

# Promoting people's happiness hand in hand with our stakeholders

Shin Nippon Biomedical Laboratories, Ltd. (SNBL)



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# 20INTEGRATED24R E P O R T

This Integrated Report aims to give stakeholders a deeper understanding of SNBL Group's business model and foster mutual
understanding through dialogue, leading to improvement in management and corporate value.
In the 2004 addition, we focus on our contribution to accial issues and our husiness strategy for achieving our 2000 Vision, "Dremati

people's happiness hand in hand with our stakeholders".

During the editing process, the IFRS Foundation's International Integrated Reporting Framework and the Ministry of Economy, Trade and Industry's Guidance for Integrated Corporate Disclosure and Company-Investor Dialogue for Collaborative Value Creation were used as references.

#### Period Covered Scope of Coverage

**Editorial Policy** 

OVERAGE Shin Nippon Biomedical Laboratories, Ltd. (SNBL) and its subsidiaries

Notes concerning forward-looking statements

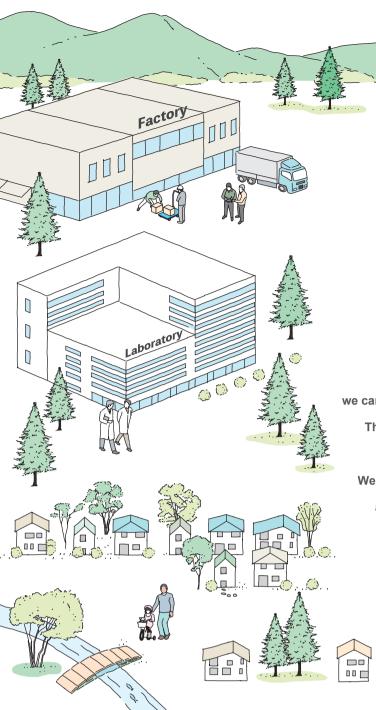
Forward-looking statements including our future plans, forecasts and strategies are based on certain assumptions deemed reasonable by SNBL in light of currently available information, and results including actual business performance may vary significantly from expectations.

#### **Our Reporting Universe**

SNBL publishes three corporate reports: the Integrated Report, the ESG Data Book, and the Annual Securities Report. We define the role of each report along two axes: quantitative information - business strategy and financial information - non-financial information.

In particular, the Integrated Report and the ESG Data Book can be read together to confirm ESG initiative progress and data in addition to business strategies. We also invite you to visit our websites for additional information.

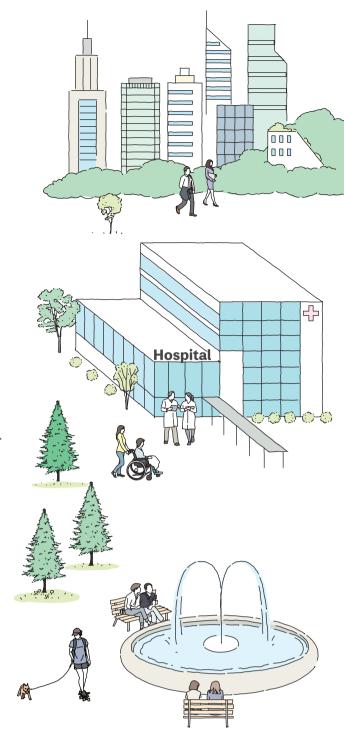


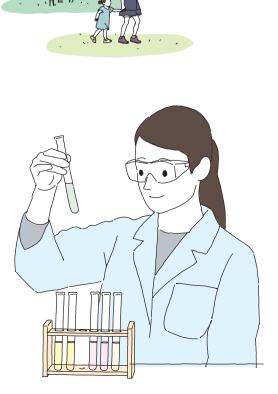


#### SNBL's Vision of the Future

# l am happy, you are happy, everyone is happy.

Everyone takes care of themselves. This is natural. We believe that by considering other people's perspectives in addition to our own, we can create a society where we help each other with gratitude and respect. This idea connects to our corporate philosophy of being "a company committed to the environment, life, and people." We have developed a unique business model centered on life sciences, and our corporate philosophy has always been at the root of this. In line with our corporate philosophy, we will continue to work in partnership with all stakeholders, fostering mutual respect and appreciation, with the aim of creating a society where everyone can be happy.









# The Key to the Success of Developing New Types of Drugs

The development of drugs is becoming more and more difficult each year, with the focus being on disease areas where the therapeutic effects of conventional drugs cannot be expected to be sufficient. The key to success can be said to be held by CROs<sup>\*1</sup>, which are development support companies that have a wealth of experience in developing new types of drugs and can become development partners for pharmaceutical companies.

