SAMSUNG
BIOEPIS

Sustainability Report 2024

PASSION FOR HEALTH

Samsung Bioepis is dedicated to enhancing access to high-quality biologic medicines for patients at affordable prices.

[SBMA_2024_0725_498_E]

About This Report

Reporting Scope

This report covers the sustainability management activities and performance of Samsung Bioepis' domestic operations. Financial data were prepared in accordance with the consolidated Korean International Financial Reporting Standards (K-IFRS). Both financial and non-financial data were prepared for the fiscal year in line with the financial disclosure standards, and data on energy consumption and Greenhouse Gas (GHG) emissions were reported based on the results of GHG emissions verification.

Reporting Cycle and Period

Following our first report in 2021, we have published sustainability reports each year since 2023. This report outlines Samsung Bioepis' economic, social, and environmental achievements and activities during the period from January 1, 2023 to December 31, 2023, and this extends to May 2024 for some significant performance. For quantitative performance, three-year data are presented from 2021 to 2023 to help understand their yearly trajectory.

Reporting Standards

This report aligns with the Global Reporting Initiative (GRI) Standards 2021. This report was also prepared in consideration of ISO 26000, the European Sustainability Reporting Standards (ESRS), principles of the UN Global Compact (UNGC), and the Sustainability Accounting Standards Board (SASB) disclosure standards for biotechnology & pharmaceutical sectors.

Assurance

To ensure the international and external credibility and impartiality of the reporting process and the information disclosed, this report received third-party assurance by Korea Management Registrar Inc. as an independent assurance provider. The detailed assurance report is on page 56.

Forward-looking Statement Disclaimer

This report may include forward-looking statements that relate to the future and the present as well as the past.

Forward-looking statements can be identified by the use of words such as "anticipate", "pursue", "goal", "strategy", "estimate" and similar expressions. It is worth noting that this report may contain statements related to Samsung Bioepis' ESG activity plans regarding the Company's future business strategy.

While Samsung Bioepis believes that expectations reflected in these forward-looking statements are reasonable, we cannot guarantee these expectations will actually materialize. Forward-looking statements are intended to assist readers in understanding Samsung Bioepis' ESG approach, strategy, and expected operational environment and may not fit other purposes such as investment. Furthermore, forward-looking statements are subject to assumptions, inherent risks, and uncertainties, many of which are associated with factors that are beyond our control or cannot be accurately estimated. As such, investors are cautioned not to place undue reliance on these forward-looking statements, recognizing that actual results may differ from what was expressed or implied in these forward-looking statements. Except as required by applicable laws or regulatory responsibilities, Samsung Bioepis assumes no obligation to update any forward-looking statements as a result of new information, future events or other developments.

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For further information on Samsung Bioepis, please visit our website at:
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For inquiries about this report, contact us at:
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Letter from Our CEO

In pursuit of our vision 'Passion for Health', Samsung Bioepis is committed to advancing sustainability management and evolving into a 'Multi-product, Multi-modality and Fully Integrated Global Pharmaceutical Company'.

Our Value Creation

We take a pride in making high-quality, affordable medicines widely available for more patients. In 2023, we launched a treatment for rare diseases in the therapeutic field of hematology, in addition to those for immunology, oncology, and ophthalmology, doing our part in increasing patient access to medicines. We will continue broadening our biosimilar portfolio to provide patients with a wider array of treatment options to choose from, and vow to deliver social value to patients, governments and other stakeholders.

Strengthening ESG Risk Management

At Samsung Bioepis, we advance our sustainability management system to ensure that ESG risks are systematically managed. In certifying our environmental, energy, health & safety, and information security systems to ISO standards, we are working to minimize any negative impact our business operations may have on society and the environment. We also pursue sustainable supply chain management to address environmental, health & safety, labor and human rights risks along the entire value chain. In collaboration with partners across our global supply chains spanning Europe, North America, and Asia, we ensure the reliable supply of our products for the benefit of patients we serve. Meanwhile, we proactively champion the implementation of the 2050 Net Zero and RE100 initiatives to respond to climate change. Besides, we uphold sound governance to integrate accountability and business ethics into our operations while promoting sustainable growth and stakeholder value improvement.

Sustainable Growth for the Future

Samsung Bioepis fosters top-notch bio talent through our systemic competency development programs to generate groundbreaking R&D outcomes while building global partnerships to cement our position as a global leader in the biopharmaceutical industry. The culmination of such endeavors became evident in 2023 as we reached KRW 1 trillion in revenue in just 12 years after our foundation, becoming the fastest to reach this significant milestone in the Korean biopharmaceutical industry.

Rather than resting on these already remarkable achievements, we choose to stay the course and build long-term growth drivers by developing next-generation therapeutic antibodies and gene therapies to lay the groundwork to grow sustainably.

Our mission at Samsung Bioepis is to ceaselessly rise to new challenges and seek innovation to change the world for the better. We look forward to your keen interest and encouragement along the way as we continue to reach new benchmarks in our journey towards sustainability.

Christopher Hansung Ko
Samsung Bioepis, President & Chief Executive Officer

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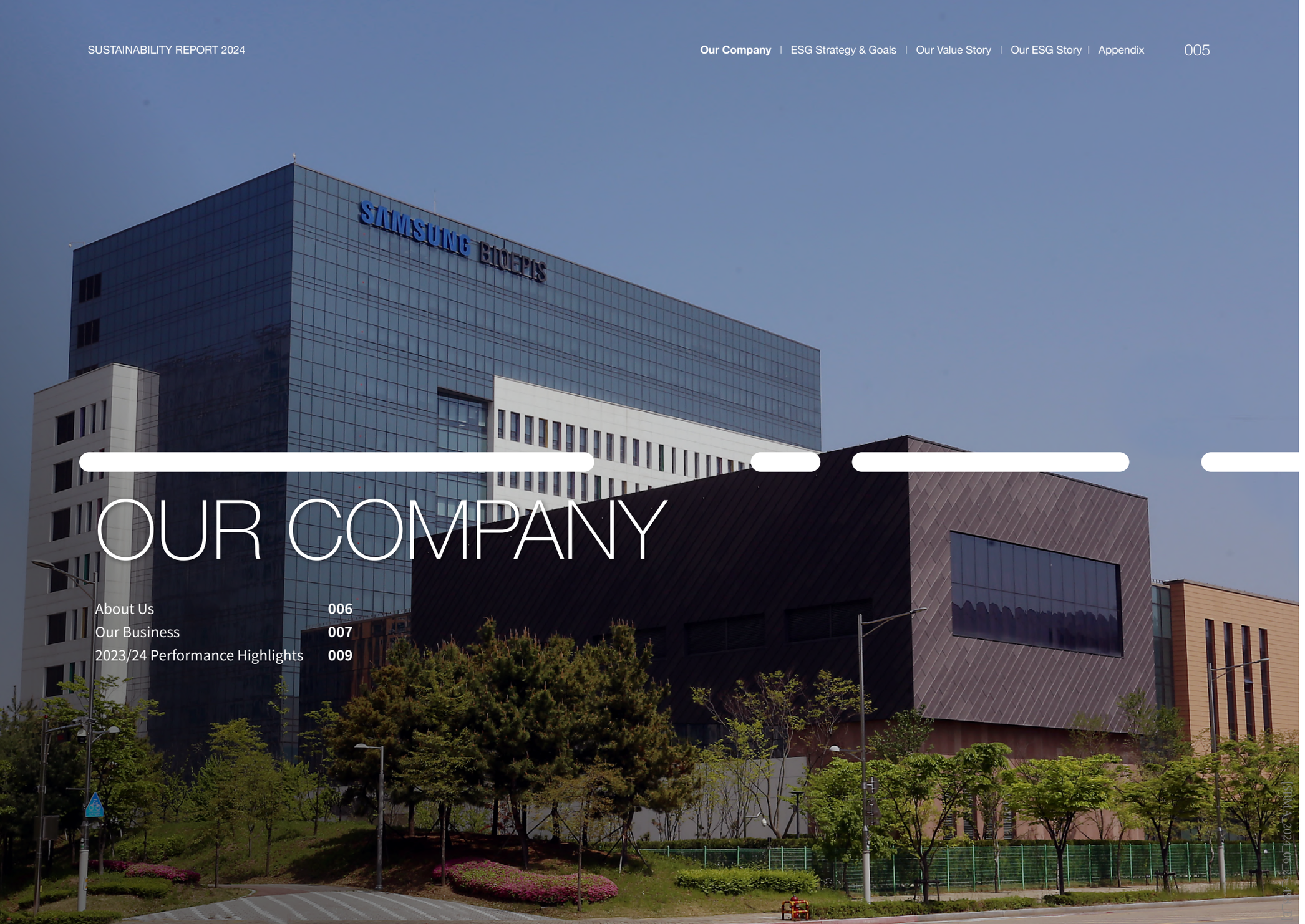


OUR COMPANY

About Us

Company Profile

Samsung Bioepis is dedicated to bringing high-quality, affordable biologic medicines to patients worldwide. Through innovative research and development platforms, combined with optimized supply chain capability and extensive marketing partnerships, we have developed a broad and industry-leading portfolio of 12 biosimilars, and among them, eight products were launched in 40 countries around the world. We will continue to drive innovations and find smarter, faster ways of bringing high-quality biologic medicines to patients in need. While continuing with the development of existing products as planned, we also engage in novel drug development and direct marketing efforts to build momentum for our sustained growth and reach new heights.

Name of company	Samsung Bioepis Co., Ltd.
Date pf establishment	Feb. 28, 2012
Employees	987 persons (as of the end of 2023)
Headquarters	76, Songdogyoyuk-ro, Yeonsu-gu, Incheon, Republic of Korea
Overseas subsidiaries	US, Netherlands, UK, Poland, Switzerland, Brazil, Australia, New Zealand, Israel, Taiwan, Hong Kong

Performance Highlights

Performance

(as of the end of 2023)

Product pipeline	8 products launched/ 4 products in development[1)]
Patients reached	Over 431,000 persons
Market presence	Approved in 45 countries / launched in 40 countries

Key Financial Metrics

(as of the end of 2023)

Revenue	KRW 1,020.3 billion (USD 782 million)
Net income	KRW 180.6 billion (USD 138 million)
Total assets	KRW 2,898 billion (USD 2,220 million)

1) As of May 2024

Vision & Mission

Vision

Passion for Health

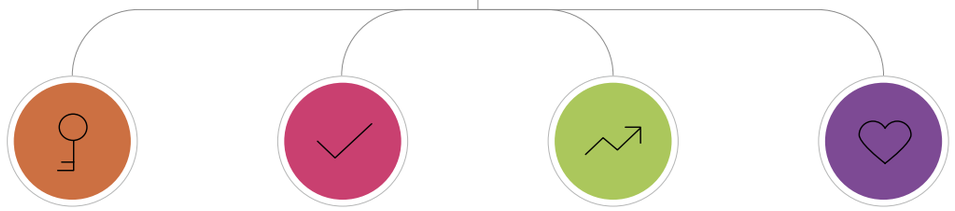
Mission

We put our passion to work

We interact with utmost integrity

We strive for constant innovation

Core Value



ACCESSIBLE

We aim to develop high-quality treatments to meet patients' needs, reach patients all over the world and increase access to medicines.

QUALITY ASSURED

We strive to discover pioneering solutions, develop safer and more effective medicines, and build a strong reputation led by our high-quality medicines.

ACTIVE

We commit to always think proactively, focus on innovation, and overcome all limits through courage.

HONEST

We intend to serve our patients with integrity, earn trust through transparency, and offer the most valuable solution with our medicines.

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Our Business

Value Creation Chain

Samsung Bioepis strives to broaden the ultimate impact of improving the quality of life for patients through our business operations. We are trying to understand our impact on the stakeholders and society in greater details to be reflected in our business decisions. Concurrently, we aim to establish a virtuous cycle of value where social value leads to our growth and expansion of intrinsic value.

Input

Financial capital
- Equity KRW 1,352.6 billion
- Liabilities KRW 1,545.3 billion

Human capital
- Employees 987 persons
- New hires 91 persons
- Employee training &exercise expenses KRW 5.0 billion

Intellectual capital
- R&D workforce 483 persons
- R&D expenses KRW 216.9 billion

Manufactured capital
- Owned lab equipment
- CMO[1], CRO[2], and CLO[3] facilities

Natural capital
- Energy 138 TJ
- Water 75,022 tons

Value creation activities

Clients

Sales

Product logistics

CMO

Biosimilars development

Output

Financial performance
- Revenue KRW 1,020.3 billion
- Net profit KRW 180.6 billion

Employment
- Training hours per person 332 hours per year
- Average age 35.1 years

Patients reached
- Countries where our products were launched 40 countries
- Patients reached with our products 431,000 persons

R&D innovation
- Therapeutic area expansion
- Products approved 9 products

Product quality and patient safety
- Zero Warning letter from regulatory authorities
- Quality training hours per person 21 hours per year
- Product recall 0 case

Environment
- GHG emissions 6,295 tCO_2eq
- Water pollutants 0.34 tons

Value created for stakeholders

Financial value
- Added value we created: KRW 244.0 billion
- Increased individual purchasing power: KRW 201.6 billion
- Increased purchasing power of governments and organizations: KRW 120.2 billion
- Our projected future profit: KRW 84.7 billion
- Increased purchasing power of creditors: KRW 34.5 billion
- Value generated for consumers: KRW 35.5 billion

Human Resource Development
- Employees: Improved biopharmaceutical expertise

Access to medicines improved
- Creation of social value from products: over KRW 2,524 billion (USD 1.9 billion)

Information and knowledge on biosimilars increased
- Stakeholders: Improved perceptions on biosimilars

Environmental costs
- Environmental costs including Social Cost of Carbon (SCC)[4]: KRW 0.8 billion

Economy

Society

Environment

1) Contract Manufacturing Organization
2) Contract Research Organization
3) Contract Laboratory Organization

4) SCC refers to an estimate of the cost of the damage done by each additional ton of carbon emissions.

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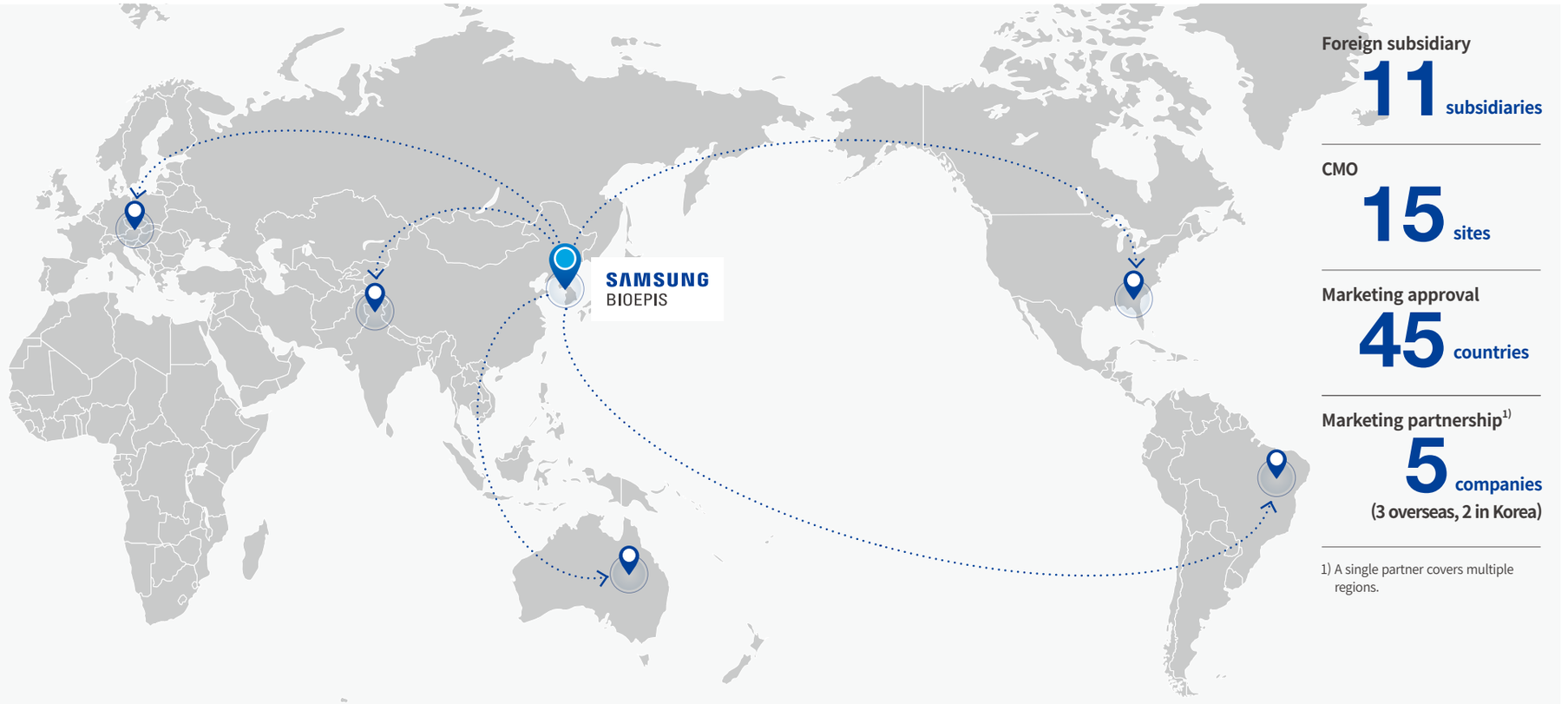
Our Business

Global Network



Foreign subsidiary
11 subsidiaries

CMO
15 sites

Marketing approval
45 countries

Marketing partnership[1)]
5 companies
(3 overseas, 2 in Korea)

1) A single partner covers multiple regions.

Headquarter (Korea)	Europe	North America	Oceania	Latin America	Middle East & Asia
• Subsidiary :	4	1	2	1	3
• Manufacturing site :	9	4	1	0	1
• Marketing approval :	32	2	2	1	8
• Marketing partnership :	3	3	1	2	3

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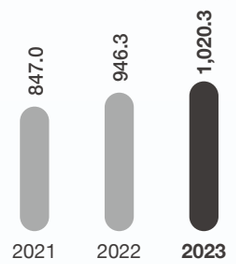
2023/24 Performance Highlights

2023/24 Achievements

Surpassed KRW 1 trillion in revenue

In the fastest time among Korean bio pharma companies

Annual Revenue (Unit: KRW billion)



Total assets KRW 2,898 billion

Product launch

SB12
EU: Epysqli™,
Korea: Epysqli®

SB5
US: Hadlima™

SB11
EU: Byooviz™,
Korea: Amelivu®

SB15
Korea: Afilivu™

Approval

SB12
US/Korea: Epysqli®

SB15
US: Opuviz™,
Korea: Afilivu™

SB11
(interchangeability)
US: Byooviz™

SB17
EU: Pyzchiva™,
Korea: Epyztek™

Approved and launched as of May 2024

Korea: 9 approved, 8 launched
Europe: 8 approved, 7 launched
US: 6 approved, 4 launched

Marketing partnership

SB17
North America/
EU: Pyzchiva™

SANDOZ

Direct sales

Korea and some European geographies[1)]

1) Korea: SB2, 4, 5, 12 Europe: SB8, 12

R&D open innovation

Invested in 3 companies specialized in gene therapy and ADC[2)]
(6 companies as of May 2024)

2) Antibody-drug Conjugate

ESG management advancement

Certified to
ISO 45001
ISO 27001

Published a TCFD[3)] Report

TCFD TASK FORCE ON CLIMATE-RELATED FINANCIAL DISCLOSURES

Product social value[4)]

Patients reached
about **431,000** persons

Social value generated
about KRW **2.5** trillion
(USD 1.9 billion)

3) Scheduled for publication in the second half of 2024
4) Based on 7 products launched in the US, five European countries, South Korea, Canada, Australia, and Brazil in 2023

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2023/24 Performance Highlights

ESG Performance

2023 Samsung Bioepis Integrated Impact Measurement and Management

We employed PwC's Total Impact Measurement and Management (TIMM) methodology to measure our positive and negative impacts on society and the environment. 2023 is our second year of measurement, and we will continue to review our measurements annually to understand the economic, social, and environmental impacts of our financial and non-financial performance to expand our positive impacts while continuing to reduce our negative impacts.

