and research facilities to the Center for Advanced Research of Gene and Cell Therapy in Shinshu University (CARS) to support the development of gene therapy methods, in which Japan is lagging behind.

The company also has a strong track record in animal welfare initiatives, and in February 2005 became the first company in Japan to receive "full accreditation" from the Association for Assessment and Accreditation of Laboratory Animal Care International (AAALAC International), an international animal welfare certification organization. AAALAC International, headquartered in the United States, is the only international independent research organization that evaluates laboratory animal facilities from the perspective of promoting the humane management of animals in science. Facilities accredited by AAALAC International are re-evaluated every three years through facility visits, and Ina Research has continuously received full accreditation.



As a pioneering effort, the company is working on conversion services for the Standard for Exchange of Nonclinical Data (SEND), a standard format for nonclinical trial data for new drug applications, which was introduced by the Food and Drug Administration (FDA) in the United States ahead of other CROs in the world, and it has one of the best track records among CROs in Japan. The number of domestic and international customers requesting SEND conversions is steadily increasing, because pharmaceutical companies filing new drug applications with the FDA will suffer losses of both time and money due to the sending back (refusal to accept) by FDA

if there is an error in their data submissions based on SEND.

By integrating Ina Research into our business operations, we aim for the following. First, we will diversify our customer base. Our customers have traditionally been major Japanese pharmaceutical companies as well as companies mainly in Europe and the United States. Ina Research's strength lies in its East Asian clientele, which we expect to be geographically complementary to ours. The effect of scaling up will also allow us to respond flexibly to our customers' wishes regarding the timing of the start of testing. Furthermore, by sharing the strengths and know-how of each other's facilities, we can offer a wider range of test types and provide higher quality services. In addition, Ina Research is an owner-operated company established in a rural area with a corporate culture similar to our own, which has valued people and refined its technology, and we expect synergistic effects to enhance our corporate value at an early stage.

News from IR & Corporate Communication Department

IR public relations

Hello, everyone. I am Senior Director Iwata of the IR & Corporate Communication Department.

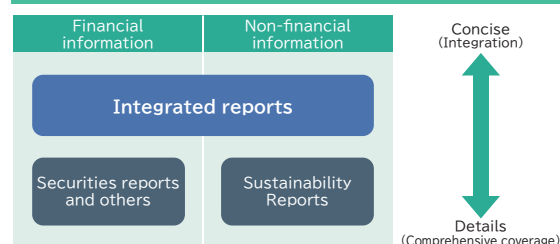
One year has passed since the establishment of our Department in June 2021.

Always keeping in mind our KGI, “Enhance corporate value,” and under the slogan “Act immediately,” as stated in Article 1 of our Job Basics, the four members of the department work cheerfully, happily, with a smile, and with a sense of speed and vigor every day.

Here, we will report our activities to date in the fiscal year ending March 31, 2023.



1. Publication of the integrated report



On October 6, SNBL prepared and published the 2022 Integrate Report. The Integrated Report integrates non-financial information such as SDGs/ESG initiatives with financial information such as corporate performance, which has traditionally been reported in securities reports, to report the “value creation story” of how corporate strategy, business model, governance structure, etc. lead to the creation of corporate value.

The future that we would like to create this time around is set up in our 2028 Vision “Be close to our stakeholders and promote people’s happiness.” Overall, the Integrated Report consists of three sections: “Value Creation Story,” “Management Strategy,” and “Management Infrastructure Supporting Value Creation,” and here are the highlights of each section.

In the “Value Creation Story,” what SNBL aims for in the medium- to long-term is described in the CEO’s message. The “Management Strategy” section includes financial targets for FY2028, seven years from now, as well as monitoring indicators we emphasize in non-financial targets. In “Management Foundations Supporting Value Creation,” we introduce five initiatives in our human resources strategy.

The 40-page report is compact for an integrated report, but we believe it will help you understand the Company. As it is disclosed in our website, we invite you to take a look.

https://ssl4.eir-parts.net/doc/2395/ir_material_for_fiscal_ym3/127683/00.pdf



2. Winning of the IR Award

In November, SNBL won the Best IR Award for Encouragement in the 2022 IR Award sponsored by the Japan Investor Relations Association (JIRA). This award is presented once a year to companies that have developed outstanding IR activities, and the Best IR Award for Encouragement is the highest award for small and medium-sized companies that are applying for the first time.

Since the establishment of the IR & Corporate Communication Department in June 2021, SNBL has been pursuing a range of initiatives to enhance its corporate value at the same time with a sense of speed. We are very pleased that these initiatives were recognized this time. We will continue to provide detailed and meticulous information about our activities in a detailed and easy-to-understand manner, even in specialized areas, in an effort to deliver a variety of exciting experiences to our investors.