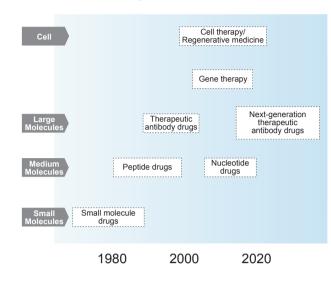
#### The Emergence of New Types of Drugs and the Increasing Difficulty of Development

Drug development is said to take at least 10 years and tens or hundreds of billions of yen, and the probability of success is estimated at around 1 in 25,000.<sup>\*2</sup> In recent years, due to advances in the technologies underlying drug developmet, in addition to conventional small molecules, various molecules, such as antibody drugs, nucleic acid drugs, gene therapy and regenerative medicine, have started being practically applied in drugs. This situation offers the potential to deliver groundbreaking therapies to patients with diseases that cannot be effectively treated with existing therapies. However, there is a growing tendency for new drug research and development to become increasingly complex. It also takes longer with each passing year, while the probability of success continues to decline.

#### The Role of a CRO

The stages of developing a drug are basic research, nonclinical studies, clinical studies, and the approval process. Pharmaceutical companies used to carry out all these processes in-house; however, rather than having facilities and human resources on their own, they now tend to outsource some basic research and nonclinical and clinical studies to clinical research organizations (CROs) that possess specialist knowledge, expertise, and experience in these areas, based on management's judgment that outsourcing is more efficient.

\*1 CRO is a company that is contracted by pharmaceutical companies to carry out some or virtually all of the work related to the implementation, operation, and management of nonclinical and clinical studies.
\*2 Source: Japan Pharmaceutical Manufacturers Association DATA BOOK 2023 **Diversification of Drug Modalities** 



#### Steps in Drug Development and the Area of SNBL Group's CRO Business



#### Nonclinical CRO business

#### Clinical CRO business

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#### Nonclinical CRO business

According to international rule for new drug development, clinical studies involving the administration of a drug candidate compound to humans must be preceded by other studies using cells, laboratory animals, and other methods to ensure efficacy and safety. These studies are called nonclinical studies.

A unique feature of our nonclinical business is that we have built a global brand in nonclinical studies using laboratory NHPs (non-human primates), which are said to be the most advantageous laboratory animals and considered excellent models for humans. In the pharmaceutical industry, the research and development of new modalities in drug discovery is in full swing, particularly in relation to nucleic acid medicine, next-generation therapeutic antibody drugs, and gene therapy. Laboratory NHPs are essential for the development of these new type of drugs.

We have strongly differentiated ourselves from our competitors by being the only CRO in

### **Clinical CRO business**

The main task of the clinical business is to connect pharmaceutical companies which are the sponsors of clinical studies, and medical institutions which conduct the trials, and to create a one-team that produces new drugs.

More specifically, our staffs visit medical institutions to see whether the clinical studies are properly conducted in compliance with the rules and standards established by the government and pharmaceutical companies, summarizes and statistically analyzes the data obtained and support the series of operations up to the preparations of the applications submitted to regulatory authorities.

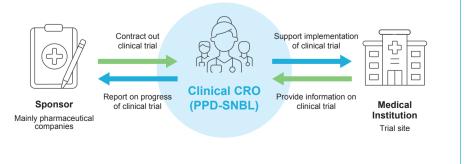
Our clinical business is carried out through a joint venture, PPD-SNBL K.K., established in 2015 with PPD, a global clinical CRO headquartered in the United States. PPD-SNBL's mainstay business is to organize and to implement a part of global studies that are outsourced to PPD, in Japan.

the world to establish an in-house breeding and supply system for laboratory NHPs. We are recognized by pharmaceutical companies as a development partner because we have introduced the state-of-the-art equipment needed to assess the efficacy and safety of new drug modalities and have built an evaluation system from an early stage.

#### NonClinical CRO Supporting Drug Discovery and Development



#### **Role of Clinical CRO in Drug Development**



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# A Pioneer in the CRO Industry, Ensuring Drug Safety and Supporting Global Health

The SNBL group plays a vital role in protecting patients by ensuring the safety of drugs before they are administered to humans. Through contract research services in nonclinical and clinical trials, we contribute to the advancement of development and the safeguarding of public health.

#### Pharmaceutical Market: The Dawn of Drug Development

#### Trends in Drug Development

Trends in the Pharmaceutical Industry

**Full-Scale Development of** 1955 Small-Molecule Drugs with the Introduction of the **Substance Patent System** The development of modern drugs began in 1897 when the German 1960 company Bayer refined a pain-relieving component of willow bark, called salicylic acid, to create a drug with fewer side effects. This drug was called "Aspirin." 1965 Chemically synthesized pharmaceuticals (known as small-molecule drugs) were easier to produce and convenient for oral administration due to their small molecular size, leading to their 1970 widespread use. The introduction of the substance patent system (introduced in Japan in 1976) significantly boosted the development efforts of 1975 pharmaceutical companies. However, despite the advantages of these drugs, their small molecular

#### **Drug Safety Issues and** the Importance of Data

and Its Evaluation The sedative thalidomide, developed in Germany, caused severe birth defects when taken by pregnant women. This led to a major drug safety incident in 1958 and the eventual recall of the drug in over 40 countries. However, in the United States, the FDA (Food and Drug Administration) examiner guestioned the submitted data on thalidomide and requested a re-examination, thus postponing the approval of this drug and avoiding the ill effects. This incident highlighted the global importance of the content and evaluation of pharmaceutical data, leading to the recognition that disclosing side

effect information is crucial in the

development of drugs.