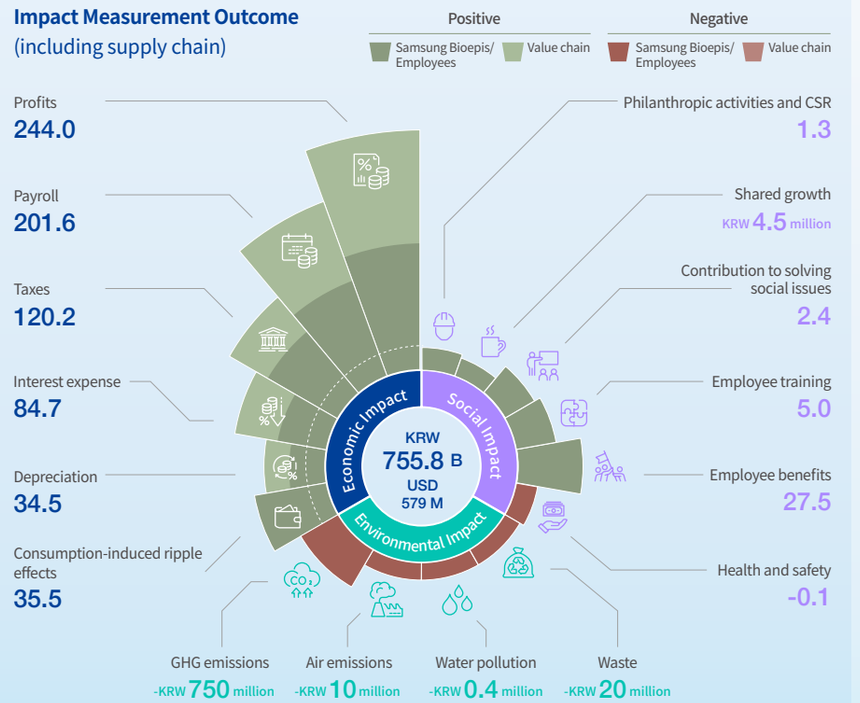
Impact measurement target	Impact measurement period
We evaluated the impact of our performance and the indirect impact of our employees and suppliers. For certain performance such as contribution to solving social issues, we measured the direct results of CSR programs.	January 1, 2023 to December 31, 2023

Measurement areas and metrics

Economic impact	**Economic and tax impact**	
	Profits	• Added value through net profit
	Payroll	• Increased personal purchasing power through employee wages
	Taxes	• Contribution to government finances through tax payments (including employees)
	Interest expense	• Benefit to creditors through interest payments
	Depreciation	• Effect of investments to generate sustainable profits for the company
	Consumption-induced ripple effects	• Economic ripple effects of employees' household consumption
Social impact	**Social impact**	
	Health and safety	• The cost of employee health and safety incidents • Benefits to employees from health promotion programs
	Employee benefits	• Improved quality of life for employees
	Employee training	• Improved knowledge on bio science through employee trainings
	Contribution to solving social issues	• Improved work-life balance for employees through family-friendly programs • Effects of providing decent jobs that ensure diversity and equal opportunities
	Shared growth	• Strengthening ESG capabilities of SMEs through ESG consultation
	Philanthropic activities and CSR	• Tripple effects of our CSR and philanthropic activities
Environmental impact	**Environmental impact**	
	GHG emissions	• Social cost of GHG emissions
	Air emissions	• Cost of nitrogen oxides and dust emissions
	Water pollution	• Cost of emissions of phosphorus and nitrogen compounds
	Waste	• Cost of waste and disposal

(Unit: KRW billion)

Impact Measurement Outcome (including supply chain)



Key Premises and Considerations

This measurement is based on performance data managed by the company and is the result of reasonable hypotheses using official statistics from national and international organizations or existing studies. Therefore, the monetary value for the year may change in the future. In addition, we will disclose Scope 3 (supply chain) emissions through the TCFD report in the second half of 2024.

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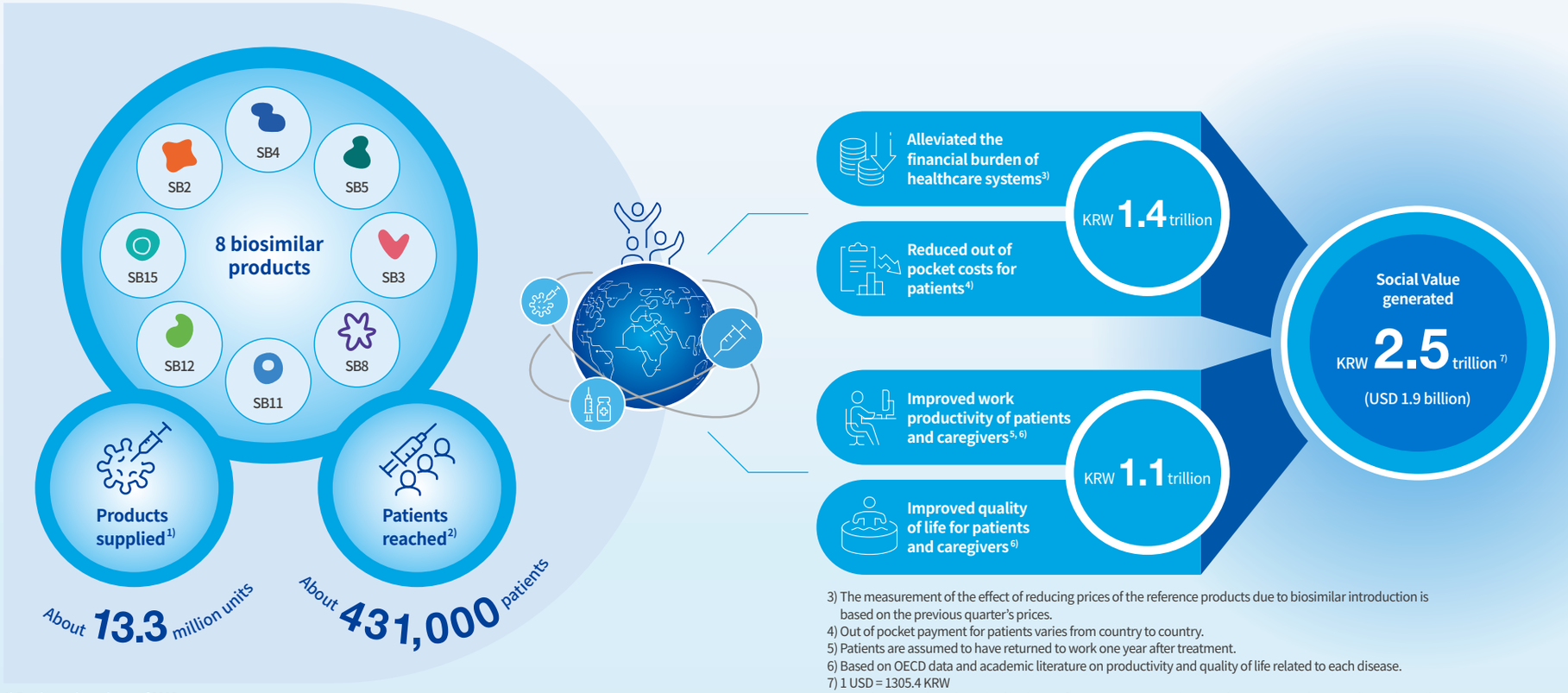
2023/24 Performance Highlights

ESG Performance

Social value of our products

Samsung Bioepis strives to improve the quality of life for patients through the development and sale of high-quality biosimilars. By providing biosimilar products, we have reduced the financial burden on national healthcare systems, decreased patients' out of pocket costs and improved the productivity and quality of life for patients and their caregivers, thereby creating over KRW 2.5 trillion in social value.



1) Product sales volume of 2023
2) As of 2023, number of patients reached (estimate)= Σ (annual sales volume/annual doses administered)

3) The measurement of the effect of reducing prices of the reference products due to biosimilar introduction is based on the previous quarter's prices.
4) Out of pocket payment for patients varies from country to country.
5) Patients are assumed to have returned to work one year after treatment.
6) Based on OECD data and academic literature on productivity and quality of life related to each disease.
7) 1 USD = 1305.4 KRW
Based on 7 products launched in the US, five European countries, South Korea, Canada, Australia, and Brazil in 2023.
This assessment is a result of collaboration with Clarivate™, which is a British-American analytics company that provides enriched data and analytics in the area of academia & government, intellectual property and life sciences & healthcare.

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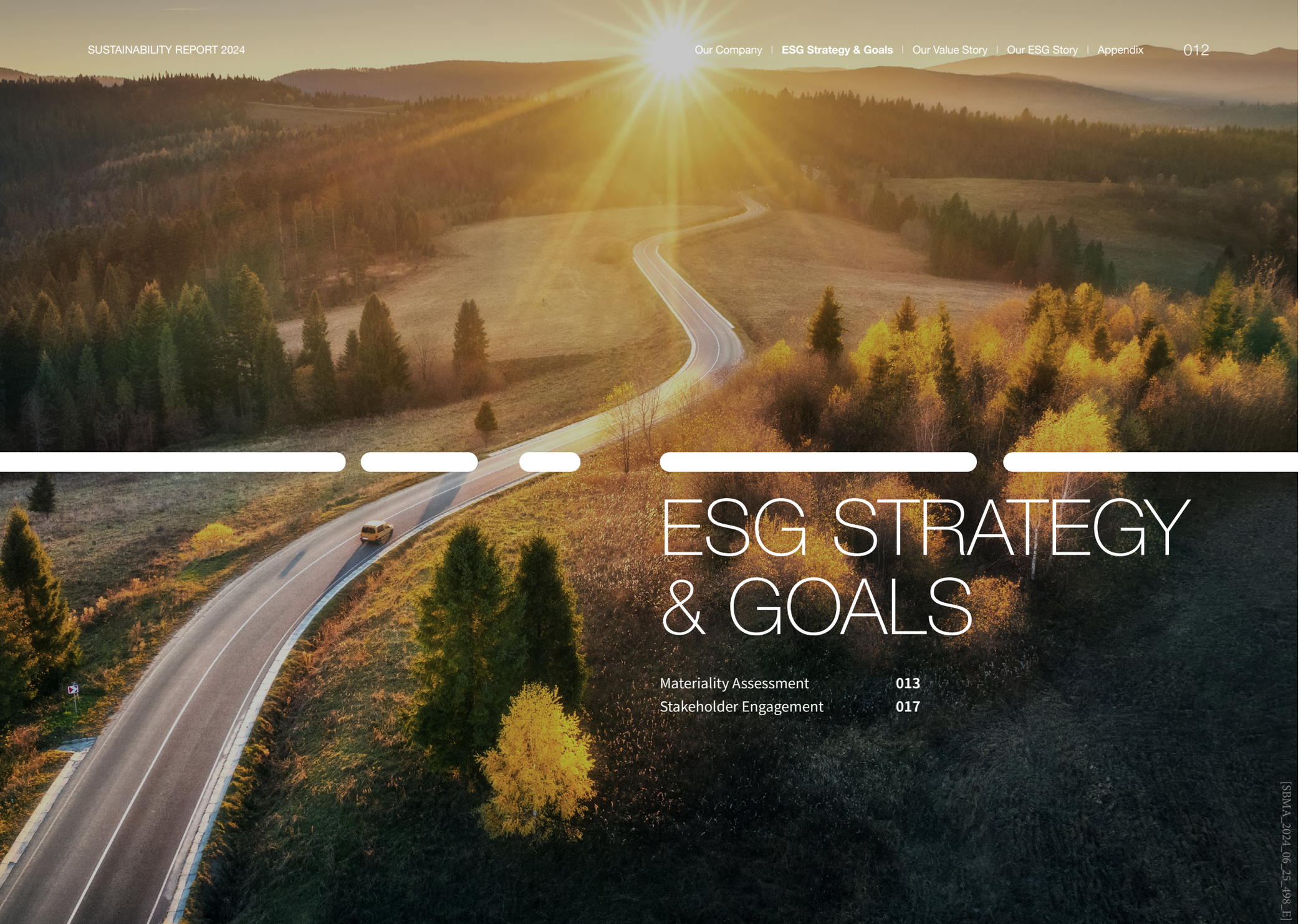

ESG STRATEGY & GOALS

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Materiality Assessment

Double Materiality Assessment Process

1 Understanding the context

Conduct a basic study for materiality assessment by identifying Samsung Bioepis' key business operations, partnerships, stakeholders, and the local contexts including the local community as well as major global economic, social, and environmental issues

2 Identifying a pool of issues

Analyze global sustainability management disclosure standards and guidelines, collect feedback from experts on sustainability, and conduct internal reviews to identify a total of 27 material ESG issues

3 Conducting double materiality assessments

Conduct a survey on 27 material ESG issues for their financial effect on Samsung Bioepis and our impacts to society and the environment and the survey results are further analyzed to prioritize 10 material issues

4 Reporting materiality assessment results

Report the results to top management prior to disclosing them through sustainability reporting, and ensure that the results are taken into consideration for Samsung Bioepis' ESG strategy setting and risk management

Data collection and analysis methods

Impact Analysis and Prioritization

Financial effect

Benchmarking	Analysis of key issues and disclosures among industry peers in 2023
Analysis of global ESG assessment initiatives and industry-specific metrics	DJSI, MSCI, KCGS, SASB, Biopharma Initiative, and public tender evaluation criteria

Social & environmental impact

Media research	Analysis of 503 major domestic/international news articles in 2023
Analysis of ESG disclosure-related international initiatives & guidelines and industry-specific metrics	GRI standards, ISO 26000, UNGC, SDGs, ESRS, PSCI, and 2022 Access to Medicine

Survey

Survey period	• Jan. 22, 2024 ~ Jan. 26, 2024
Survey method	• Online survey
Survey target	• Samsung Bioepis employees • Suppliers and other external stakeholders • Sustainability management experts
Ques-tionnaire	• Gather stakeholder feedback on financial risk & opportunity, and social & environmental impact concerning 27 ESG issues • Select ESG issues that Samsung Bioepis should address for advancing sustainability management

Financial effect (Magnitude)	• Rate each material issue for its magnitude of impact on business operations on a scale of 1 to 5
Social & environmental impact (Severity)	• **Scale of impact** Rate the severity of positive/negative impact on a scale of 1 to 5 • **Scope of impact** Rate the scope of stakeholders impacted on a scale of 1 to 5 • **Irremediability** Additional review on the possibility of post-impact damage reversal on a scale of 1 to 5

ESG Expert Review

Risk and opportunity assessment	• Assess risk & opportunity in full consideration of the magnitude and likelihood of financial impact
Impact characteristic assessment	• Analyze each issue for its impact on employees, customers, the environment, and other stakeholders • Assess the characteristics of issues (positive/negative, actual/potential) by comprehensively analyzing the magnitude and likelihood of their social & environmental impact

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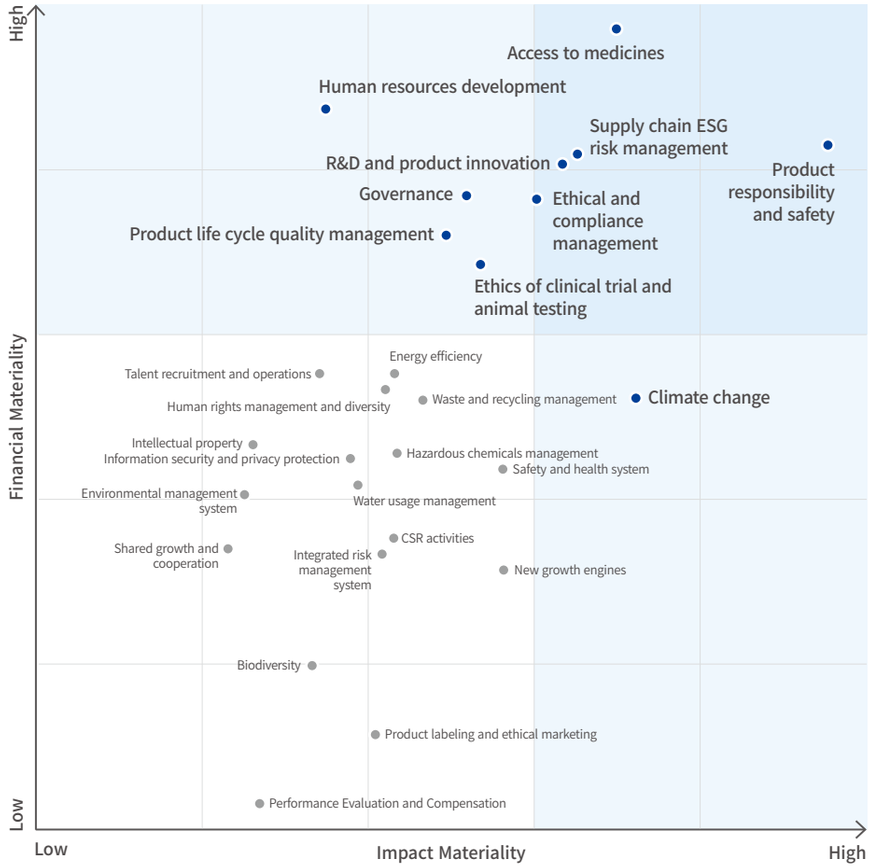
Materiality Assessment

Materiality Assessment Results

Materiality Map



Materiality Assessment Results by Issue

No.	Material Issue	Financial Materiality			Impact Materiality			Change from the 2023 report	Pages
		Impact	Risk/ Opportu-nity	Likeli-hood	Impact	Positive/ Nega-tive	Likeli-hood		
1	Product responsibility and safety		Risk	Potential		Nega-tive	Potential	-	27
2	Access to medicines		Oppor-tunity	Actual		Positive	Actual	-	19-21
3	Supply chain ESG risk management		Risk	Potential		Nega-tive	Potential	-	46
4	R&D and product innovation		Oppor-tunity	Potential		Positive	Actual	-	23
5	Ethical and compliance management		Risk	Potential		Nega-tive	Potential	New	33
6	Climate change		Risk	Potential		Nega-tive	Potential	New	35-36
7	Governance		Risk	Potential		Nega-tive	Potential	New	32
8	Human resources development		Oppor-tunity	Actual		Positive	Actual	-	25, 41
9	Product life cycle quality management		Risk	Potential		Nega-tive	Potential	-	39
10	Ethics of clinical trial and animal testing		Risk	Potential		Nega-tive	Potential	-	29