Number of meetings with institutional investors
157



Results for 1H, FY2022
(Annually 121 in FY2021)

Number of participants in financial results briefings
93



Results for November 2022
(45 people in November 2021)

Briefings for individual investors
4 times/503 people



Results for FY2021 and thereafter
*We plan to hold company information sessions for individual investors in all 47 prefectures of Japan.

IR Blog
121 posts



Results for FY2021
*Once every three days

Corporate Data (As of September 30, 2022)

Capital	9,679,070,000 yen
Year of Foundation	September 1957 (Established: May 1973)
Number of Employees	1,219
Headquarters	St. Luke's Tower 28th floor, 8-1 Akashicho, Chuo-ku, Tokyo, 104-0044 (Location of main branch: 2438 Miyanouracho, Kagoshima-shi, Kagoshima)
Business	CRO business to support the development of pharmaceutical products



Kagoshima HQ/
Drug Safety Research
Laboratories

Board of Directors (As of September 30, 2022)

President and Chairman	CEO and CHO	Ryoichi Nagata
Executive Vice President	Group Corporate Management and Global Business	Ken Takanashi
Managing Director	Corporate Development and Corporate Finance	Shinji Nitanda
Managing Director	Preclinical Company President and Global Business Development	Hideshi Tsusaki
Executive Director	Preclinical Company Vice President, CEO Office Senior Director, and Hospitality Division Senior Director	Ichiro Nagata
Independent External Director		Shinichi Fukumoto
Independent External Director		Takashi Yamashita
Independent External Director		Tsuyoshi Hanada
Independent External Director		Keiko Toya

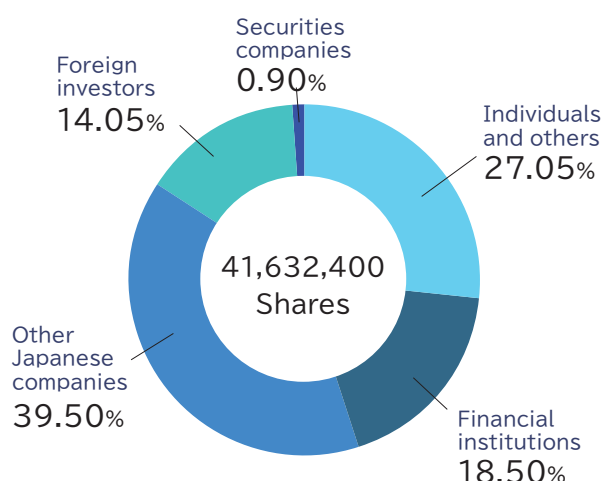
Shares Status (As of September 30, 2022)

Total Number of Shares Issued	41,632,400 shares
Number of Shareholders	9,641

Major Shareholders (Top 10)

Name	Total Number of Shares Held (thousand shares)	Shareholding Ratio (%)
Nagata and Company Co., Ltd.	14,690	35.28
The Master Trust Bank of Japan, Ltd. (Trust account)	4,426	10.63
Takahisa Nagata	2,080	4.99
Custody Bank of Japan, Ltd. (Trust Account)	1,889	4.53
Medipolis Medical Research Institute	1,474	3.54
Ikue Nagata	1,024	2.45
Ichiro Nagata	1,024	2.45
Rie Umehara	1,024	2.45
The KAGOSHIMA BANK, LTD.	1,000	2.40
ML PRO SEGREGATION ACCOUNT	491	1.17

Distribution of Shares by Shareholder (as of September 30, 2022)



Commemoration of the 65th anniversary of the Company's founding



SNBL was founded in September 1957 when its founder Tsugio Nagata established the Southern Japan Dog Center (including animal hospital) attached to a livestock hospital. 2022 marked the 65th anniversary of the Company's founding, and financiers and madeleines made with Kagoshima's Chiran tea and other ingredients were distributed to all executives and employees on the anniversary of the Company's founding in September. These were created by Executive Pastry Chef Yoichi Kurosa (winner of the 2016 National Sweets Contest ROLL-1 Grand Prix) at AMAFURU & Co., a healing resort hotel run by our Group company in Ibusuki City, Kagoshima, and were also distributed at our general shareholders meeting held in June 2022. They are original baked goods, which we very much hope our stakeholders to enjoy.

Our website



<https://www.snbl.co.jp>

Shin Nippon Biomedical Laboratories

Search



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UD FONT

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