#### **SNBL's History**

#### Japan's First Nonclinical CRO

The predecessor of SNBL was the Southern Japan Dog Center, which was founded in Kagoshima City in 1957 by Tsugio Nagata, the father of SNBL's current president, for the purpose of breeding and improving laboratory beagles.

In 1960, the company received its first commission for a nonclinical study of a drug from a leading overseas pharmaceutical company, thus becoming Japan's first nonclinical CRO.

In 1974, SNBL adopted its current name and has since pioneered the development of the nonclinical CRO market in Japan. As a trailblazer in the CRO industry, we have played a vital role for many years in ensuring the safety of drugs before they are administered to humans, thereby supporting the health and wellbeing of people worldwide.



History

# 1957

Founded as Southern Japan Dog Center (with an attached animal hospital) in Kagoshima City

#### 1960

Began accepting contracts for nonclinical studies as the first CRO in Japan

#### 1973

Incorporated as Southern Japan Dog Center, Ltd.

#### 1974

Company name changed to Shin Nippon Biomedical Laboratory, Ltd. (SNBL)

Inside the laboratory, 1970s (Kamoike-cho, Kagoshima)

Size of the global rmaceutica market

1980

Estimated at

70 billion dollars

1985

Estimated at

94 billion dollars

1990

Estimated at

140 billion dollars

Year

#### **Growth of Small-Molecule Drug Market**

#### Trends in Drug Development

#### Shift in Target Diseases: **From Infectious Diseases** to Cancer

size led to a lower specificity for target molecules, increasing the

likelihood of side effects.

In the past, infectious diseases posed the greatest threat to humanity. However, with the advent of antibiotics like penicillin, these diseases were perceived to be under control, leading the United States to declare in 1967 that the war against infectious diseases had been won. Following this milestone, research focus shifted toward cancer At the same time, lifestyle changes brought about by rapid economic growth and aging populations led to a rise in lifestyle-related diseases. As a result, new medications targeting conditions such as hypertension, high cholesterol, and diabetes emerged. These developments drove significant growth in the global pharmaceutical market.

#### Trends in the Pharmaceutical Industry

**Emergence of Biotech Companies and** the Development of **Biopharmaceuticals** 

The discovery of the double-helix structure of DNA in 1953 marked a turning point in understanding the mechanisms of the human body at the molecular level. This breakthrough paved the way for the development of drugs-medications formulated from biological substances naturally produced within the human body, rather than from chemical compounds. The first biopharmaceutical to reach the market was insulin, developed by a U.S. biotech company for the treatment of diabetes using recombinant DNA technology. Another groundbreaking advancement was therapeutic antibody drugs, which leverage the immune system to combat diseases and gained attention as a revolutionary cancer treatment. Due to their large molecular size, therapeutic antibody drugs brought significant changes to both safety studies and manufacturing processes in the pharmaceutical industry.

#### **SNBL's History**

**Establishing a Comprehensive System** for Contracting Both Nonclinical and Clinical Studies in Japan

Following the introduction of Good Laboratory Practice (GLP) standards in Japan, our company became the first domestic nonclinical CRO to undergo a GLP inspection by the Ministry of Health in 1984, earning the highest rating of "A" for compliance. In the 1990s, we expanded into the clinical trial sector, becoming the first in Japan to offer an integrated service encompassing the entire drug development process.

Furthermore, in 1999, we launched our nonclinical

History

#### 1983

1993

Began Good Laboratory Practice (GLP) -compliant safety studies

Began accepting contracts for clinical pharmacological testing and Phase 1 clinical trials

#### 1997

Began accepting contracts for

SNBL's Value Creation

1995 Estimated at 280 billion dollars



CRO business near Seattle, USA. We have also contributed to animal welfare advancements by developing restraint devices designed to minimize the burden on laboratory NHPs.



Phase 2 and 3 clinical trials

#### 1998

Established the Pharmacokinetics and Bioanalysis Center in Kainan, Wakayama Prefecture

#### 1999

in Washington State

Established SNBL USA, Ltd. in Washington State

Established SNBL USA, Ltd.