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Materiality Assessment

Material Issue Management

No.	Material Issue	Issue analysis[1)]	Our Approach	Metrics & Targets
01	**Product responsibility and safety**	It is imperative that product quality and safety is ensured in the biopharmaceutical industry. Any issue with product quality may cause severe, irremediable impact on patient health and safety, and this could bring fatal business risks, such as declining revenues and reputation.	Samsung Bioepis has established a quality management system to oversee the entire life cycle of medicines to prevent quality risk. If quality issues occur, we take prompt decisions and actions to make necessary improvements.	- Improve the quality management system and inspection readiness - Reinforce regulatory capacity to comply with clinical trial laws and regulations - Expand training for building capacity and competency of quality management
02	**Access to medicines**	Increased supply of biosimilars provides patients affordable treatment options to lead a healthy life and reduces a country's financial burden to help establish a sustainable healthcare system. Improving access to medicines also allows companies to facilitate their sustainable growth.	We bring the values of biosimilars through broader and diverse treatment options, affordable prices, and sustainable healthcare systems towards increased access to medicines.	- Expand the product pipeline - Increase the number of patients reached - Expand novel drug business opportunities in terms of fulfilling unmet medical needs
03	**Supply chain ESG risk management**	Tightening global regulations on supply chain due diligence require companies to manage ESG risks along their entire value chain. While this change expands the scope of our responsibility and increases the burden of risk management, bolstering our suppliers' capabilities to manage their ESG risks could also lead to enhanced reliability and resiliency in our business operations.	We have developed our policy on sustainable supply chains to ensure reliable supply of our products through regular ESG risk assessment and supply chain diversification.	- Conduct and advance regular supply chain ESG assessments - Identify and reduce high ESG risks of our suppliers
04	**R&D and product innovation**	A broader product portfolio, improved quality of medicines, and productivity gains enable companies to tap into wider markets and raise revenues. This also increases access to medicines to help improve the quality of life for patients.	We continue to invest in nurturing bio talent and establish advanced development platforms to build R&D capabilities. We also bolster our partnerships to secure next-generation therapeutic technology.	- Expand therapeutic areas - Discover sustainable, next-generation technology
05	**Ethical & compliance management**	While companies bear the fundamental responsibility to adhere to regulatory and ethical standards, they may face a variety of compliance issues, including incidences of unfair trade practice and corruption. This may result in penalties, suspension of business operations, and other legal sanctions, and also negatively impact employees, supply chains, and other internal/external stakeholders.	Our compliance organization under the leadership of the CEO is dedicated to operating company-wide compliance programs. Incidents of non-compliance are constantly monitored through whistleblowing channels, and compliance training program is provided to employees and suppliers to raise the bar on ethical and compliance management.	- Prevent non-compliance incidents such as corruption, unfair trade and violation of marketing/labeling regulations

1) Impact, Risk, Opportunity analysis

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Materiality Assessment

Material Issue Management

No.	Material Issue	Issue analysis[1]	Our Approach	Metrics & Targets
06	**Climate change**	The global climate change is causing grave damage and losses, and threatening human wellbeing and health of the planet. Companies are also expected to be exposed to greater climate change risk – both physical and transition risks. In this context, global regulations on ESG disclosure increasingly require companies to take on greater responsibility for responding to climate change risks.	Samsung Bioepis has developed our climate change strategy to set and attain our 2050 Net Zero and RE100 goals. Our ESG Office under the leadership of the CEO together with other departments such as ESH is orchestrating implementation for global disclosure requirements such as IFRS, TCFD, and ESRS.	- Achieve our 2050 Net Zero goal - Reduce energy consumption
07	**Governance**	Establishing sound governance in a way that satisfies regulatory requirements is essential to ensuring sustainable business operations. Any failure to ensure the expertise, independence, and transparency of governance may dampen management efficiency and corporate value, and erode trust with employees, investors, and other stakeholders.	We ensure the expertise and diversity of our Board of Directors to drive sustainable growth through a rational decision-making system. To hold our senior management to higher accountability standards, a long-term incentive scheme was implemented to better align management remuneration to business performance.	- Ensure diversity and expertise at the Board of Directors
08	**Human resources development**	The biopharmaceutical industry's performance has direct impact on the safety and life of patients, which underscores the need for a high level of employee expertise. Nurturing talented employees through competency development is a direct source of a company's increased competitiveness and sustainable growth, and improved access to medicines helps deliver positive social value.	Guided by our talent development vision 'Our growth is determined by the competency of our employees', we have been operating an innovation taskforce exclusively responsible for talent fostering and competency development. This TF operates wide-ranging capability improvement programs to help employees enhance their expertise and work efficiency while developing program-specific performance metrics and regularly monitoring progress.	- Aim for 8 hours of weekly training through job competency training, Lessons Learned, and the Training Lab.
09	**Product life cycle quality management**	Biologic medicines are directly concerned with the life and health of patients, and this highlights the importance of quality management of the entire product life cycle from development to production and distribution. Any exposure to quality risk in each phase of this cycle may bring severe risks, including declining corporate reputation and revenues.	We operate a rigorous monitoring system to ensure patient safety and life throughout the entire product life cycle. We ensure 24/7 supervision and swift response through our quality monitoring system, and implement data-based risk management through our pharmacovigilance and automated adverse event analysis systems.	- Manage counterfeit medicines - Implement pharmacovigilance activities
10	**Ethics of clinical trial and animal testing**	Any clinical trial conducted in the biopharmaceutical industry should abide by the requirements set out by applicable international guidelines and country-specific regulations. Non-compliance with such requirements may result in business risks, including suspension of clinical trials and/or legal sanctions, and negatively impact the health of patients.	For clinical safety management, we stringently abide by the regulations and guidelines in line with the characteristics of respective medicines. We put patients' safety at the center of our clinical trial operations, and uphold the 3Rs principles to minimize animal testing for nonclinical operations.	- Comply with international clinical trial guidelines - Abide by the 3Rs principles to minimize animal testing

1) Impact, Risk, Opportunity analysis

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Stakeholder Engagement

Stakeholder Communication

Samsung Bioepis reaches out closer to stakeholders through a wide array of channels. We fully gather feedback from key stakeholders and integrate it in our overall business operations and ESG materiality assessment process.

	Customer/ end-user	Employee and other worker	Supplier	Investor/ Shareholder	University & Research Institute	Local Community	Government/ Media/Trade Association
Definition	Stakeholders provided with Samsung Bioepis' products	Agents of business activities at Samsung Bioepis	Stakeholders who supply products and services required for our business operations	Stakeholders who provide us with financial capital	Institutions which nurture professionals expected to serve as the agents of business activities (employees) at Samsung Bioepis	Local communities and stakeholders impacted by the Company's business operations	Stakeholders who enact laws related to the bio-pharmaceutical industry and determine the level of regulations
Key issues of interest	Quality management from the customers' perspective, more rigorous protection for customer data privacy, ethical management, increased communication	Corporate culture, benefits, win-win labor relations, fair performance assessment and compensation, competency development	Fair trade, shared growth, occupational health and safety, transparent communication	Sound governance, risk management, ethics, increased communication	Business and R&D, job creation	Environmental protection, contribution to the local economy, job creation, CSR	Response to domestic/ international regulations and policies, industry trends, job creation, business expansion
Communication channel	Website, media, Social media	In-house bulletin board, internal communication channels (EPIS IN), Labor-Management Council, counseling center, whistleblowing channels	Regular committee meetings with CMOs	Audit reports, media	Recruiting website, mentoring programs for bio talent, Research Note competition for university students	CSR activities	Meetings, seminars, newsletters, websites, Social media
Responsible organization	Communication	HR (labor relations, corporate culture), Communication	Production operation, Purchasing	Finance, Communication	HR (recruitment)	HR (corporate culture), ESG	Communication, ESG, PM[1], RSP[2]

1) Program Management
2) Regulatory Strategy and Policy

[SBMA_2024_06_25_498_E]

OUR VALUE STORY

[SBMA_2024_06_25_498_E]

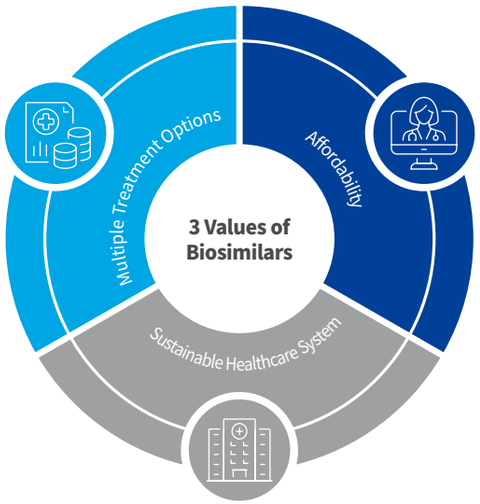
Access to Medicines

Increasing Access to Medicines

3 Values of Biosimilars

The biopharmaceutical industry fulfills its social responsibility through enhancing access to medicines. While biologic medicines play a central role in treating severe chronic conditions, inequalities in accessing these medicines exist due to their high prices.
Samsung Bioepis remains committed to developing biosimilars with an aim to make biologic medicines more readily available and address such inequalities in so doing. Providing high-quality biosimilars at affordable prices compared to reference products, we broaden options for patients and healthcare professionals while alleviating governments' financial burden of healthcare costs, doing our part in ensuring the sustainability of healthcare systems.

Provide a broader choice of medicines for patients and healthcare professionals

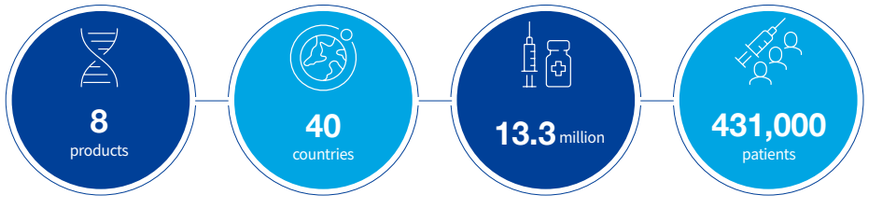


Ensure affordable prices compared to reference products

Alleviate governments' financial burden through reducing healthcare expenses

Multiple Treatment Options

We offer biosimilars that are equivalent to reference products in their efficacy and safety compliance across a wide array of therapeutic areas. We launched a total of eight biosimilar products in the four therapeutic areas of immunology, oncology, ophthalmology, and hematology in 40 countries, and reached over 431,000 patients.



1) The number of launched products varies by country
2) Cumulative product sales of 2023
3) The number of patients reached in 2023 (estimated)= Σ (Annual sales volume/ annual doses administered)

Key Product Category

Therapeutic Area	Product	Description
Immunology	SB2 (Infliximab biosimilar)	- 1st in Europe to obtain approvals for biosimilars referencing all three anti-TNF-α blockbusters.
	SB4 (Etanercept biosimilar)	
	SB5★ (Adalimumab biosimilar)	
Oncology	SB3★ (Trastuzumab biosimilar)	- 1st oncology biosimilar approved in Europe for cancer treatment (SB3)
	SB8★ (Bevacizumab biosimilar)	- Cancer medicines to expand treatment options for various solid tumors, including breast, colorectal, and gastric cancer
Ophthalmology	SB11 (Ranibizumab biosimilar)	- 1st ophthalmology biosimilar in Europe and the US to gain approval (SB11)
	SB15 (Aflibercept biosimilar)	
Hematology	SB12 (Eculizumab biosimilar)	- Treatment for the rare diseases of Paroxysmal Nocturnal Hemoglobinuria (PNH) and atypical Hemolytic Uremic Syndrome (aHUS)

★Holding three biosimilars listed on the WHO Essential Medicines List

[SBMA_2024_06_25_498_E]

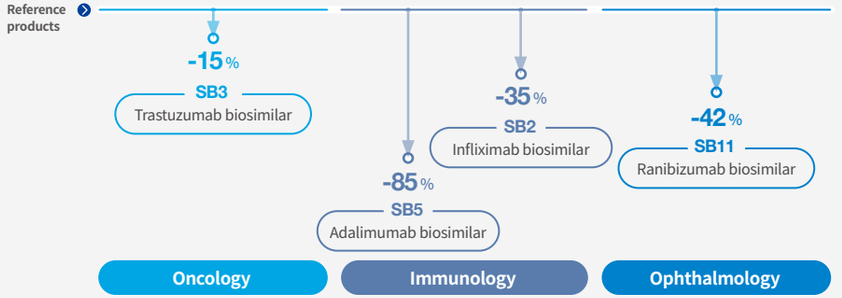
Access to Medicines

Increasing Access to Medicines

Affordability

While biologic medicines are considered as the optimal standard of care for multiple diseases, their high costs deter patients from readily accessing them. On the back of our proprietary, advanced development platforms, innovative processes, and superior clinical development capabilities, we bring high-quality, affordable biosimilars to market. In so doing, we commit to improving access to medicines by reducing patients' financial burden.

Discounts made available in our WAC[1] compared to reference products (As of Q1 2024, WAC in the US)



Samsung Bioepis Biosimilar Market Report (2024. Q1)

1) Wholesale Acquisition Cost

Case SB12 (Epysqli® eculizumab biosimilar)

We sequentially launched our first hematology biosimilar, SB12, starting with Germany in July 2023, followed by Italy, Spain, and Korea. SB12 is a biosimilar to Soliris® (eculizumab) used to treat such rare diseases as PNH and aHUS.

The reference product, Soliris®, is an expensive medicine in Korea, costing nearly 400 million to treat one single adult patient per year, and it was urgently needed that biosimilars were made available to increase access for patients. To meet such unmet healthcare needs, we released SB12 (Epysqli®) in Korea at half the price of the reference product. Our launching of SB12 (Epysqli®) also prompted the reference product to reduce its price by approximately 30%. Delivering high-quality biologics at affordable prices, not only do we provide broader treatment opportunities but we also help the government save on its healthcare finance.

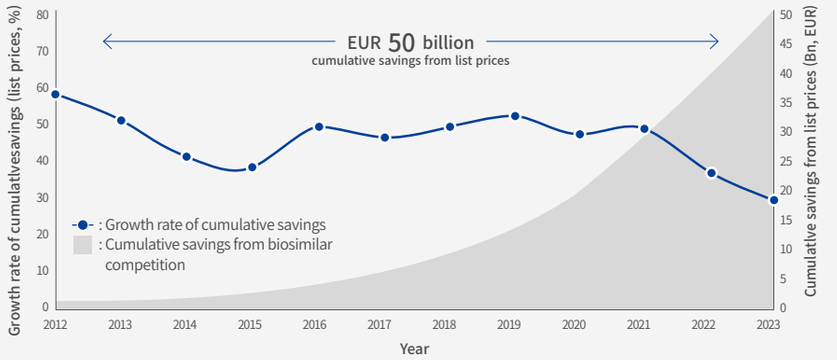
Savings in annual treatment expenses per patient in Korea: Over KRW **200** million

Social value of Our Products

Sustainable Healthcare System

Biosimilars provide affordable alternatives to their reference products and thus help significantly reduce national healthcare expenses. This enables countries to direct the savings towards their healthcare industry to establish a sustainable healthcare system. According to IQVIA, a healthcare analytics service provider, the total savings in healthcare spending across Europe from 2012 to 2023 are estimated to be approximately EUR 50 billion.

Savings in healthcare spending in the EU attributable to price competition among biosimilars[1]



1) Source: IQVIA white paper 2023

Productive Development Partnership led by the Brazilian government

As a member of the Productive Development Partnership (PDP) program of Brazil, the largest biopharmaceutical market in Central and Latin America, Samsung Bioepis is contributing to the development of the local biopharmaceutical industry. Under this program, we formed a three-party partnership with BioManguinhos, a state-funded research institute under the Brazilian Ministry of Health, and Bionovis, a local pharmaceutical company. We transferred our manufacturing technology to Brazil and supplied SB3 (trastuzumab biosimilar) and SB4 (etanercept biosimilar) through government tender, providing treatment opportunities to nearly 18,000 patients in 2023 alone and contributing to establishing a sustainable healthcare system in Brazil.

Nearly **18,000** patients reached with SB3 and SB4 in Brazil, as of 2023

[SBMA_2024_06_25_498_E]

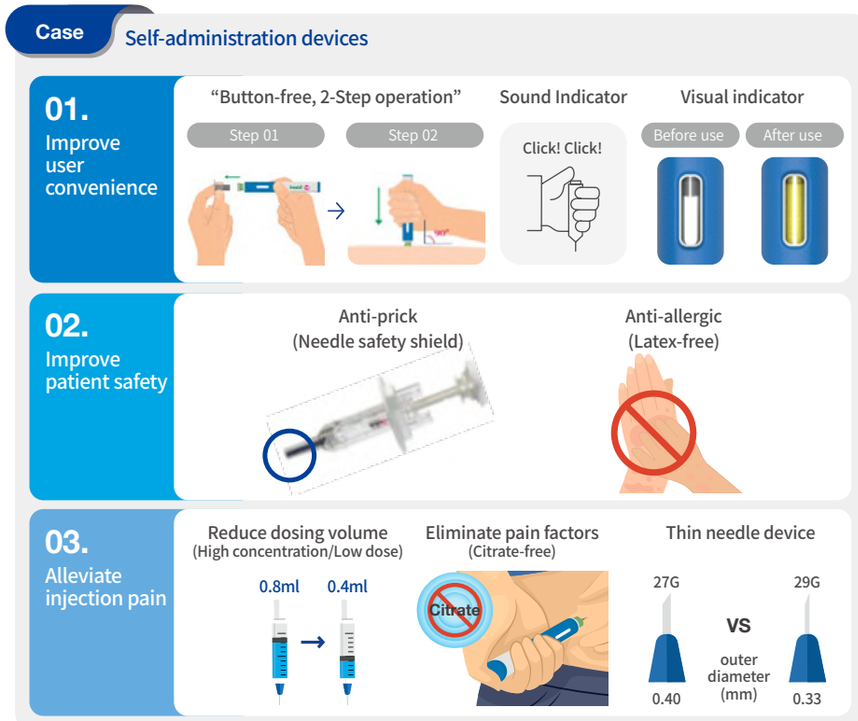
Access to Medicines

Increasing Access to Medicines

Improving Patient Convenience

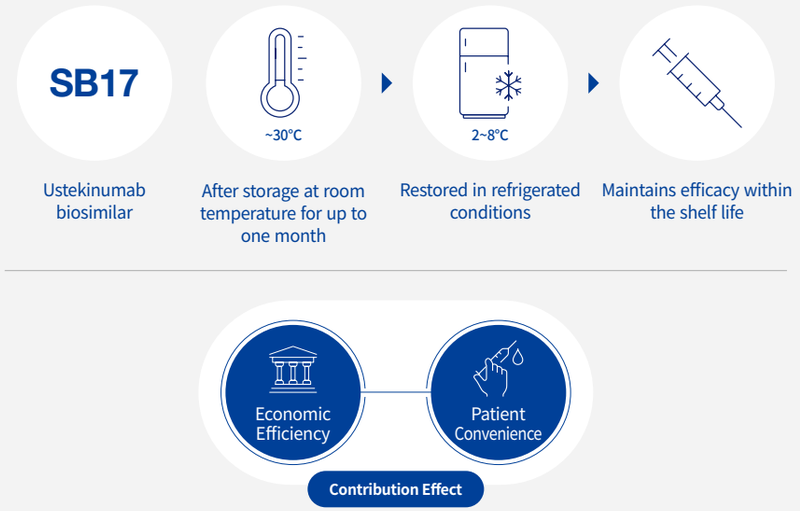
Samsung Bioepis considers patient safety and convenience as its top priority throughout the entire development process. We develop devices that are differentiated to prioritize patient convenience and safety in the development phase, and explore patient-friendly treatment options. Specifically for immunotherapy that requires self-administer medicines, we improved our devices to help patients overcome a fear of needles, mitigate the risk of pricking that may occur in using devices, and alleviate their pain at the injection site.

Case Self-administration devices



Case Improved storage convenience

Biologic medicines, mainly composed of proteins, are directly injected into the human body, requiring highly demanding administration and storage procedures depending on usage and dosing. These characteristics raise concerns over potential degradation in product quality once exposed to room temperature. The maximum duration of room temperature storage and storage conditions for medicines are directly linked with their efficacy maintenance and shelf life.
In developing SB17 (ustekinumab biosimilar), we ensured that this product remains stable in quality and efficacy when it is put back into a refrigerator even after one month of storage at room temperature of up to 30°C. The product was approved for use under such storage conditions by the EMA. This significantly improved the convenience of storage and lowered the risk of product degradation as compared to competitor products, offering advantages in terms of drug distribution and inventory management.



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Access to Medicines

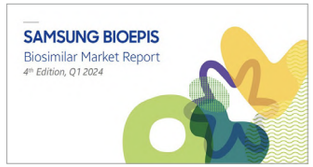
Increasing Access to Medicines

Raising Awareness on Biosimilars

Samsung Bioepis illuminates the values of biosimilars for patients, healthcare professionals, regulatory authorities, and other stakeholders as a way to engage in various awareness-raising efforts to enhance trust in biosimilars. We actively participate in biosimilar regulatory policy improvement activities so that our awareness improvement initiatives actually result in increase access to medicines. Our Regulatory Strategy and Policy (RSP) unit was created as an organization dedicated to raising awareness on biosimilars, and is currently collaborating with the Biosimilar Forum, Medicines for Europe, the International Generic and Biosimilar Medicines Association (IGBA), and other diverse global associations. In so doing, we commit to increasing access to biosimilars among a broad array of stakeholders, from patients and healthcare professionals to governments.

Publishing the Biosimilar Market Report

This report provides up-to-date information on our biosimilar products launched in the US, including their price and market share, as well as in-depth analyses of key bio market trends each quarter.



EHA Congress 2023

We attended the annual meeting of the European Hematology Association 2023 (EHA2023) held in Frankfurt, Germany to present additional analysis results related to the SB12 (EPYSQLI™) clinical study. We introduced the results from the population pharmacokinetic (PK), pharmacodynamic (PD) and efficacy studies of SB12 to over 1,300 Healthcare Professionals (HCPs). Additionally, we organized an Advisory Board Meeting with experts in PNH and carried out various activities to support the direct sales in European market.

2023 SAMBA (SAMsung bioepis Biosimilar Awareness) Symposium

In September 2023, we hosted the SAMBA symposium to share data of our products and facilitate academic discussions for HCPs in the areas of rheumatology, gastroenterology, and ophthalmology in Korea to publicize the socioeconomic role of biosimilars and raise awareness on patient benefits. A survey of symposium participants showed that the event produced positive outcomes in improving their understanding of and preference for biosimilars as well as their intent to switch from originators to biosimilars.

Survey Results (scale of 1 to 5)

Understanding of biosimilars

Before	3.90	
After	4.49	a 15% rise

Preference for biosimilars

Before	4.15	
After	4.64	a 12% rise

Intent to switch from originator to biosimilar

Before	3.79	
After	4.59	a 21% rise

ICKSH 2024

Recently, our company attended the International Congress of the Korean Society of Hematology (ICKSH) 2024 to present a post-hoc analysis pf the Phase 3 clinical study results for Epysqli®, a medication designed to enhance patient access to medicines compared to the reference product. We presented not only the safety and efficacy data of SB12-treated patients but also introduced our Epysqli® launch and marketing strategy in Korean market through a promotional booth at the conference.

2023
- Apr. — Biosimilar Market Report inaugural edition
- Jun. — EHA (European Hematology Association)
- Jul. — Biosimilar Market Report Q3 2023
- Sep. — SAMBA Symposium
- Oct. — Biosimilar Market Report Q4 2023

2024
- Jan. — Biosimilar Market Report Q1 2024
- Mar. — International Congress of the Korean Society of Hematology
- Apr. — Biosimilar Market Report Q2 2024

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R&D Innovation

Expanding Therapeutic Areas

Bolstering biosimilar capabilities over the years, Samsung Bioepis has laid the groundwork to drive growth spanning from basic R&D to production and commercialization of biologic medicines. We launched eight biosimilars in the therapeutic areas of immunology, oncology, ophthalmology, and hematology on the strength of our sustained innovation and advanced, optimized development platforms, cementing our position as a global leader in the biosimilar business. Rather than resting on our past achievements, we continue to broaden our pipeline of competitive biologic medicines in the fields of endocrinology and gastroenterology.

Samsung Bioepis' 6 Therapeutic Areas and 12 Products[1)]

Pipeline	Therapeutic Area	Phase 1	Phase 3	Approval	Launch
SB4 (etanercept biosimilar)	Immunology				
SB2 (infliximab biosimilar)	Immunology				
SB5 (adalimumab biosimilar)	Immunology				
SB3 (trastuzumab biosimilar)	Oncology				
SB8 (bevacizumab biosimilar)	Oncology				
SB11 (ranibizumab biosimilar)	Ophthalmology				
SB12 (eculizumab biosimilar)	Hematology				
SB15 (aflibercept biosimilar)	Ophthalmology				
SB17 (ustekinumab biosimilar)	Immunology				
SB16 (denosumab biosimilar)	Endocrinology				
SB26 (ulinastatin-Fc fusion protein)	Gastroenterology				
SB27 (pembrolizumab biosimilar)	Oncology				

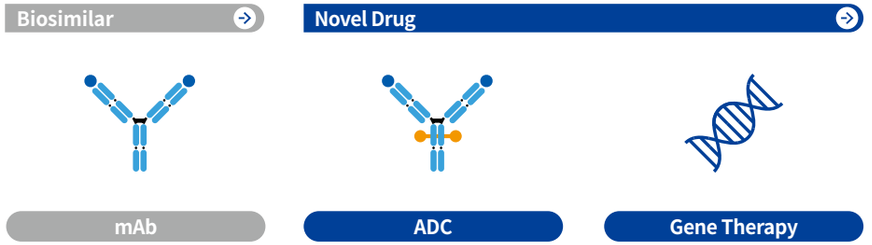
Completed In progress

1) As of May 2024, product launch varies by country

Exploring Next-generation Growth Drivers

We are taking our first step towards new biologics development to drive sustainable growth. Progress is being made to secure next-generation therapeutic technology on the back of the R&D and open innovation capabilities accumulated through our biosimilar business. Development of the Gene and Cell Therapy (GCT) area is underway to select drug candidates for rare diseases by using proprietary gene therapy development platforms. We also engage in proactive R&D investment and joint research in developing new biologics. We are teaming up with other companies to research and develop new Antibody-Drug Conjugate (ADC) and gen therapy technologies with the help of the Samsung Life Science Fund. These endeavors will surely enable us to help patients meet their medical needs and dramatically improve their quality of life.

Multi-product & Multi-modality



Samsung Life Science Fund (LSF)

The Samsung Life Science Fund, valued at KRW 240 billion in total, was set up through joint contributions by Samsung C&T, Samsung Biologics, and Samsung Bioepis to explore next-generation growth drivers in the bio industry at the Samsung Group level. We have invested in six companies from 2022 to May 2024, and will continue to actively pursue investments and partnerships to secure next-generation ADC and gene therapy technologies.

[SBMA_2024_06_25_498_E]

R&D Innovation

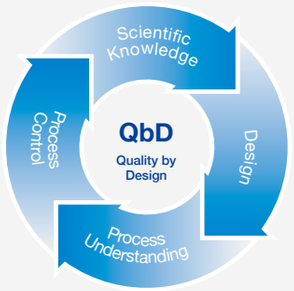
Advanced Development Platform

Samsung Bioepis commits to continuous process innovation in each step of our development process to enable extensive analyses and rigorous quality management, and are establishing and operating an advanced development platform. This, in turn, allows us to successfully and promptly develop high-quality biosimilars while minimizing risk that may occur in each process step.

Development platform system

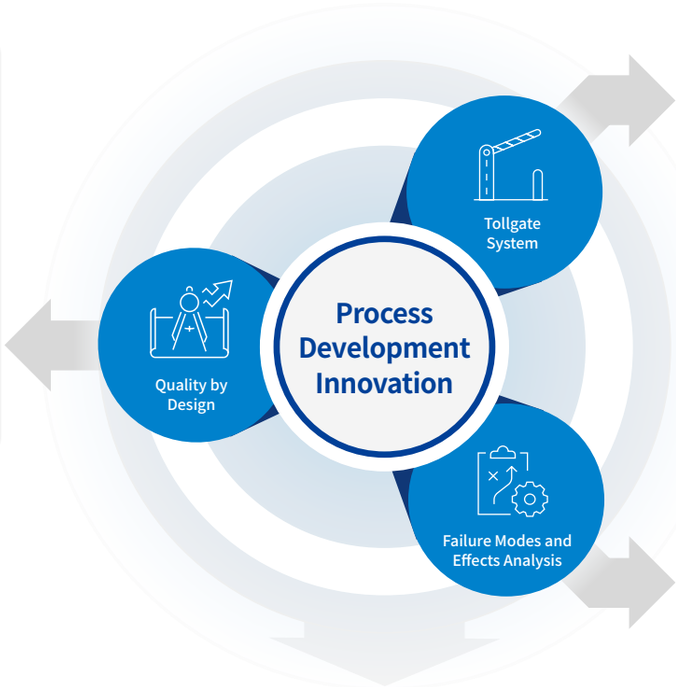
Apply Quality by Design

Take a systemic approach to ensure the quality of biological medicines by employing statistical, analytical, and risk-management methodologies in the design, development and manufacturing of medicines.



Case_ Analysis of Critical Quality Attributes

Set physical, chemical, and biological quality goal metrics and manage critical quality attributes impacting product quality and improve their efficacy.



Implement the Tollgate System

Determine whether quality goals for products are met at each inflection point and move up to the next stage of the scale-up process if the quality attributes are satisfied with the predefined goals.

Perform Failure Modes and Effects Analysis

Predict potential risks and identify risk mitigation strategies in each step of the development process through scenario-based planning and simulations based on knowledge and experience obtained from the implementation of previous projects.

Process development innovation effect

01_Expediting development
- Adopt High-throughput Screening (HTS) technology for cell line development
- Optimize a process development platform

02_Improving productivity
- Establish a cell line with high productivity
- Optimize a robust scale-up platform

03_Optimizing resource use
- Automation of analytical methods
- Enhancing capabilities of protein analysis
- Improve the efficiency of data management through the electronic laboratory notebook system

04_Accelerating technology transfer
- Optimized process modeling
- Conduct computer simulation

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R&D Innovation

Bio Talent Development

To nurture professionals to drive our sustainable growth, Samsung Bioepis provides training programs that are anchored on Process Map, spanning from Lessons Learned and job competency training to Training Lab.

Work Management System and Training Programs

Lessons Learned

Our Lessons Learned training program identifies key learnings from previous projects in terms of managing risks and opportunities to improve employee trainings and work processes.

Lessons Learned Program Outcomes in 2023

Process	Detail	Note
Company-wide case identification	In total 367 cases identified	
Company-wide/ department training	25 company-wide training programs chosen out of 155 departmental cases	Training completion rate 100%

Training Lab

Training Lab is our tailormade, intensive training program to help our employees develop technical competency. The program is categorized into three tracks to promote proactive skill management at the department level and for new hires/newcomers and new experimental methods.

Training Lab Outcomes in 2023

Track	Description	Training Programs
Track 1	Essential experiment method skill management	22
Track 2	Experiment skill development for new hires/newcomers	38
Track 3	New experimental method and new equipment operating skill development	18

Job Competency Training

We provide systemic training programs tailored for employees with different job levels and competencies to aid in their growth into job experts.

Job Competency Training Outcomes

Category	No. of Job Positions	No. of Training courses	Description
Job-based competency development program	113	5,499	• Job Analysis: Analysis of job positions according to departmental goals • Required Job Competencies: Determination of necessary competencies (knowledge/skills) • Job Levels: (Lv.1)-(Lv.5) level-specific training provided

Basic Company-wide Training Programs (E-life Program & training on Cross-functional Experiment Method)

To help our employees nurture basic competencies, we provided the E-life Program (EPIS Lifecycle) for theoretical and practice-based experimental method training. A survey conducted on employees who completed the E-life Program in 2023 testified to its positive outcomes in improving knowledge on product value chains (43.7%) and other departments' work (32.7%), enhancing expertise (19.0%), and building competencies applicable to their own work (4.6%). Cross-functional experiment method training also served to positively benefit our employees with greater understanding of our experiment operations (56.3%), resolving their questions on experimentation (28.2%), and building the capability to apply their learnings to work (14.1%).

E-life Program/Cross-functional Experiment Method Training Outcomes in 2023

Category	No. of Training courses	Description
E-life Program (EPIS Lifecycle)	107	• Biosimilar Lifecycle Value (81) • Product development planning/strategy setting (10) • Early development of novel drugs (16) • Completed by 5,094 employees (including duplicate attendees)
Cross-functional training on experimental methods	68	• Experimental method practice and observation training for product development purposes • Attended by 291 employees (including duplicate attendees)

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Product Quality and Patient Safety

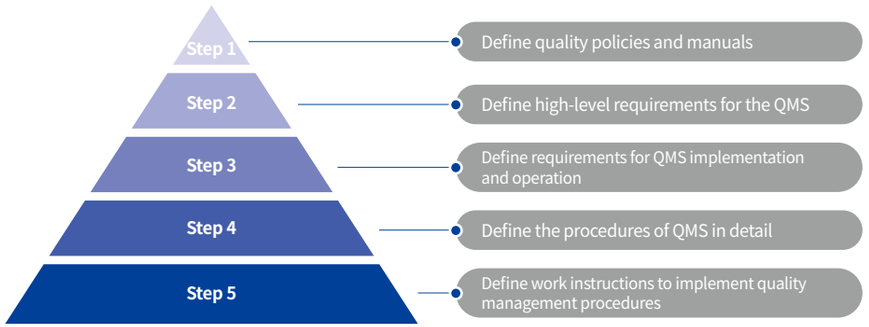
Product Quality Management System

Samsung Bioepis established the Quality Management System (QMS) designed to oversee the entire medicine life cycle to ensure product quality and patient safety, preventing quality risk and making prompt decisions in the event of quality issues to pursue necessary improvements. In doing so, we can bring safety-assured, high-quality medicines to patients worldwide.

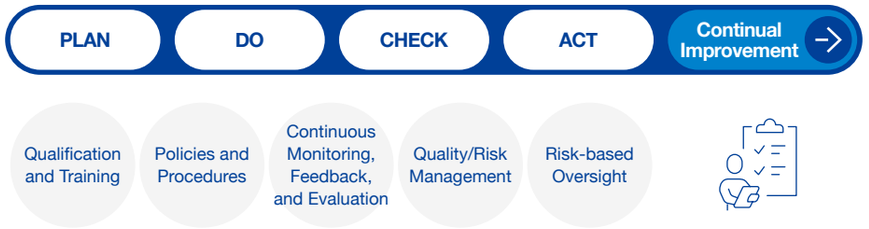
Quality Management System

We advance quality management on an on-going basis through our rigorous QMS. Our quality assurance process was established in conformity with the guidelines of the Korean Ministry of Food and Drug Safety, the US Food and Drug Administration, and the European Medicines Agency.

5-step Quality Management Policy



Quality Management Process



Quality Management Review (QMR) Committee

Our QMR Committee convenes annually to discuss pending quality issues and integrate them in policy development, ensuring that Samsung Bioepis is committed to advancing quality management and supervision to the fullest extent.

2023 Major Agenda	Committee Attendance (%)
Quality management review, quality risk management, supply chain quality management, product quality review, safety, product quality complaints, adverse events to patients recalls, etc.	100

Quality Management Documentation System

To ensure our QMS satisfies global standards, our quality management documentation system sets five levels of governing the entire quality management system. This starts with our quality policies and manuals serving as the highest-level document to define our quality responsibilities as well as quality principles and goals. This system also stipulates quality goals, principles, and responsibilities engaging in any work that may impact our products, service quality, and all cGMP activities.

[SBMA_2024_06_25_498_E]

Product Quality and Patient Safety

Product Quality Management System

Product Quality

Quality Management

We conduct qualification assessments for the entire process of development, manufacturing, and distribution. We also systematically manage changes, deviations, and complaints, and comply with process-specific quality assurance procedures to hold our products to high quality standards.

In selecting new CMOs, we thoroughly assess them for their quality management capabilities and cGMP compliance. Such efforts continue for registered CMOs as we apply detailed assessment criteria for their capability to address production process issues and risks.

1) Corrective Action and Preventative Action

Bolstering QA Competency

We provide systemic quality training programs to help employees better understand the importance of quality in medicines. New employees take basic training on our quality management policies, and employees engaging in work that directly impacts product quality are required to complete regular GxP trainings each year. In doing so, individual employees develop quality assurance capabilities and apply them to their day-to-day work.

Category	Description	Cycle	Trainees
Onboarding training	Understand our quality management policies	Upon recruitment	New/experienced employees
R&D training	Improve the performance of personnel engaging in Good Development Practice work	Year-round	R&D staff
GMP training	Improve knowledge on GMP guideline and procedural performance for personnel engaging in GMP-related work	Annual	Production management staff
GCP training	Improve GCP understanding and performance for personnel engaging in clinical trial-related work	Biennial	Clinical trial related staff
PQC[1] training	Improve competency to understand the procedure concerning quality complaints raised for our products and to take action	Annual	All staff

1) PQC : Product Quality Complaints

Quality Inspection

We strictly abide by and and monitor the guidelines of domestic and international regulatory bodies, including the US FDA, the EMA, and the Korean MFDS, and receive regular inspections by these regulatory authorities. In total, 35 inspections were conducted over the past three years, including 20 inspections in 2023, and zero warning letters were issued. Consequently, Samsung Bioepis and our third-party production, lab, and research partners to successfully achieved GxP certification.