Size of the global pharmaceutica market

2000

Estimated at 360 billion dollars

2005

Estimated at

600 billion dollars

2010

Estimated at

880 billion dollars

2015

Estimated at

1.1 trillion dollars

2020

Estimated at

1.3 trillion dollars

#### Growth of the Biopharmaceutical Market (Especially Antibody Therapeutics)

Trends in the Pharmaceutical Industry

#### Trends in Drug Development

Antibody Therapeutics Dominate the Pharmaceutical Landscape

Biopharmaceuticals, which

leverage the natural mechanisms and functions of the human body, have become a cornerstone of drug development due to their high efficacy and reduced side effects. Among these, antibody therapeutics—protein-based drugs that target the immune systemhave risen to prominence, accounting for over half of the 10 best-selling pharmaceuticals globally Despite their success, antibody therapeutics face several challenges. Their large molecular size prevents them from crossing

cell membranes to target intracellular disease mechanisms. Additionally, high manufacturing costs contribute to the elevated prices of these drugs. With the expiration of basic patents in the late 2010s, efforts to develop new drug modalities aimed at becoming the next-generation market leaders have intensified.

#### Increased Outsourcing to CROs

Drug development involves several stages, including basic research, exploratory research, nonclinical studies, manufacturing of investigational drugs, clinical trials, and regulatory review. In the past, pharmaceutical companies handled all these steps internally. However, with the growing dominance of biopharmaceuticals, research and development costs have surged. This has driven a widespread realization that outsourcing certain areas is more efficient than doing everything in-house. As a result, tasks such as exploratory research, nonclinical studies, and clinical trials are increasingly being entrusted to CROs with specialized expertise and a proven track record. Looking ahead, the emergence of new drug discovery companies leveraging AI and IT technologies is expected to further accelerate the trend toward

outsourcing in the pharmaceutical

industry.

SNBL's History

#### Supporting the Development of New Drug Modalities as a Development Partner

We have proactively introduced state-of-the-art equipment to evaluate the efficacy and safety of new drug modalities and established the necessary evaluation systems at an early stage. Additionally, we were the first CRO in the world to establish an in-house framework for breeding and supplying laboratory NHPs. Laboratory NHPs are essential not only for antibody drugs but also for the development of new drug modalities such as nucleic acid drugs and gene therapy, and we have built a global reputation on our NHP nonclinical studies.

These initiatives have been highly recognized, positioning us as a trusted development partner for pharmaceutical companies looking to advance new drug modalities.



#### History

#### 2003

Established NHP breeding facility in Guangdong, China

#### 2004

Established SNBL Clinical Pharmacology Center, Inc. in Baltimore and built a medical facility specializing in clinical studies, with clinical operations beginning in

#### 2005

Listed on the Tokyo Stock Exchange (TSE) Mothers Market

2007

Established NHP breeding facility in Cambodia

2015

Established PPD-SNBL, a joint venture with U.S. clinical CRO PPD

Kagoshima Headquarters Studies for overseas customers are also conducted in Japan

Size of the global pharmaceutical market

#### **Expansion of New Drug Modality Market**

#### Trends in Drug Development

#### 2030 Estimated at 2.1 trillion dollars

#### A New Era of Innovation Driven by Advanced Therapeutics

Following the expiration of basic patents for antibody drugs, development efforts have intensified around next-generation therapies such as nucleic acid therapeutics, next-generation antibody drugs (e.g., ADCs), peptide drugs, and gene therapies, all poised to become major breakthroughs in medicine. Innovations in delivery technologies are enabling smoother targeting of disease-causing molecules, while advances in biotechnology, such as genome editing, allow for highly selective action at specific sites. Production technologies are also evolving rapidly to meet the demands of these cutting-edge medicines. Governments worldwide increasingly recognize the importance of strengthening drug discovery capabilities—not only to deliver optimal medicines and medical care to their populations swiftly but also as a critical driver of national economic growth. To this end, many countries are investing heavily in the development of a drug discovery ecosystem, ensuring robust infrastructure and support for fostering innovation in this field.

#### Trends in the Pharmaceutical Industry

# Leveraging the Drug Discovery Ecosystem

Pharmaceutical companies face increasing challenges in addressing the complexity and sophistication of developing new drug modalities alone. As a result, a growing trend involves active collaboration with academia and biotech ventures to integrate innovative drug discovery technologies and promising development candidates. This collaborative framework extends to using CROs, as well as CMOs/CDMOs specializing in the manufacturing of candidate compounds and investigational drugs. This integrated approach, leveraging the drug discovery ecosystem, represents a transformative model for pharmaceutical innovation and is expected to become the dominant strategy in the future.

#### SNBL's History

#### Actively Contributing to the Growth of the Global Drug Discovery and Development Ecosystem

As our core nonclinical CRO business has a strong track record of supporting the development of new drugs, we view the current environment as an opportunity for further growth. To this end, we are making large strategic upfront investments, including significant workforce expansion, enlargement of our research facilities, and the establishment of a domestic breeding system for laboratory NHPs.