Category	Inspections Performed				Warning Letters[1]
	FDA (US)	EMA (Europe)	MFDS (Korea)	Others	
Subtotal	14	9	9	3	ZERO
2023	7	3	7	3	
2022[2]	3	3	1	0	
2021[2]	4	3	1	0	

1) For our products related inspection only
2) The 2021 and 2022 data from the previous year's report has been changed to include CQA cases from this year

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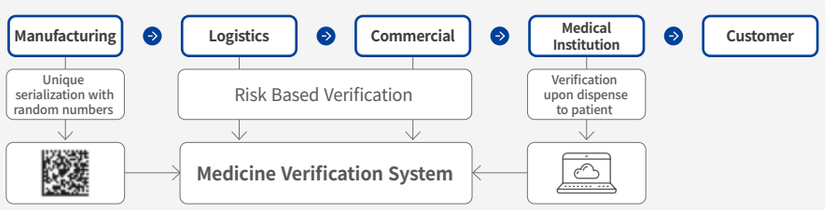
Product Quality and Patient Safety

Reinforcing Pharmacovigilance along the Entire Product Life Cycle

Strengthening Counterfeit Medicine Management

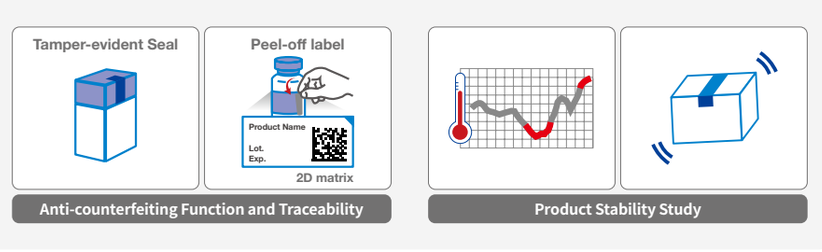
Process of Managing Counterfeit Medicines

Samsung Bioepis cooperates with regulatory authorities in fulfilling their responsibility to protect public health through counterfeit medicine management. We employ and support serialization and traceability technology to prevent the distribution of counterfeit medicines and safeguard patients as a result. Upon receiving information on the distribution of fake Samsung Bioepis medicines, we immediately alert regulatory authorities. When complaints are raised on product quality in the market, we instantly initiate an investigation according to internal procedures. If the product concerned is suspected to be counterfeit, we take follow-up actions on this in line with the pharmaceutical verification process suggested by regulatory authorities.



Strengthening Product Supply Management

Our products are packed with tamper-evident seals and peel-off labels[1] detailing product information to prevent medicine counterfeiting and enable traceability, and to maintain product stability even under extreme conditions, stability studies are conducted in consideration of temperature and duration. Also, we ensure safety in the shipping, storage, and use of our products.



1) SB2, SB3, SB8 (400 mg), SB12

Rigorous Pharmacovigilance

We strive to take on greater responsibility throughout the entire product life cycle from development to production, distribution, and use. To this end, we established a data-based pharmacovigilance system and are collecting and monitoring product safety-related real-world data through healthcare professionals, patient support programs, call centers, regulatory authorities, and other varying channels. We also subscribe to intelligence databases to swiftly respond to the requirements of regulatory authorities.

Automated Signaling Analysis System

Our automated pharmacovigilance system enables us to collect and analyze adverse reactions that occur in product use and to immediately respond to the pharmacovigilance requirements of regulatory authorities. This automated signaling analysis system improves the efficiency of data analytics and helps us detect and address any change in product safety information early on.

Risk Management Action

To ensure the safe and effective administration of our products, we continue to take additional risk minimization action even in the post-marketing phase in consideration of characteristics of respective medicines. For instance, SB12 (eculizumab biosimilar) could pose serious risk for meningococcal infection when administered, and this prompted countries to operate their own management programs. We have provided countries with educational materials tailored for their needs to help patients and healthcare professionals prevent and swiftly detect meningococcal infection. We also optimized the controlled distribution system to promote the timely and safe administration of the medicine.

Providing Accurate Information

Our product labels are designed to provide accurate medicine information to protect consumers while preventing any misuse of medicine. We strictly prohibit off-label marketing which refers to advertising medicines for uses not approved by pertinent authorities, and offer regular training to our employees.

Information Disclosed on a medication Label

Active ingredient	Main ingredient that provides intended effects	**Uses**	Symptom(s) the medicine intends to treat
Dosage and administration	Doses, dosing frequency, maximum daily dose, etc.	**Warnings**	Precautions, safety information, adverse reactions, etc.
Inactive ingredients	Substances that are added but do not intend to have direct therapeutic effects (preservatives, etc.)	**Additional information**	How to store and dispose of the medicine, contact information to seek counseling for side effects, etc.

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Product Quality and Patient Safety

Safe, Patient-centered Clinical Trial

Compliance with Clinical Trial Quality Guidelines

From clinical trial to approval and commercialization, Samsung Bioepis upholds patient safety, data integrity, data privacy, and patient-centered treatment approaches. Any and all clinical trials conducted on our products adhere to the International Council for Harmonization Guidelines for Good Clinical Practice and Good Pharmacovigilance Practice in full compliance with the regulations of regulatory authorities.

Design and Operation of Patient-centered Clinical Trials

Guided by the principle of 'patient-centered clinical operations' which prioritizes patient experience and feedback, we put patient health and safety before all else throughout the entire clinical trial process. In the clinical trial participant screening phase, we provide training to help CROs and investigators comply with our rigorous eligibility criteria and the set clinical trial plan. After kicking off a clinical trial, we keep participants up to date with information on the investigational drug on a regular basis to provide accurate information and strengthen communication with trial subjects. If unexpected side effects are anticipated during the clinical trial, we make sure patients are given the opportunity to reconsent whether to continue their participation in the trial. In the event that any serious adverse event is identified after completion of the clinical trial, we swiftly collect and report information as specified in the regulations and guidelines of national regulatory authorities to take proactive follow-up action.

Minimizing Animal Study

Leveraging our advanced scientific expertise and capabilities, we strive to demonstrate the equivalence of our products through in-vitro studies and engage with regulatory authorities to minimize the need for animal testing and seek exemptions when possible. In the event animal studies are inevitably justified in line with the standards and requirements of national regulatory authorities, we commit to the 3Rs principles to obtain comparable levels of information from the use of fewer animals, minimize unnecessary pain through the review of experimental methods and technology, and consider animal welfare & ethics and management standards.

3Rs Principle

Replacement	Reduction	Refinement
Approaches that directly replace the use of animals as much as possible	Methods that help obtain comparable levels of information from the use of fewer animals	Study procedures that minimize or eliminate animals' pain and distress and improve their welfare

Bolstering Clinical Trial Capabilities

We established a data-driven clinical quality monitoring system to bolster our global clinical trial capabilities and seek continuous improvement in quality. This system applies to over 700 clinical trial sites worldwide to help us accumulate global clinical experiences. In particular, we make the safety of clinical trial participants our first priority in designing clinical trials and selecting optimal country sites and CROs to maximize the efficiency of clinical trials. While pooling our global clinical trial experiences, we also build clinical data assets, develop clinical trial Standard Operating Procedures (SOPs), and expand training to nurture our employees to internalize clinical trial capabilities.

Rigorous quality management

- Adhere to ICH, GCP, data privacy laws, and country-specific clinical regulations
- Meet the quality standards of FDA, EMA and other regulatory authorities
- Closely collaborate with CROs
  - Constantly monitor clinical quality
  - Establish a continuous CRO training and quality management system

Patient-centered clinical trial design

- Put the safety of clinical trial participants at the center of clinical trial design
- Continue to monitor and eliminate safety hazards and risks for patients during the clinical trial
- Secure clinical data that are valuable from the patient perspective

Maximum efficiency in clinical trial

- Select country sites and CROs in consideration of target indications and patients
- Directly manage CROs
  - Initiate clinical trials by country/CRO
  - Directly manage the recruitment of trial participants
- Review clinical risks in advance and develop preventive measures
- Closely consult with CROs/ vendors

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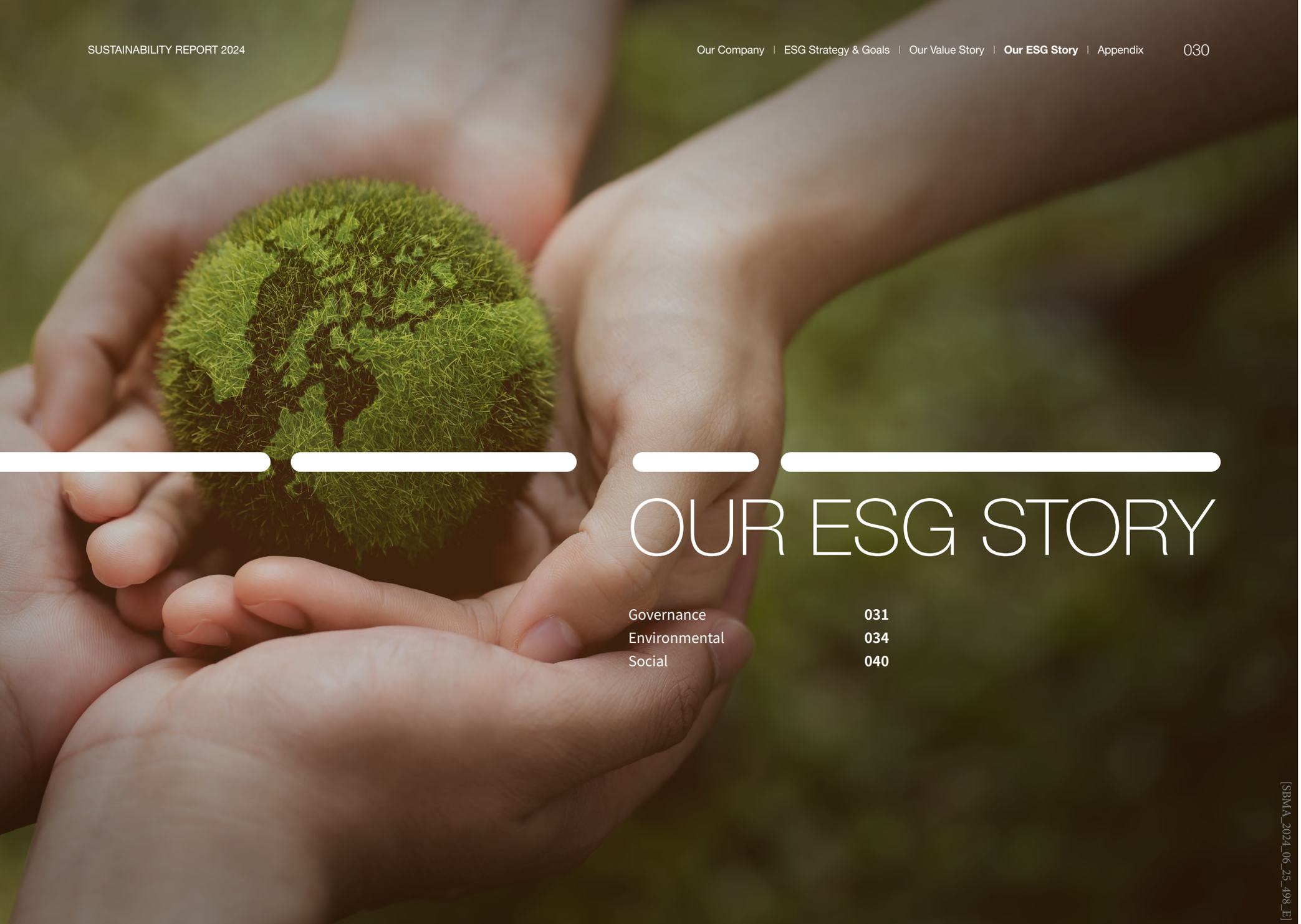

OUR ESG STORY

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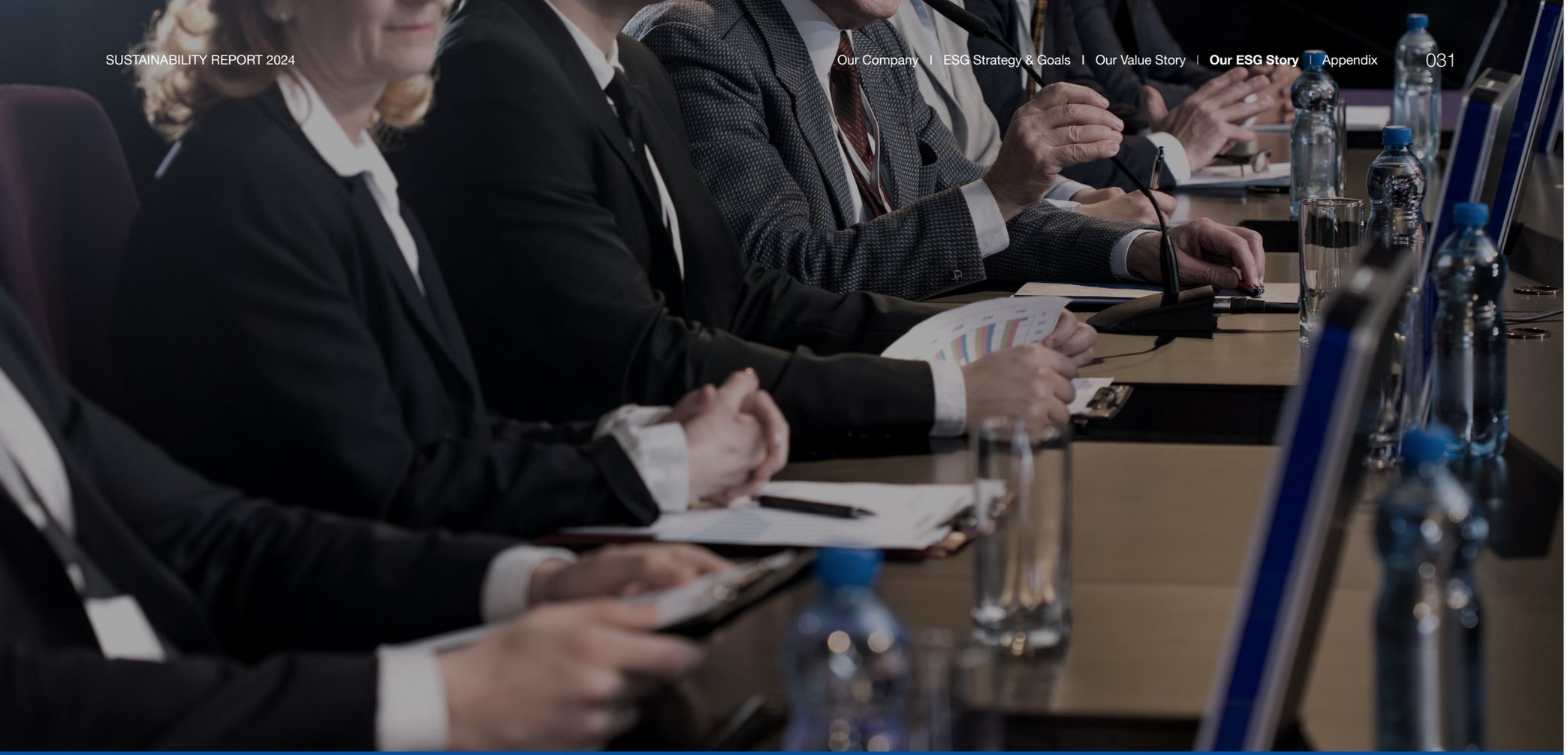

Governance

[SBMA_2024_06_25_498_E]

Embracing Responsibility in Governance

Corporate Governance

Management Accountability led by the Board of Directors

Composition of the Board of Directors

To establish a decision-making system for reasonable business operations and facilitate our long-term growth, Samsung Bioepis bans any type of discrimination on the grounds of gender, age, nationality and race among others, and prioritizes expertise in the biopharmaceutical industry in the composition of the Board of Directors. We ensure the transparency of the director appointment process and the independence of the Board in accordance with the Korean Commercial Act and our Articles of Incorporation.

Director	Christopher Hansung Ko	Kyung-Ah Kim	Kun Lo
Position	Chair of the Board, President & CEO	Inside director, Executive Vice President of R&D	Non-executive director
Gender	Male	Female	Male
Term [1]	11 years and 10 months	2 years and 3 months	1 year and 10 months
Career	(Current) CEO, Samsung Bioepis (Former) Head of Bio Health Lab, Samsung Advanced Institute of Technology	(Current) Executive Vice President, Samsung Bioepis (Former) Vice President, Samsung Advanced Institute of Technology	(Current) Head of the EPCV Center, Samsung Biologics (Former) Senior Vice President, New Business Division, Samsung Engineering
Expertise	• Biopharmaceutical business development and research • Leadership	• Biopharmaceutical research • Leadership	• Biopharmaceutical process design and construction • R&D on chemicals business

1) Tenure was calculated as of the end of December, 2023.

Board Assessment and Compensation

We provide inside directors with compensation that consists of base pay and performance pay within the limit approved by the Annual General Meeting of shareholders. Director performance assessment aligns with the long-term performance incentive program governed by the relevant guidelines of Samsung Group as well as risk management items, and compensation for inside directors reflects Samsung Bioepis' business performance.

Operational Performance of the Board

In 2023, our Board of Directors convened five times in total to deliberate and decide on key issues across the entire business operations, including making new investments, operating the internal accounting control system, approving the authorities and responsibilities of the health and safety manager, and making financial donations. Director attendance was 100%, indicating all our directors faithfully assumed their role at the Board of Directors.

Risk Management

Risk Management System

Companies today face increasingly complex and diversifying risks amid the rapidly-evolving business landscape. We established a company-wide risk management system to ensure reliable operations and business continuity and to preemptively address and mange business risk drawing on our expertise, cross-functional collaboration, and swift decision-making.

Category	Risk	Management Approach
Sustainability risk	Overall ESG management	• Identify improvement tasks for company-wide ESG management risk to implement such tasks through collaboration among relevant departments
	Supply chain ESG risk	• Perform preliminary screening on new suppliers and regular supply chain ESG risk assessment in line with our policy to establish sustainable supply chains
	Climate change	• Develop resilience strategy in preparation for potential financial impact from transition risk and physical risk
Financial risk	Financial settlement	• Create a dedicated internal accounting organization currently operating for the appropriate design and operation of control activities to prevent any distortions to financial statements
	Tax and foreign exchange	• Prepare for tax risks by analyzing mismatches in tax laws among countries and potential disputes • Regularly monitor and hedge currency fluctuation risk
Business and operational risk	R&D	• Preemptively identify potential risk in each phase of R&D and develop tailormade response measures
	Quality management	• Operate a drug safety management organization • Regularly monitor regulatory compliance in relation to quality standards
	Information security	• Establish a year-round security monitoring system, conduct regular security drills, and engage in other measures to prevent and mitigate security risk
	Compliance	• Assess and review compliance risk at all levels • Implement separate procedures to prevent any provision of economic benefits to healthcare professionals given the distinctive characteristics of the pharmaceutical industry, and conduct employee training and monitoring

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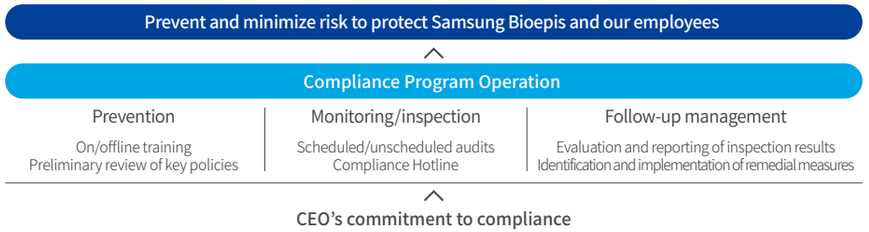
Mitigating Risk with Business Resilience

Compliance Management

Business Ethics and Compliance Management

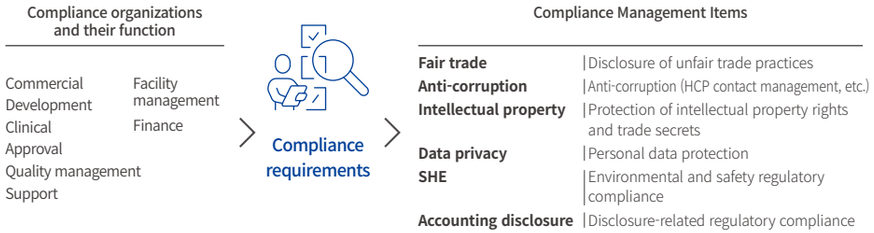
We prioritize 'integrity management' as our key value in responsibly conducting business and faithfully fulfilling our social responsibility. Our compliance organization under the direct leadership of the CEO ensures that we thoroughly abide by country-specific laws, and European and other regional norms. This also allows us to establish our compliance process in conjunction with relevant departments and continuously monitor compliance risk to minimize potential business losses.