In 2024, in collaboration with SBI Holdings, the SNBL group launched a biotech startup incubator

#### History

#### 2022

Relisted on Prime Market of TSE

#### 2024

Completion of new headquarters and research building in Kagoshima

Strategic Alliance with SBI Holdings to Jointly Operate Biotech Startup Incubation and Fund Management in the United States -Term Busi

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and joint fund initiative, leveraging our facility in Washington State, USA, as a base of operations. These efforts reflect our active contribution to the growth of the global drug discovery and development ecosystem.

Collaboration with Astellas Pharma in Tsukuba to Strengthen the Drug Discovery Ecosystem

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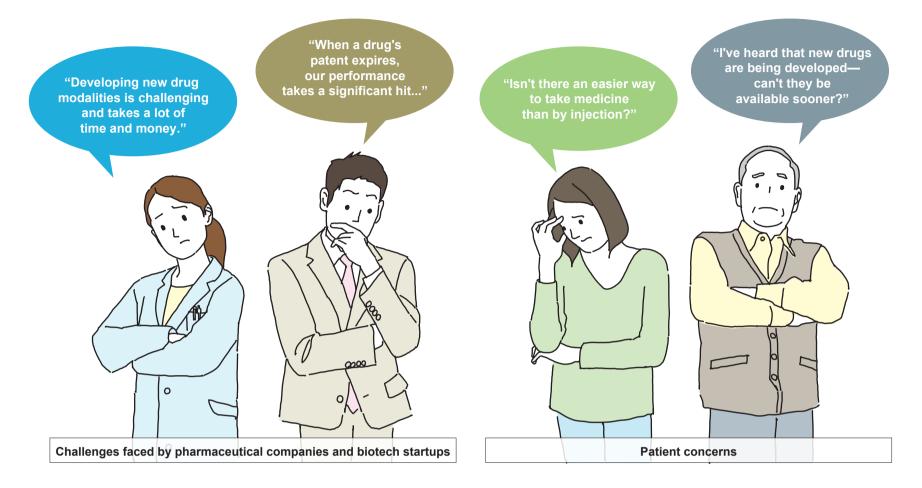
Social Issues Related to the Pharmaceutical Business

# Social Issues in Drug Development

SNBL's mission is to free patients from suffering by supporting drug development and improving medical technology.

Guided by this mission, we have built a unique business model centered on life sciences related to drug development.

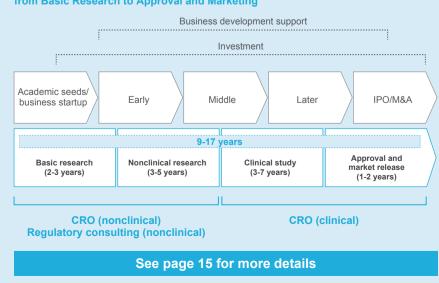
We are currently expanding our business in all areas of drug development, helping to give patients access to more effective drugs as quickly as possible.



# SNBL is committed to addressing societal and client challenges



Total Support for Drug Development at Every Stage, from Basic Research to Approval and Marketing Platform Technology for Transforming Existing Drugs into New Nasal Drug Formulations





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**SNBL's Value Creation** 

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#### Value Creation Story

The touchstone for all of SNBL's management decisions is our corporate philosophy of being a company "committed to the environment, life, and people." We are strengthening the management foundation that underlies our creation of value while enabling us to anticipate societal shifts and harnessing six types of management resources (financial capital and five types of non-financial capitals), as we work to develop new businesses and maximize the value we create in existing businesses. This way, we will generate a virtuous cycle of increasing capital through our business activities. SNBL's mission is to free patients from suffering by supporting drug development and improving medical technology. With this mission in mind, we formulated the 2028 Vision, which calls for us to be a company that promotes people's happiness hand in hand with our diverse stakeholders and generates economic and social value through our business activities.



# Creating a Drug Discovery Ecosystem to Deliver New Drugs to Patients as Quickly as Possible

As a pioneer in the CRO industry, we are working to strengthen collaborative relationships with various stakeholders, including pharmaceutical companies, and to reduce the time needed for development of new drugs.

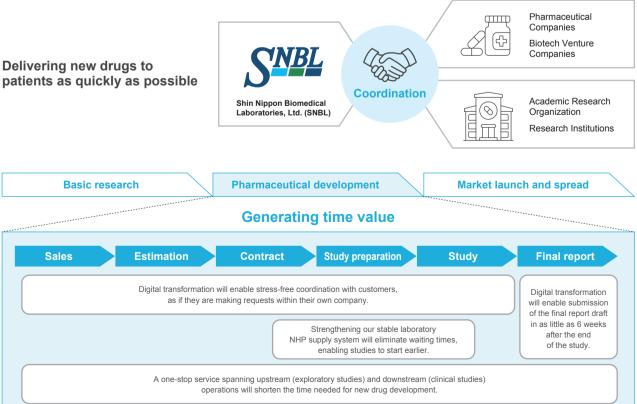
Through our contract research and development, we play an important role in ensuring the safety of new drugs and protecting patients.

In recent years, new types of drugs under development hold promise for effectively treating diseases that cannot be adequately addressed by conventional drugs. However, research and development timelines are becoming longer.

We are working to create a new drug discovery

#### The Drug Discovery Ecosystem We Want to Create

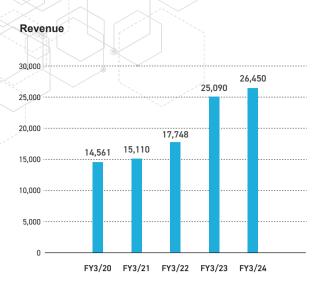
patients as quickly as possible



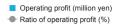
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ecosystem that reduces the time needed for development of new drugs to deliver new drugs to patients as quickly as possible.

We believe that this new ecosystem will help maximize benefits not only for patients, but also for the pharmaceutical companies, biotech venture companies, academic institutions, and research organizations we work with. We believe that an environment where clinical development can begin sooner, from selection of compounds for new drug candidates onward, will eliminate "drug lag" and lead to the growth of the pharmaceutical industry as a whole.

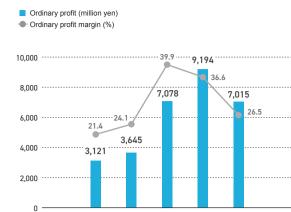


#### Operating profit / Ratio of operating profit to revenue





#### Ordinary profit / Ordinary profit margin



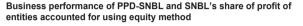
FY3/20 FY3/21 FY3/22 FY3/23 FY3/24

#### Orders received in the Nonclinical Business / Percentage of orders received from overseas customers

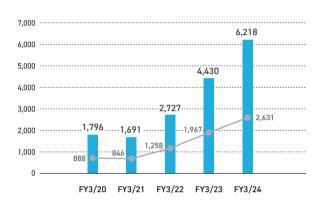
Orders received in the Nonclinical Business (million yen)

- Percentage of orders received from overseas customers in the Nonclinical Business





Net profit of PPD-SNBL - SNBL's share of profit of entities accounted for using equity method (million yen)



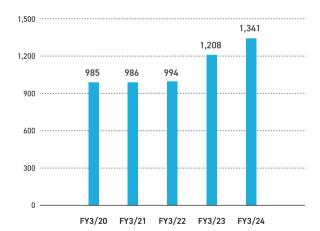
#### **Dividends / Dividend payout ratio**

Dividend (yen) Dividend payout ratio (%)



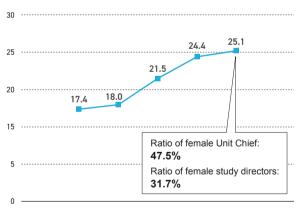
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#### Number of employees (persons)



#### Ratio of female managers

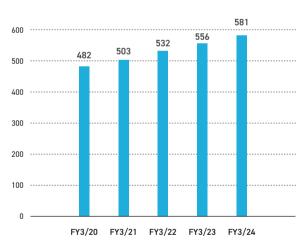
Greenhouse gas emissions



FY3/20 FY3/21 FY3/22 FY3/23 FY3/24

\* Including the SNBL Ina Research Center from the FY3/2024

#### Average annual salary (ten thousand yen)



16

SNBL Integrated Report 2024

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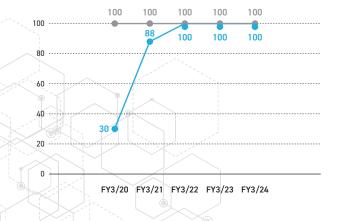
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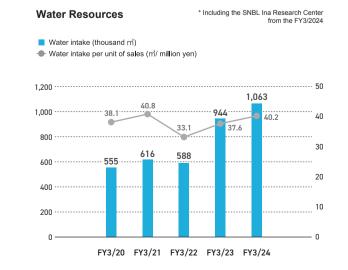
#### Percentage of employees taking childcare leave

 Percentage of eligible staff taking maternity leave (%) Percentage of eligible staff taking paternity leave (%)



Greenhouse gas emissions (Scope 1 and 2) Greenhouse gas emissions per unit sales (t-CO<sub>2</sub>/million yen) 0.80 20,000 0.8 0.72 17,347 0.7 0.65 0.66 14,623 15,000 0.6 0.58 11,648 10,806 11,561 0.5 10,000 0.4 0.3 0.2 5,000 0.1 0 0

FY3/20 FY3/21 FY3/22 FY3/23 FY3/24



Term Business Plan

Message from the CEO

Representative Chairman and President **Ryoichi Nagata** 

# Foresee the future and act preemptively to promote people's happiness

In our core nonclinical CRO business, we see the current business environment as an opportunity for further growth. We have designated three key pillars—strengthening human capital, expanding facilities, and advancing digital transformation and are making large strategic upfront investments in these areas while focusing on capturing overseas markets.