Company-wide Compliance Program



Organization-level Compliance Management

We established an internal management process to abide by country-specific laws and regulations in the areas of fair trade, anti-corruption, intellectual property, and data privacy, and integrate this process into our day-to-day operations.



Compliance Specific to the Pharmaceutical Industry

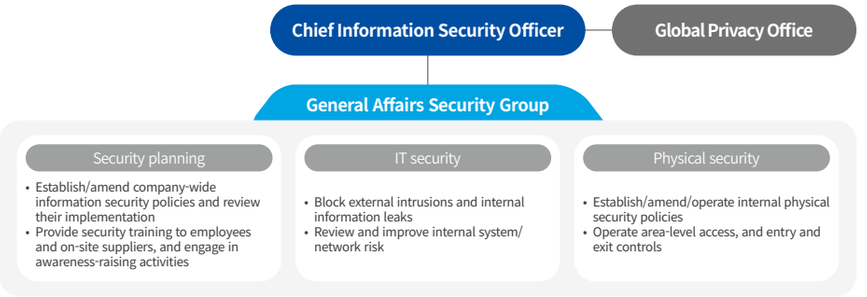
Our compliance policy ensures that we do not engage in any provision of undue economic benefits to healthcare professionals in reflection of the distinctive characteristics of the pharmaceutical industry. We also strictly prohibit any form of off-label promotion which is advertising the use of medicines for purposes not approved by the regulatory authorities.

Information Protection

Rigorous Information Security Management

Due to the inherent nature of the biopharmaceutical development industry, Samsung Bioepis handles personal data for wide-ranging stakeholders including clinical trial subjects, patients, and healthcare professionals, and any breach of such data may cause significant damage to our business operations. Therefore, to safeguard our critical information assets including stakeholders' personal data collected throughout the entire value chain, we engage in a host of information security activities based on our robust information security system.

Information Security Organization



Information Security Management System (ISO 27001)

In August 2023, we were awarded the ISO 27001 certification, establishing a globally recognized information security system to ensure the confidentiality, integrity, and availability of our information assets.

Case Internal Communication Channel for Information Security

We have operated the Security Agent (SA) program since 2022 to strengthen information security communication and protection activities at the departmental level. We heed the voice of employees with respect to department-specific security matters and enhance communication to ensure that employees can voluntarily stay alert to information security and protection.

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Environmental

[SBMA_2024_06_25_498_E]

Driving Climate Solutions

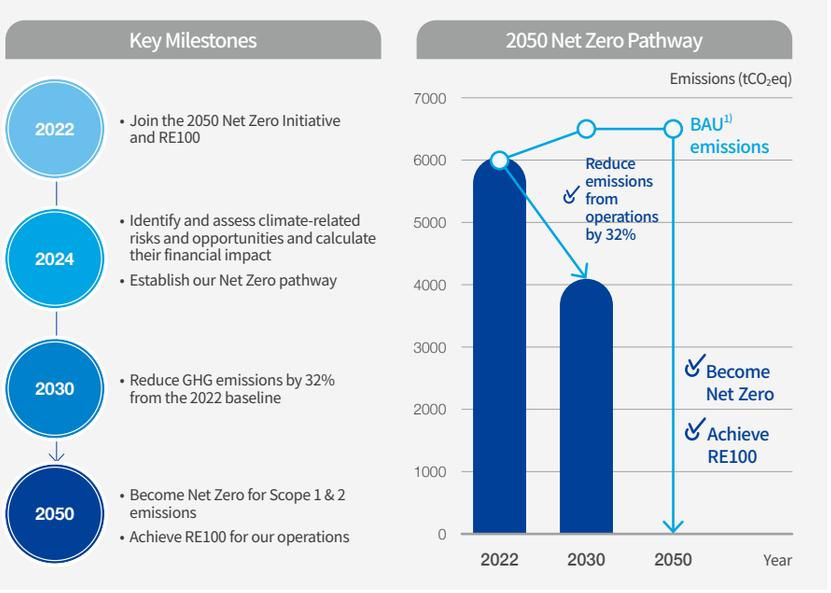
Strategy

Net Zero Pathway

Samsung Bioepis' Net Zero pathway aims to appropriately respond to the identified climate-related risks and opportunities and join hands with the global efforts to tackle climate change, reaching our Net Zero goal as a result.

We will take a phased-in approach to transitioning to and purchasing eco-friendly energy sources to become Net Zero in our Scope 1 and 2 emissions. For Scope 1 emissions, we will switch from LNG to greener energy sources for boilers and freezers over the mid-to-long term while reducing Scope 1 emissions by shifting from internal combustion engine vehicles to Electronic Vehicles (EVs). As to Scope 2 emissions, we will increase the proportion of renewable energy and mitigate carbon emissions through the purchase of Renewable Energy Certificates (REC).

Samsung Bioepis' Net Zero Pathway



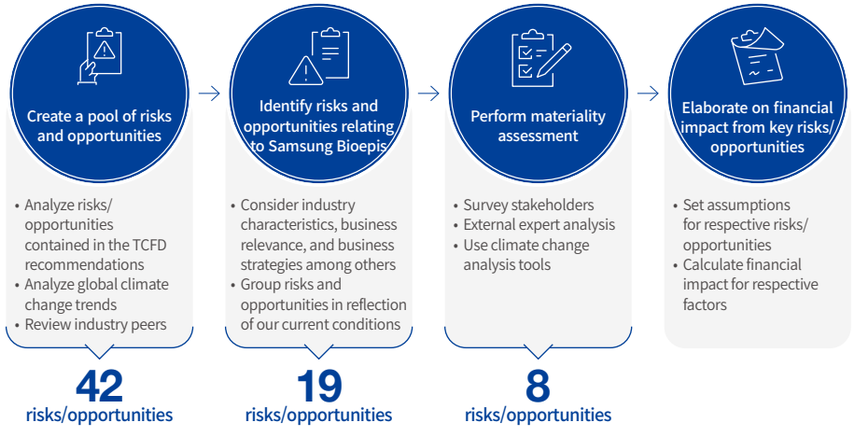
1) Business As Usual

Climate-related Risk and Opportunity

Assessment of Climate-related Risk and Opportunity

In identifying climate-related risks and opportunities that are relevant to Samsung Bioepis, we referred to TCFD and Carbon Disclosure Project (CDP) recommendations and the current responses made to climate change across the biopharmaceutical industry. We then identified risks and opportunities closely associated with us, chose priority ones through materiality assessment, and calculated financial impact for the key risks and opportunities selected.

2024 Assessment Process



Risk and Opportunity for Samsung Bioepis

Risk	**Climate-related hazards** 1) Cyclones, floods and other natural hazards 2) Heatwaves	**Markets/reputation** 3) Change in customer behavior 4) Increasing costs of raw materials	**Technology** 5) Rising costs for low-carbon transition	
Opportunity	**Resource efficiency** 6) Use of efficient production processes	**Markets** 7) Growing product demand	**Reputation** 8) Increased stakeholder communication	

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Driving Climate Solutions

Summarized Results of Climate-related Risk and Opportunity Analysis

Item	Category	Risk/Opportunity	Potential Financial Impact	Our Response
Physical risk	Acute	Cyclones, floods and other natural hazards	Operational equipment and other assets damaged due to cyclones and floods, and costs occurring for damaged asset recovery	• Operate business continuity plans, develop natural disaster response scenarios, and conduct annual drills • Incheon City is operating flood prevention facilities
	Chronic	Heatwaves	Cooling costs to cope with 35-degree and above heatwaves and the loss of sales occurring due to diminishing labor productivity	• Establishment and operation of procedures to respond to extreme heat risks
Transition risk	Markets	Change in customer behavior	Increasing number of customers demanding climate change response which could reduce revenue when proper response is lacking	• Set our Net Zero goal and implement specific reduction plans • Identify and assess climate-related risks and opportunities and measure their financial impact to proactively respond to climate disclosure requirements • Measure product carbon footprint in line with the LCA process
	Markets	Increasing costs of raw materials	Rising carbon costs, including increasing carbon credit costs, and the resulting passing-on of the transition costs suppliers bear for climate change to Samsung Bioepis, leading to increasing costs of purchasing raw materials	• Improve the supply chain ESG risk assessment and management system • Strengthen cooperation in reducing supply chain GHG emissions and advance the Scope 3 emissions calculation system • Boost productivity through process innovation and save on the use and cost of raw materials
	Technology	Rising costs for low-carbon transition	Investment costs and renewable energy sourcing costs occurring to achieve our Net Zero goal	• Join the RE100 initiative and operate photovoltaic power generators • Make mid/long-term low-carbon transition investments to achieve Net Zero taking into account the economic feasibility of respective green energy sources
Opportunity	Resource efficiency	Use of efficient production processes	Boosting productivity made possible with process innovation and the resulting improvement in raw material input efficiency and reduction in energy consumption that affect carbon emissions	• Pursue productivity gains through continuous process innovation during the development phase
	Products & services	Growing product demand	Expanding revenue due to the growing demand for treatment for climate-related diseases	• Forecast and monitor the growing demand for treatment for diseases caused by climate change
	Reputation	Increased stakeholder communication	Elevating brand image through climate-related disclosures and proactive response to disclosure regulations	• Proactive climate disclosures through sustainability reports and TCFD reports

Risk Management

Following the identification and assessment of climate-related risks and opportunities, we review the priorities of respective key risks and opportunities to develop countermeasures and monitor progress accordingly. In particular, climate-related risks that have impact on our business operations and reputation are managed in alignment with our company-wide risk management system.

Risk Management

Metrics & Targets

To contribute to achieving Net Zero globally and transitioning to a low-carbon economy and society, we set our 2050 Net Zero goal, and joined the RE100 initiative alongside Samsung Biologics in November 2022. Our goal is to reduce our Scope 1 and 2 emissions from operations by 32% by 2030 from the 2022 base year and to pursue a range of mitigation activities including shifting to greener energy sources and purchasing renewable energy.

We work to assess emissions from our suppliers in addition to our Scope 1 & 2 emissions to advance our Scope 3 emissions calculation methodology.

2024 Data Book

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Environment Management

Environment Management System

Environmental Management System and Principles

At Samsung Bioepis, a dedicated working-level environmental management organization is running under the Chief Safety Officer (CSO) to develop and implement environmental management plans in a broad range of areas, including energy saving, lawful management of wastewater and waste, and reduction of hazardous chemical discharge. We also established systemic SOPs in line with our environmental management system to minimize the environmental impact of our business operations.

Environmental Management Policy

We establish safety, environmental, and energy management policy in line with international standards to make our commitment to environmental management internally and externally, and integrate such commitment into our day-to-day operations. All our employees and our on-site suppliers are aligned towards the shared value and goal of environmental management in accordance with our safety, environmental, and energy management policy.

Environmental Management System (ISO 14001)

In September 2022, we were awarded the ISO 14001 certification. Going forward, Samsung Bioepis will preemptively identify, assess and manage environment-related risks to continue operating our environmental management system on par with global standards.

Environmental Impact Assessment Process

We perform annual environmental impact assessment to regularly identify the environmental impact of our operations and mitigate negative impact that may arise. Key resources that we consume for conducting business operations and materials that we discharge are assessed for their compliance with the set management standards, and improvement action is taken when such standards are not satisfied. As a result, in 2023, we confirmed that we met management standards across all assessment items of the environmental impact assessment. For issues such as climate change that inherently entail uncertainties, risks and opportunities are evaluated based on scenarios, and our response measures and improvement status will be disclosed through the TCFD report that we will publish in the second half of 2024.

Environmental impact identification
- Identify resources used and materials discharged
- Identify key assessment items

→

Environmental impact assessment
- Perform impact assessment for key assessment items (once a year)

→

Improvement
- Take improvement measures when the standards are not met based on assessment results
- Monitor environmental impact

Environmental Management Activity and Performance Management

We develop company-wide environmental goals and implementation plans each year, and commit to attain the goals. The scope of our quantitative data management extends beyond Net Zero, RE100, and other GHG emissions reduction activities into such far-reaching areas as energy consumption, water resources, wastewater, air pollutants, and waste to systematically manage the achievements and improvements made in our environmental management.

2024 Data Book

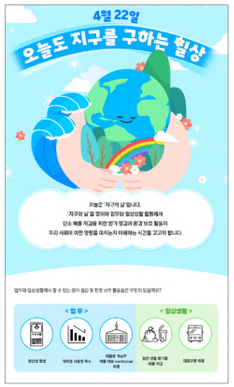
Disseminating a Green Corporate Culture

Publishing SHE (Safety, Health, Environment) and ESG Newsletters

We regularly publish SHE and ESG management newsletters to communicate our environmental management activities and results at all levels and raise employees' awareness on environmental management. In particular, these newsletters serve to share our energy consumption status and working environment data to build company-wide consensus on environmental safety management and invite greater employee participation.

Epis Eco Campaign

We launch the Epis Eco Campaign to encourage employees to properly sort out waste and save on paper consumption in the office and lab. This provides our employees with an opportunity to take action to reduce negative environmental impact in their daily routine.



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Protecting Natural Resources

Energy

Energy Management

We focus on managing and reducing our energy consumption in line with our safety, health, and environmental management principles. We ensure the efficient management of primary energy consumption sources such as electricity and HVAC equipment at buildings to minimize negative environmental impact and respond to climate change in the process.

GHG Intensity (Scope 1 + Scope 2)[1)]

Unit	2021	2022	2023
tCO_2eq/KRW 1 billion	8.1	6.4	6.2

1) GHG emissions per KRW 1 billion of revenue

Energy Management System (ISO 50001)

In September 2022, our company obtained the ISO 50001 certification for Energy Management Systems. Based on the energy management system that conforms to international standards, we have established goals and action plans for efficient energy management.

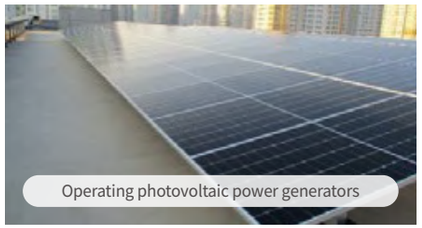
Energy Reduction Activities

Operating Photovoltaic Power Generators

In December 2022, we installed 200kW-capacity photovoltaic power generators on the rooftop of our office building. This allowed us to produce 272MWh of power in 2023, representing nearly 3% of our annual power consumption.

Efforts to Reduce Energy Consumption

We fully shifted to LED lights at our office building in Songdo, Incheon and opted for high-efficiency equipment such as high-efficiency heat pumps, power factor correction capacitors, and standby power saving outlets to lower energy consumption. We also established a HVAC system using district heating and absorption chiller-heaters. Additionally, we have allocated 2% of the entire parking lot exclusively for EVs and installed EV chargers within our office building to contribute to energy saving and green energy transition.



Operating photovoltaic power generators

Installing electric vehicle chargers

Water

Water Resources Management

We engage in rigorous review from the planning phase to minimize water consumption and prevent the unnecessary discharge of wastewater in conducting all types of experiments in the process development covering cell culture and purification.

Effluent Monitoring and Wastewater Treatment System

We monitor effluents once a day to maintain the quality of treated water below 30% of the legally allowable threshold. To this end, we installed a facility capable of treating contaminants in all wastewater generated from our bio laboratories, and operate a wastewater treatment system to record and manage the composition and discharge amounts of wastewater.

Water Pollutant Management in 2023

Category	Unit	Total Organic Carbon (TOC)	Suspended Solids (SS)	Total Nitrogen (T-N)	Total Phosphorus (T-P)
Our discharge concentration	mg/L	4.5	0.2	10.7	0.1
Legal threshold	mg/L	75	120	60	8

Emergency Response System Development

To prepare for and cope with such hazards as floods and inundation, we secure two day's reserve capacity for our wastewater storage tank. Our drainage facility also holds more than twice the drainage capacity compared to the highest recorded precipitation in the region (145mm/h, 1953) to brace for flood damages.

Biodiversity

Protecting Biodiversity

As a subsidiary of Samsung Biologics, Samsung Bioepis abides by the biodiversity pledge of our parent company. Our operations are surrounded by key biodiversity areas, including Sihwa Lake (within 5km of HQ), Yeongjong Island (17km), Yeongheung Island (18km) and the Songdo Tidal Flat registered as a Ramsar site (2km). As such, we are actively collaborating with Samsung Biologics to recognize the impact and risks on biodiversity. Wastewater generated from our business operations undergoes our internal purification treatment and is then discharged into the West Sea of the Korean peninsula after passing through the Incheon Songdo Sewage Treatment Plant. We will continue identifying and reviewing key impacts related to biodiversity, such as GHG emissions, wastewater, and waste disposal, in our efforts to protect biodiversity.

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Reducing Product's Environmental Impact

Circular Economy

Resource Circularity Management

We work on multiple fronts to mitigate the environmental impact of product packaging as well as waste generated from the product R&D process. The development and expansion of eco-friendly packaging helps us reduce waste and improve stacking efficiency for product transportation and storage. Starting with product carbon lifecycle management, we aim to identify, assess and manage the environmental impact of our products more accurately.

Resource Circularity Management Activity

Eco-friendly Packaging

The biopharmaceutical industry puts patient safety first and thus applies rigorous standards to the use, storage, and packaging of raw materials, which makes it less feasible to opt for recycled materials. Still, Samsung Bioepis strives to reduce waste from the early product development stage to minimize the negative environmental impact our products may cause.

Development/ manufacturing	→	Transportation	→	Disposal
• Optimize packaging sizes • Minimize the use of packaging materials		• Enhance transportation efficiency • Improve utilization of storage space		• Reduce the generation of waste • Expand material recycling

Case Optimizing packaging sizes

In 2023, we explored diverse ways to change carton materials, reduce paper consumption, and minimize packaging sizes, thereby saving on development costs and mitigating carbon emissions. The packaging improvements that were additionally identified will be applied across all products to contribute to the circular economy.

Case Participating in the e-labeling pilot project

To improve mobile device access to medicine information, Samsung Bioepis is participating in the pilot e-labeling project led by the Korean Ministry of Food and Drug Safety. E-labeling allows consumers and Healthcare Professionals (HCPs) to use their mobile devices to scan the QR code or bar code affixed to the containers or outer packaging of medicines and check on the compliance information of their medicine in real time. Through our participation in this project, we enable users to access the latest information associated with medicine safety more swiftly and efficiently while avoiding paper consumption to help mitigate carbon emissions. Going forward, we will actively join in on countries' policies encouraging the adoption of e-labeling.

Case Using shipping boxes made of recyclable materials

We use recyclable paper for product shipping boxes to minimize our environmental footprint while upholding the value of eco-friendliness. To minimize the environmental impact of these materials, our shipping boxes are packed with LDPE wraps in lieu of PVC which generates dioxins when incinerated.

Case Paper certified to forest protection programs

The paper we use for leaflets and trays that are included in product packaging is free from hazardous substances, and was certified to such international forest protection standards as the FSC[1] and the PEFC[2].

Improving Productivity while Minimizing the Use of Raw Materials

We engage in productivity innovation activities[3] in the development phase and apply such activities to the drug substance manufacturing process implemented by our CMOs. This allows us to reduce the number of annual manufacturing batches required for sales, which leads to reduced carbon emissions of CMOs. We also meticulously review raw materials used for our manufacturing process to assist CMOs in reducing the consumption of raw materials and minimizing our environmental impact in so doing.

Product Life Cycle Assessment (Carbon Footprint)

Measuring negative impact that occurs across the overall product value chain is key to managing the product life cycle to reduce environmental impacts. To ensure the more accurate and transparent identification of negative environmental impact throughout the product value chain, we established our carbon footprint assessment methodology in line with the ISO 14040 standard, and are engaging in pilot assessment by employing the methodology in 2024. Moving forward, we will make assessment on more products, and the assessment results will inform our decision-making in the entire production process including product design and supplier selection.

1) Forest Stewardship Council
2) Programme for the Endorsement of Forest Certification
3) Improvement in culturing titer, purification yield and others in the DS (Drug Substance) production process

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Social

Empowering & Investing in Our People

Talent Development

Talent Recruitment

We value talent with expertise in biotechnology as our most important asset. We define a specific profile of the ideal Samsung Bioepis employee to secure professionals who align with our core values, and follow a transparent and impartial recruitment process to attract top-notch talent.

Ideal Samsung Bioepis Employee

Recruitment

In line with our expanding business portfolio, we hired 91 persons, including 56 new and 35 experienced employees in 2023. Product development roles and women accounted for over 80% and 45% of our total new hires respectively. We established a performance-centered and fair recruitment process, and apply blind recruitment to eliminate such factors as gender, age, and academic background in the hiring process. To secure talent with job function-specific expertise, we disclose detailed job description information in advance and hire year-round as the need arises to recruit professionals in a timely manner. SAMSUNG BIOEPIS

Employee Data in 2023

49.4%	35.1 years old
Percentage of female employees	Average age of employees

Compensation and Performance Appraisal

Our performance management system is anchored on the Management by Objectives (MBO) process to align individual goals with organizational strategies and goals. We also make multi-source performance assessment to improve the completeness of our performance appraisal, and continue to embed greater fairness and reliability into our assessment process.

Goal setting	Interim review	Assessment
• Goal/metric-setting interview with appraisers • Individual annual goal-setting	• Review of MBO progress • Feedback and goal adjustment	• Self-assessment for the attainment of annual goals • Ranking session with the departmental head • Confirmation of the final grade

All our employees receive regular performance appraisal. Our salary grading system tied to performance assessment ensures that our employees are fairly compensated according to their achievement. Providing fair compensation based on reliable assessment results strongly motivates our employees and also increases their engagement in the workplace, promoting organizational performance improvement in the process.

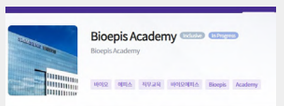
Talent Development

Guided by our training philosophy that 'company growth is driven by the growth of our employees', we assist our employees in improving their job competency and honing their competitive edge. To help employees design their own career path and develop expertise, we operate a range of training programs spanning onboarding training for new hires, GxP job training, and programs for career development. We also provide an opportunity for internal job transfer and mentoring programs to support employees' accelerated adaptation and assimilation within the organization.

Bio Talent Development

Case **Bioepis Academy selected as an excellent Creative intelligence Campus (CiC)**

In 2023, our Bioepis Academy was selected as one of the best practices in the community learning category out of 2,513 campuses on 'Multicampus CiC', Samsung Group's learning platform.



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Empowering & Investing in Our People

Corporate Culture

Corporate Culture for Work-Life Balance

We pursue the happiness of our employees through work-life balance as the underlying foundation of our corporate culture. We support a wide array of fringe benefits programs, including flexible work arrangements and an in-house daycare center, to lead the charge as a family-friendly business. As a result, in 2023, Samsung Bioepis was certified to the family-friendly business program of the Ministry of Gender Equality and Family Affairs.

Corporate Culture of Diversity and Mutual Understanding

Our top priority for talent management is to provide an environment for our employees with diverse perspectives and backgrounds to engage in free-flowing interaction to generate greatest-possible outcomes. This is why we guarantee all employees equal pay for work of equal value irrespective of gender, religion and race among others.

Nurturing a Sound Corporate Culture

To establish a healthy and dynamic corporate culture, we promote communication based on mutual respect and care among employees.

Leadership communicating with millennials and Gen Z	Our CEO and other members of leadership attended events celebrating employees' 1st, 3rd, and 5th year of employment and Change Agent (CA) discussions to interact with employees on diverse topics including employee grievances and the prospect of Samsung Bioepis' present and future.
Corporate culture improvement initiatives	CAs, our departmental corporate culture leaders, plan and operate activities to improve departmental communication and corporate culture, contributing to a healthy organizational culture in so doing. CAs also plan Great Work Place (GWP) programs to facilitate department-level unity and communication.
Corporate culture assessment	Based on the results of the SCI (Samsung Culture Index) survey conducted as Samsung Group's unique employee satisfaction survey, we identify issues and specific improvement measures at the department, division, and company-wide levels, pursuing positive change and improvement in our corporate culture.

Leadership communicating with millennials and Gen Z

Personalized Benefits Programs

Welcome to Hi EPIS, Hi Family

The family invitation event held in 2023 was attended by 1,628 persons (425 employees and 1,203 employee family members) to participate in various activities together and tour around our labs, offices and other workspaces. This helped employees' families to deepen their understanding on the tasks and working environment of our employees.

5-minute caricature for family members

Lab tour for employee families

10-week Health Challenge

We launched the '10-week Health Challenge' program to promote employees' physical health: health-related metrics such as individual body weight and skeletal muscle mass were measured for 10 weeks, and employees who made excellent improvements were awarded accordingly. A total of 281 employees applied for this program, and 99 of them successfully reduced their weight by an average of 4.6% and increased their muscular power by an average of 2.2%.

Smoking Cessation Program

As part of our health recovery program, we also planned a smoking cessation program in partnership with the public healthcare center in Yeonsu-gu, Incheon where we are located to support our employees to quit smoking. A total of 36 employees applied for this program, and 35 of them succeeded in smoking cessation.

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Respecting & Promoting Human Rights

Human Rights Management

Human Rights Management

Samsung Bioepis makes sure that our employees are not discriminated against on the grounds of gender, race, ethnicity, nationality, religion, disability, age, or political association. We stipulated our Human Rights Charter in 2022 specifying the principles of equal pay for work of equal value and zero tolerance for sexual discrimination or racial discrimination. The Human Rights Charter serves to improve the non-discrimination principle stated in the employment regulations, and set the course ahead in advancing human rights management across all areas.

Human Rights Charter of Samsung Bioepis

Human Rights Risk Management Process

Risk Assessment

- Operate internal/external channels to identify human rights risk
- Assess risk levels

→

Corrective Actions

- Analyze causes behind respective risks
- Identify and review improvement plans for institutions
- Suggest departmental improvement measures and recommend corrective action

→

Implementation & Feedback

- Implement improvement solutions and share feedback
- Review continuous improvement

Facilitating Labor-Management Communication

Our labor-management council runs various communication channels to collect employees' grievances and experiences concerning human rights violation. Proactive improvement action is taken to address concerns raised.

CA for corporate culture improvement

CAs are appointed at respective teams and departments to serve to facilitate departmental and labor-management communication and disseminate corporate culture innovation programs.

Labor-Management Council

Quarterly Labor-Management Council meetings and the anonymous bulletin board 'Our Voice' all help us gather grievances of our employees on a variety of agendas concerning wages, benefits, and absence of leave, and discuss and take improvement action.

Grievance Handling Procedures

In receiving grievances, we ensure the identity of whistleblowers and their concerns remain confidential to protect them from any disadvantages. While we immediately take action and notify the results for concerns raised in principle, we address issues that elude immediate resolution by communicating our action plan and timeline within 24 hours to ensure their smooth handling. In 2023, we received 29 grievances through the anonymous bulletin board, Bamboo Forest meetings, and through the counseling center and the Labor-Management Council, and resolved these grievances according to our grievance handling procedures.

Receive grievances

- Receive grievances through the hotline, the anonymous bulletin board, and other whistleblowing channels

→

Verify & review

- Establish factual grounds
- Protect whistleblowers
- Review action to be taken according to verified facts

→

Notify review outcomes

- Notify review outcomes and collect feedback

→

Resolve grievances

- Take HR action against perpetrators according to the issue at hand and provide company-wide training to prevent reoccurrence

Case Training to prevent workplace bullying

In 2024, we invited a psychological expert to provide all our employees with training to prevent workplace bullying. This was specifically followed by a two-week intensive whistleblowing period (Feb. 6 ~ Feb. 16, 2024) on workplace bullying cases. Corporate Culture 112, our anonymous hotline available 24/7/365, allows us to detect workplace bullying early on and build a healthy corporate culture in so doing.

Caring for Safety & Health

Occupational Health & Safety

Health and Safety Management

Samsung Bioepis puts the health and safety of all our stakeholders, including customers, employees, and suppliers, above all else. In 2022, we established our safety, health and environmental management principles to deliver on our commitment to improving the work environment and disseminate a safety-first culture. We also achieved certification of the Occupational Health and Safety Management System international standard (ISO 45001).

Health and Safety Committees

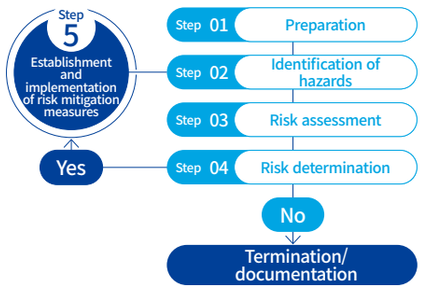
Our health and safety activities span the overall value chain. The occupational safety and health committee gathers together labor and management to deliberate and decide on health and safety agendas, and the supplier health and safety committee serves to communicate with suppliers on health and safety issues. The biosafety management committee which consists of experts convenes to perform risk assessment on Living Modified Organism (LMO) to review the stability of the entire laboratory process on an on-going basis.

Health and Safety Activity

Workplace Risk Assessment

We implement a rigorous risk assessment system to prevent the risk of occupational injuries from ever occurring. As part of such efforts, regular safety inspections are made on facilities and equipment within our operations, and potential risk identification competitions are held to disseminate a self-directed culture of safety.

Risk Assessment Process



Risk Assessment Activity

Category	Cycle	Description
Risk assessment	Annual	Identify potential risk by team/ process, assess, and make improvements
Potential risk identification competition	Semi-annual	Identify safety-related risks across internal business operations and make improvements

Improvements made according to risk assessment results

Following the risk assessment performed in 2023, we completed improvement for 44 cases[1] in total.

1) Including improvements identified through potential risk identification competitions

Health and Safety Impact Management

The health and safety assessment system supervised by our Chief Safety Officer (CSO) and management supervisors serves to raise company-wide awareness on the importance of health and safety and establish a self-initiated safety culture. Health and safety qualification assessment also ensures that we select suppliers based on their excellent safety management performance while assisting suppliers whose scores declined to improve overall safety management performance.

Case 1 Potential Risk Identification Competition

Since 2022, we have hosted the potential risk identification competition on a semi-annual basis to preemptively identify and improve potential risks in the workplace. In 2023, 73 submissions gathered from employees and suppliers were reviewed and 40 of them were chosen as potential risks. We completed improvement for 27 out of 29 risks that fall into the category of on-site equipment risk, and took improvement action for eight out of 11 lab risks. In 2024, we will host the competition on an on-going basis.

Case 2 Selected as an Excellent Organization for LMO Safety Management

In recognition of our company-wide efforts for LMO safety management, we were honored with the Minister of Science and ICT Award at the Study and Research LMO Safety Management Awards hosted in November 2023.

Chemicals Management

We abide by the Chemical Substances Control Act, the Act on the Registration and Evaluation of Chemical Substances in Korea, and other applicable regulatory requirements, and established our chemical substances and materials management system. This enables us to manage the entire process from receiving to disposing of all chemicals to proactively prevent chemical incidents. We keep the MSDS[1] of all chemical products up to date and manage such data accordingly to deter chemical incidents, perform risk assessment on all chemicals that we handle based on the updated MSDS, and develop appropriate safety management plans. Going forward, we will fully comply with laws and regulations associated with chemical substances and regularly conduct statutory inspections on our facilities handling hazardous chemicals, doing our utmost to prevent chemical and safety incidents across our operations.

1) Material Safety Data Sheet

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Promoting Shared Growth

Supply Chain Management

Supply Chain ESG Risk Management

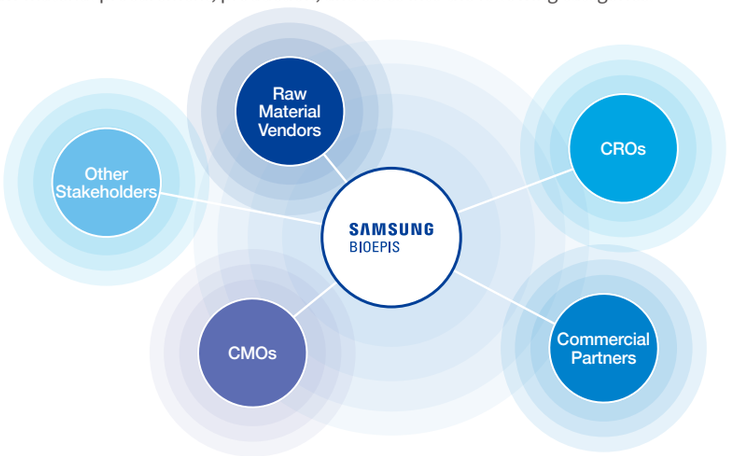
Samsung Bioepis aims to deliver high-quality medicines at reasonable costs and optimal lead times.[1] To this end, we build reliable supply chains to grow together with suppliers while ensuring seamless business operations at Samsung Bioepis. Amid the aggravating uncertainties over global geopolitical issues and the climate crisis, supply chain diversification and management of suppliers ESG risks are gaining greater prominence.

Sustainable Supply Chain Policy

In response to the tightening regulations on global supply chain due diligence and ESG disclosure, we established our sustainable supply chain policy, Third-Party Code of Conduct, and supply chain ESG risk assessment process. We also recommend our suppliers and their employees to abide by this policy and regularly review their compliance to preemptively prevent and manage supply chain ESG risk.

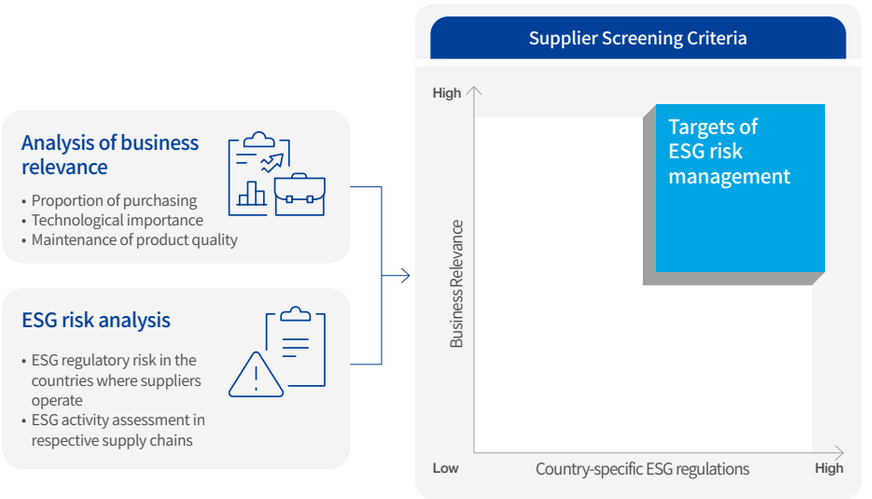
Overview of Samsung Bioepis' Supply Chains

Our company classifies its business partners across the entire value chain, including R&D, clinical trials, raw material procurement, production, and sales into the following categories.



Supplier Screening

Our supplier screening process is up and running to systematically manage supply chain risk. This enables us to comprehensively analyze and prioritize key suppliers in terms of their relevance with our business and levels of ESG risk. Business relevance is determined by suppliers' proportion in our total purchasing, technological importance, and quality performance while ESG risk analysis considers ESG regulatory risks such as the CSRD[2] and the CSDDD[3] in the countries where suppliers are located to identify major target companies for ESG risk management.



1) The time between the design and production of a product
2) EU Corporate Sustainability Reporting Directive
3) EU Corporate Sustainability Due Diligence Directive

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Promoting Shared Growth

Supply Chain Management Activity

Supply Chain ESG Assessment in 2023

In selecting new suppliers, we assess them across 10 basic compliance categories including environment, human rights, and health & safety. For incumbent suppliers, we regularly assess them for 55 specific assessment items covering overall ESG management. We conducted a self-administered survey assessment on key suppliers identified (22 companies) in the screening process between July and August of 2023. The assessment results showed that none of the surveyed suppliers fell in the high-risk category (below 40 points in overall assessment score) and this allowed us to analyze their strengths and weaknesses in the given business category to identify possible improvements. We share assessment results when requested by our suppliers, and will actively pursue key improvements.

Considering that our 2023 assessment covered more suppliers than 2022 and added climate change response in the scope of risk analysis, it is not readily feasible to directly compare assessment results over the past two years. Still yet, it was demonstrated that the ESG risk management performance of our suppliers improved across overall assessment criteria. We are extending the scope of our supply chain ESG assessment and fine-tuning our questionnaire in line with global due diligence and disclosure regulatory requirements. In so doing, we ensure that our supply chain ESG assessment serves as an effective and substantive tool for risk monitoring.

Supply Chain ESG Assessment Average Scores in 2023

Category	Average Score	
	2022	2023
ESG management system	71	83
Ethical management	69	72
Labor and human rights	76	86
Environment in general	59	62
Health and safety	85	86
Sustainable supply chain	60	86
Response to climate change[1)]	-	51

1) Assessment on climate change response was initiated in 2023.

Case Supply chain climate change risk management

We are working to systematically measure and manage Scope 3 GHG emissions with the help of external consulting. We also analyzed the climate change risks of our CMOs[1)] with their immense impact on our business operations. In particular, we will identify their production sites and size of assets exposed to physical climate risk and verify whether they established appropriate prevention, response, and recovery measures for identified risk through the use of checklists and other methods. This will allow us to strengthen cooperation with CMOs to protect their production sites from any damage caused by physical climate risk and minimize damages once they occur.

1) We will publish our TCFD report in the second half of 2024.