#### **SNBL's Mission**

Our mission is to free patients from suffering by supporting drug development and improving medical technology. With the healthcare business as our focus, we are dedicated to alleviating patients' pain and fulfilling our responsibilities with sincerity and care. The realization of this mission is a challenging, arduous, and lengthy journey. However, we approach it with steadfast principles and unwavering passion. We adhere to five fundamental guidelines that serve as the foundation for carrying out our daily responsibilities:

- 1. I act immediately.
- 2. I give my best.
- 3. I am truthful.
- 4. I think ahead.
- 5. I take pride in and responsibility for my work.

Although these principles may appear basic, employees

detailed operational levels, are regarded as exemplary within our company. A company is not defined by its name or buildings but is built upon its workforce. The growth of a company directly reflects the growth of its employees. Establishing a workplace environment where each individual can grow is the responsibility of the company president. Through the indispensable healthcare business of developing new drugs, we aim to foster the growth of our employees and contribute to society as a whole.

I believe that corporate management involves managing an organization that contributes to society, i.e., an organization that engages in activities essential to the community. By continuing such endeavors, we can generate both economic and social benefits. In our Medipolis Business, which focuses on expanding social benefits, we are steadily preparing for the mass production of glass eels on Okinoerabu Island, Japan, using proprietary tanks developed by our company. Alongside our efforts in geothermal energy generation, using hot springs. This initiative involves using surplus steam from hot springs and heating operations to produce electricity, and our commitment to renewable energy continues to garner attention.

At the Medipolis Proton Therapy and Research Center, our support teams work to ensure that patients feel at ease when undergoing proton therapy, which is increasingly covered by insurance. We also organize seminars and initiatives aimed at promoting wellbeing not only to patients undergoing treatment, but also to the general public.

Going forward, we will remain committed to our corporate philosophy, maintaining a balance between economic and social value while continuing to grow and contribute to society.

#### **Three Growth Engines**

Our company was founded in 1957 by my father, Tsugio Nagata. In 1960, we accepted our first contract for

who consistently implement them, even at the most

we are also beginning development of power generation

nonclinical studies from an overseas pharmaceutical

 First Growth Driver:
 Second Growth Driver:

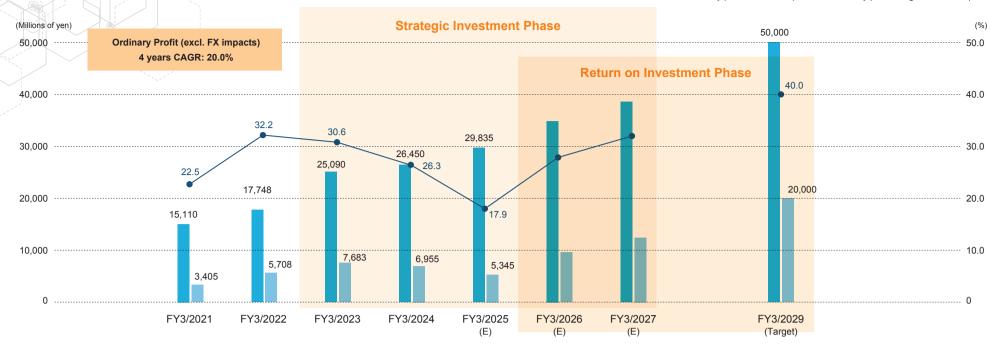
 Clinical business (PPD-SNBL)

 Fy3/1980

 Fy3/1980

Fy3/200
Fy3/202
Fy3/204

#### Revenue Ordinary profit(excl. FX impact) 🔶 Ordinary profit margin(excl. FX impact)



company, becoming Japan's first nonclinical CRO. After assuming the role of president in 1991, I focused on sustainable growth. This included initiating clinical pharmacology studies (Phase 1 trials) in 1992 and analytical research services (bioanalysis) in 1997. Subsequently, we significantly expanded our business domains by launching the Translational Research (TR) business in 1997 and clinical trial support services (Phase 2/3 trials) in 1998. In 1999, we constructed a laboratory for nonclinical studies outside Seattle, followed by a 96-bed medical facility for clinical studies built on the campus of the University of Maryland.

Our nonclinical business has since become the largest in Japan and continues to secure substantial orders from international clients. With the accelerated development of new drug modalities, such as antibody drugs and nucleic acid therapeutics, the importance of laboratory NHPs for research has grown significantly. Since the 1980s, we have maintained breeding facilities for laboratory NHPs and are the only CRO worldwide to have established an in-house breeding and supply system for these animals. This initiative has proven successful, making our nonclinical business, centered on laboratory NHPs, our first growth engine.

Our clinical business is conducted through a joint venture, PPD-SNBL K.K, which we established a decade ago with PPD, a global clinical CRO headquartered in the United State. PPD-SNBL primarily manages Japanese operations for global studies contracted by PPD. While operating as part of a global enterprise, our long-standing commitment to a workplace environment that values harmony has resulted in exceptional employee retention and the delivery of high-quality services. By leveraging

the strengths of both PPD and our company, the clinical business has become our second growth engine. In the TR business, our intranasal drug delivery platform technology has the potential to become our third growth engine. Since 1997, we have been developing intranasal formulations for various drugs based on proprietary powder formulation technologies using carriers we independently discovered, combined with our self-developed devices (medical devices). The intranasal migraine treatment "STS101," which is currently under review for approval by the U.S. FDA, is a product of this platform technology. Over the years, we have made substantial and continuous investments in this area, and we are now poised to enter the phase of investment recovery.

#### Focusing on Capturing International Markets

Currently, we are prioritizing the capture of international markets. As part of this initiative, we have expanded the laboratory for nonclinical studies at our Kagoshima headquarters and established a domestic breeding system for laboratory NHPs. This year, we further strengthened our research staff by forming the Global Study Team (GST) and promoting a program to support the acquisition of DABT (Diplomate of the American Board of Toxicology) certification. The GST conducts various training programs as part of its DABT acquisition support initiative. These include training sessions led by in-house DABT-certified professionals, foundational courses using resources such as the Japanese Society of Toxicology textbook and Casarett & Doull's Toxicology, as well as training on ICH guidelines and U.S. chemical handling regulations. English education within GST is conducted on a regular basis with the cooperation of native English-speaking instructors from Veritas Academy. Within the next three years, internal communication within GST is expected to

be conducted entirely in English.

In addition to these efforts, we have established U.S. sales offices in Seattle, Boston, and San Diego to provide services that eliminate the challenges presented by time zone differences. Looking ahead, we anticipate increased contracts from major pharmaceutical companies in Europe and the United States.

#### Strategic Investments Toward Vision 2028

We set out our vision for FY2028 as "Vision 2028: Promoting People's Happiness Hand in Hand with Our Stakeholders." As part of this, we set financial goals for the 2028 fiscal year (ending March 31, 2029) as follows: revenue of ¥50 billion, ordinary profit of ¥20 billion, and an ordinary profit margin of 40%.

Regarding our first growth engine, the nonclinical CRO business, we perceive the current business environment as an opportunity for further growth. We have designated three key pillars— strengthening human capital, expanding facilities, and advancing digital transformation (DX)—and are making large strategic upfront investments in these areas. Strengthening human capital means increasing the number of staff engaged in the CRO business and enhancing their skills. I have always managed based on the belief that the development of people lies at the root of business. I believe that human capital is the most important strategic core that enables us to build a competitive edge and differentiate ourselves from other companies, and I also see it as the means to enhance our corporate value. Since 2002, SNBL Academy, an in-house training academy, offers various programs for employees at all levels, from new hires to managerial candidates and managers. I personally dedicate a significant amount of time to mentor young employees and conduct leadership training (the Nagata Juku program), and I place great importance on having direct

discussions with our employees.

We continue to invest strategically in equipment and expand our facilities. At the Kagoshima Drug Safety Research Laboratory, we built a new headquarters and research building (two eight-story buildings), significantly increasing the number of analytical equipment and expanding our laboratories. We have also increased our capacity in order to respond to the growing number of overseas orders. While a global shortage of laboratory NHPs has been an industry issue for the past few years, our new domestic breeding system, together with our breeding facility in Cambodia, enables us to guarantee a stable supply of laboratory NHPs.

As part of our ongoing digital transformation efforts, we have been working on a project called Zero Mission, which aims to eliminate the use of paper. In 1981, we were the first CRO in the world to successfully transition data to an online format. However, due to the increasing number and complexity of examinations in studies, some data could not be converted online and had to be handled on paper data sheets. The goal of the Zero Mission project is to reduce paper usage to as close to zero as possible. Five years ago, our paper usage averaged 300,000 sheets per month, but we have successfully reduced it to 180,000 sheets, with the next goal being to reduce it to fewer than 100,000 sheets. This process has transformed our organization into one where the trend is to digitalize study data. In addition, we have also advanced the adoption of AI and robotics. Moving forward, we plan to rapidly accelerate digital initiatives, such as the use of AI in protocol and report creation and the automation of studies. The results of these preemptive initiatives are steadily becoming visible in tangible ways. We remain eager to continue promoting happiness together with all of you. We kindly ask our stakeholders to continue supporting our sustainable growth and to watch over our progress with the same trust and encouragement as always.

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