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Promoting Shared Growth

Mutual Growth

Support for Bio Raw Material Companies towards Win-win Partnership

The sustainable procurement of bio materials, parts, and equipment from small/mid-sized companies are the utmost priority to ensure the sustainable growth of the biopharmaceutical industry.

Samsung Bioepis has implemented the Bio Materials, Parts, and Equipment Test Program since May 2022 in Korea to test products of Korean bio materials/parts/equipment suppliers at no cost and provide feedback for their commercialization. In total 18 products have been tested as of March 2024, helping improve the technological maturity of products tested in addition to offering reviews of product use. This allows us to constantly capture data on products from small/mid-sized companies and to review cost benefits available by switching to alternative products.

Category	Description
Areas of support	• Operate a program to test products and prototypes of materials/parts, equipment companies • Provide consulting to bio materials/parts, equipment companies
Product areas tested	• Cell line development • Cell culture process • Purification process • Quality Control (QC) and others

ESG Management Support for Small/mid-sized Biotechnology companies

We provide ESG capacity-building support to small/mid-sized biotechnology companies facing challenges in improving their ESG management and responding to disclosure requirements.
Under the leadership of the Korea Biotechnology Industry Organization, we surveyed its members – small/mid-sized biotechnology companies – to identify their needs for ESG consulting, selected four of these companies, and then offered 4-week consulting to each of them.
In so doing, we pursue win-win partnerships with small/mid-sized biotechnology companies and play a pioneering role in creating a bio ecosystem in Korea.

Select consulting targets
- Survey small/mid-sized biotechnology companies to identify their consulting needs

→

Assess current ESG status
- Assess current ESG management levels
- Select areas for ESG consulting

→

Produce ESG content
- Produce job descriptions for ESG management (23 areas)

→

Provide consulting
- 2 companies each in the first and second half respectively in 2023

Feedback from companies

Company A

"We've come to meet with Samsung Bioepis through the ESG consulting support project led by the Korea Biotechnology Industry Organization, and Samsung Bioepis provided us with customized tasks drawing on stepwise short/mid/long-term ESG implementation procedures and best practices to identify our ESG needs and areas of improvement in vulnerable areas. This greatly helped us prioritize ESG strategies and systematically set our achievable goals."

Company B

"The ESG consulting conducted along with Samsung Bioepis helped us meet our most pressing needs by identifying shortcomings in the environment and health & safety areas. Samsung Bioepis also presented clear directions to categorize necessary tasks into short and mid/long-term ones, which was of great help to us."

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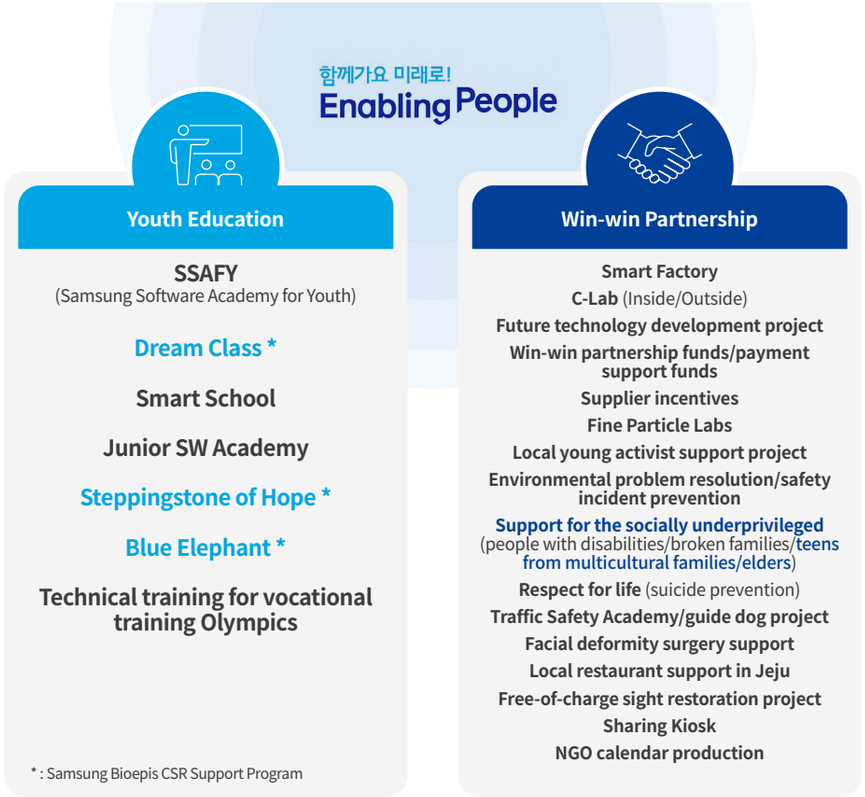
Promoting Shared Growth

Corporate Social Responsibility

CSR System

Samsung Bioepis and Samsung Group affiliates commit to resolving a range of social challenges in the areas of youth education and win-win partnership under Samsung's Corporate Social Responsibility (CSR) vision of 'Together for Tomorrow! Enabling People'. Samsung Bioepis specifically focuses on Dream Class, Steppingstone of Hope and other programs supporting socially underprivileged groups such as teens from multicultural families and elders.

Samsung Group's CSR Approach



* : Samsung Bioepis CSR Support Program

CSR Programs

Dream Class

Samsung Group's Dream Class program has provided middle school students facing financial challenges in their pursuit of learning with English and math learning opportunities since 2012, and has additionally supported career exploration and future capacity building courses since 2021. The number of middle school mentees and undergraduate mentors who participated in Dream Class reached 99,000 and 25,000 persons respectively on a cumulative basis.

Steppingstone of Hope

This program aims to support teens who turn 18 years old and help them to prepare for self-sufficiency due to the termination of protection provided at childcare institutions. We offered one room per person for residence for up to two years, along with training on technology, finance, and asset management.

Blue Elephant

This cyber violence prevention program is operated in partnership with the Blue Tree Foundation to provide education on the prevention of cyber violence to help teens build stronger social skills and reduce cyber violence.

Support for the Socially Underprivileged

The Sports Class for Multicultural Teens program selects 300 elementary and middle school students each year to support them with sports, career counseling, and psychological counseling. The Samsung Senior Digital Academy program, a digital capacity-building program for elderly people, helps elders better use digital devices such as smartphones and kiosks and land a job in the private and public sectors.

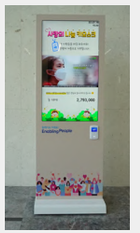
Case

Donation Market to Make You Feel Better

160 employees donated 913 items of baby supplies, clothes, and food & beverages.
Attended by **329** employees
Donated proceeds worth nearly KRW **7.5** million

Kiosk donation

The donation kiosk installed within the office building encouraged employees to make donations at any time.



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APPENDIX

[SBMA_2024_06_25_498_E]

Financials

Consolidated Statements of Financial Position

(Unit : KRW million)

Category	2021	2022	2023
Assets			
Current assets	1,718,448	1,632,058	1,604,188
Cash and cash equivalents	107,681	123,727	126,842
Trade and other current receivables	247,397	289,093	317,595
Prepaid income tax	8,214	8,863	2,624
Inventories	1,289,939	1,163,558	1,098,184
Other current assets	64,878	40,442	58,943
Non-current assets	339	6,375	0
Non-current financial assets	1,065,523	1,202,565	1,293,738
Other non-current receivables	4,588	1,954	3,230
Property, plant and equipment	8,817	6,137	8,204
Intangible assets	224,136	224,174	229,018
Right-of-use assets	630,620	718,597	779,144
Deferred tax assets	933	974	969
Other non-current assets	191,210	247,909	272,227
Other non-current financial assets	1,974	1,799	946
Employee benefits	3,245	0	0
Net defined benefit assets	0	1,021	0
Total assets	**2,783,971**	**2,834,623**	**2,897,926**
Liabilities			
Current liabilities	1,498,458	1,295,986	1,273,856
Trade and other payables	231,015	184,147	206,523
Short-term borrowings	464,450	532,783	434,500
Current portion of long-term borrowings	344,000	88,019	145,000
Unearned revenues	440,532	442,940	459,880
Current lease liabilities	410	476	496
Current tax liabilities	14,511	44,845	25,012
Advance payments	0	0	79
Withholdings	3,540	2,776	2,366
Non-current liabilities	329,605	362,541	271,429
Long-term borrowings	185,565	220,000	120,000
Non-current lease liabilities	329	129	32
Other non-current payables	3,798	8,713	14,372
Non-current unearned revenues	133,699	133,699	131,908
Employee benefits	6,214	0	5,117
Other non-current financial liabilities	0	0	0
Total liabilities	**1,828,063**	**1,658,527**	**1,545,285**

Consolidated Statements of Financial Position

(Unit : KRW million)

Category	2021	2022	2023
Equity			
Equity attributable to owners of the company	955,908	1,176,096	1,352,641
Share capital	103,419	103,419	103,419
Share premium	930,267	930,267	930,267
Accumulated other comprehensive loss	-6,298	-4,533	-8,613
Retained earnings (accumulated deficit)	-71,480	146,943	327,568
Non-controlling interests	0	0	0
Total equity	**955,908**	**1,176,096**	**1,352,641**
Total liabilities and equity	**2,783,971**	**2,834,623**	**2,897,926**

Consolidated Statement of Comprehensive Income

(Unit : KRW million)

Category	2021	2022	2023
Revenue	846,977	946,340	1,020,297
Cost of revenue	332,250	365,634	408,271
Gross profit	514,727	580,706	612,026
Selling, general and administrative expenses	321,989	349,170	406,665
Operating profit (loss)	192,738	231,536	205,361
Other non-operating income	-18,168	-18,794	-16,957
Other non-operating expenses	2,039	733	6,819
Finance income	-162	-213	-928
Finance costs	49,057	110,939	77,400
Profit before income tax	-69,102	-130,253	-100,248
Income tax expense (profit)	174,570	212,742	188,404
Profit for the year	22,578	-5,681	7,778
Other comprehensive income (loss)	151,992	218,423	180,626
Items that will never be reclassified to profit or loss	1,305	1,765	-4,080
Defined benefit plan measurement			
Items that are or may be reclassified to profit or loss	1,248	1,552	-4,384
Foreign currency translation differences for foreign operations			
Total comprehensive income for the year	57	213	304
XI. Total Comprehensive Income	153,297	220,188	176,546

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GRI Standards Index

Universal Standards

GRI 2 : General Disclosure

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	2-13	Delegation of responsibility for managing impacts	Not Applicable
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GRI 3 : Material Topics

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GRI Standards Index

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	416-2	Incidents of non-compliance concerning the health and safety impacts of products and services	Not happened
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Supplier Social Assessment	414-1	New suppliers that were screened using social criteria	46
	414-2	Negative social impacts in the supply chain and actions taken	46
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	305-4	GHG emissions intensity	38, Data Book
	305-5	Reduction of GHG emissions	Data Book
	305-6	Emissions of ozone-depleting substances (ODS)	Not Applicable
	305-7	Nitrogen oxides (NOx), sulfur oxides (SOx), and other significant air emissions	Data Book

Category	Code	Disclosure	Page
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1) To be published in a TCFD report in the second half of 2024

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GRI Standards Index

Topic-specific Standards

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Indirect Economic impacts	203-1	Infrastructure investments and services supported	48
	203-2	Significant indirect economic impacts	10, 11
Energy	302-1	Energy consumption within the organization	Data Book
	302-3	Energy intensity	38, Data Book
	302-4	Reduction of energy consumption	38, Data Book
Water and Effluents	303-2	Management of water discharge-related impacts	38
	303-3	Water withdrawal	Data Book
	303-4	Water discharge	Data Book
	303-5	Water consumption	Data Book
Biodiversity	304-1	Operational sites owned, leased, managed in, or adjacent to, protected areas and areas of high biodiversity value outside protected areas	38, Data Book
Waste	306-1	Waste generation and significant waste-related impacts	39
	306-2	Management of significant waste-related impacts	39
	306-3	Waste generated	Data Book
	306-4	Waste diverted from disposal	Data Book
	306-5	Waste directed to disposal	Data Book

GRI	Code	Disclosure	Page
Employment	401-1	New employee hires and employee turnover	41, Data Book
	401-3	Parental leave	Data Book
Occupational Health and Saefety	403-1	Occupational health and safety management system	44
	403-2	Hazard identification, risk assessment, and incident investigation	44
	403-3	Occupational health services	42, 44
	403-4	Worker participation, consultation, and communication on occupational health and safety	44
	403-5	Worker training on occupational health and safety	Data Book
	403-6	Promotion of worker health	42
	403-7	Prevention and mitigation of occupational health and safety impacts directly linked by business relationships	44
	403-8	Workers covered by an occupational health and safety management system	44
	403-9	Work-related injuries	Data Book
	403-10	Work-related ill health	Data Book
Diversity and Equal Opportunity	405-1	Diversity of governance bodies and employees	32, 43, Data Book
Non-Discrimination	406-1	Incidents of discrimination and corrective actions taken	43, Data Book
Freedom of Association and Collective Bargaining	407-1	Operations and suppliers in which the right to freedom of association and collective bargaining may be at risk	Not Applicable
Child Labor	408-1	Operations and suppliers at significant risk for incidents of child labor	Not happened, 46
Forced or Compulsory Labor	409-1	Operations and suppliers at significant risk for incidents of forced or compulsory labor	Not happened, 46
Local Communities	413-1	Operations with local community engagement, impact assessments, and development programs	48
	413-2	Operations with significant actual and potential negative impacts on local communities	Not happened
Public Policy	415-1	Political contributions	Not happened
Customer Health and Safety	416-1	Assessment of the health and safety impacts of product and service categories	27
	416-2	Incidents of non-compliance concerning the health and safety impacts of products and services	Not happened
Marketing and Labeling	417-1	Requirements for product and service information and labeling	28
	417-2	Incidents of non-compliance concerning product and service information and labeling	Not happened
	417-3	Incidents of non-compliance concerning marketing communications	Not happened
Customer Privacy	418-1	Substantiated complaints concerning breaches of customer privacy and losses of customer data	Not happened

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Sustainability Accounting Standards Board (SASB) Index

Health Care (Biotechnology & Pharmaceuticals)

SASB code	Accounting Metric	Reference	Page
Safety of Clinical Trial Participants			
HC-BP-210a.1	Discussion, by world region, of management process for ensuring quality and patient safety during clinical trials	We put the safety and rights of participants as our top priority throughout the entire clinical trial process, and operate clinical trials according to clinical trial monitoring plans.	29
HC-BP-210a.2	Number of FDA Sponsor Inspections related to clinical trial management and pharmacovigilance that resulted in: (1) Voluntary Action Indicated (VAI); and (2) Official Action Indicated (OAI)	We commit to cooperating with regulatory authorities and taking all necessary action to address issues including clinical trial management and pharmacovigilance.	-
HC-BP-210a.3	Total amount of monetary losses as a result of legal proceedings associated with clinical trials in developing countries	Did not occur	-
Access to Medicines			
HC-BP-240a.1	Description of actions and initiatives to promote access to health care products for priority diseases and in priority countries as defined by the Access to Medicine Index	Under our vision Passion for Health, Samsung Bioepis provides many patients with high-quality biosimilars at affordable prices compared to their reference drugs. This vision guides our efforts to improve access to medicines.	19
HC-BP-240a.2	List of products on the WHO life of Prequalified Medicinal Products as part of its Prequalification of Medicines Programme (PQP)	SB3 (trastuzumab biosimilar) is listed on the WHO List of Prequalified Medicinal Products.	19, 23
Affordability & Pricing			
HC-BP-240b.2	Percentage change in : (1) average list price and (2) average net price across US product portfolio compared to previous year	We sell our products in global markets except for some countries such as Korea, through marketing partnership agreement with Biogen, Organon and others.	-
HC-BP-240b.3	Percentage change in: (1) list price and (2) net price of product with largest increase compared to previous year		
Drug Safety			
HC-BP-250a.1	List of products listed in the Food and Drug Administration's (FDA) MedWatch Safety Alerts for Human Medical Products database	Not applicable. Samsung Bioepis is not recognized for any potential safety issues by the MedWatch Safety Alerts for Human Medical Products database or the US FDA.	-
HC-BP-250a.2	Number of fatalities associated with products as reported in the FDA Adverse Event Reporting System	All fatality information associated with our products is reported in the FDA Adverse Event Reporting System.	-
HC-BP-250a.3	Number of recalls issued, total units recalled	No recalls	27
HC-BP-250a.4	Total amount of product accepted for takeback, reuse, or disposal	Undiscussed	-
HC-BP-250a.5	Number of FDA enforcement actions taken in response to violation of current Good Manufacturing Practices (cGMP), by type	Did not occur.	27

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Sustainability Accounting Standards Board (SASB) Index

Health Care (Biotechnology & Pharmaceuticals)

SASB code	Accounting Metric	Reference	Page
Counterfeit Drugs			
HC-BP-260a.1	Description of methods and technologies used to maintain traceability of products throughout the supply chain and prevent counterfeiting	We employ serialization and tamper-evident labeling for each package in accordance with country-specific regulations, and work with marketing partners and global regulatory authorities.	28
HC-BP-260a.2	Discussion of process for alerting customer and business partners of potential or known risks associated with counterfeit products		
HC-BP-260a.3	Number of actions that led to raids, seizure, arrests, and/or filing of criminal charges related to counterfeit products	Did not occur	-
Ethical Marketing			
HC-BP-270a.1	Total amount of monetary losses as a result of legal proceedings associated with false marketing claims	Did not occur	-
HC-BP-270a.2	Description of code of ethics governing promotion of off-label use of products	We make our code of conduct constantly available on our website to declare our commitment to ethical and compliance management. Our code of conduct stipulates that we do not advertise the safety or efficacy of unauthorized products.	28
Employee Recruitment, Development & Retention			
HC-BP-330a.1	Discussion of talent recruitment and retention efforts for scientists and research and development personnel	We categorize our research personnel pursuant to Article 14-2 of the Basic Research Promotion and Technology Development Support Act, and increase investment in recruiting and retaining our research and development personnel while supporting the continuous development of our employees.	25, 41
HC-BP-330a.2	(1)Voluntary and (2) involuntary turnover rate for: (a) executives/senior managers, (b) midlevel managers, (c) professionals, and (d) all others	Unreported	-
Supply Chain Management			
HC-BP-430a.1	Percentage of (1) entity's facilities and (2) Tier 1 suppliers' facilities participating in the Rx-360 International Pharmaceutical Supply Chain Consortium audit program or equivalent third-party audit programs for integrity of supply chain and ingredients	Out of 19 suppliers, 89% of them participated in EcoVadis and 16% of them in the PSCI.	-
Business Ethics			
HC-BP-510a.1	Total amount of monetary losses as a result of legal proceedings associated with corruption and bribery	Did not occur	-
HC-BP-510a.2	Description of code of ethics governing interactions with health care professionals	We manage the provision of economic benefits to HCPs in advance and in line with the HCP interaction guidelines within the CPMS, and provide relevant status reports.	33
Activity Metrics			
HC-BP-000.A	Number of patients treated	Estimated at approximately 431,000 patients as of 2023	19
HC-BP-000.B	Number of drugs (1) in portfolio and (2) in research and development (Phases 1-3)	(1) 8, (2) 4	19, 23

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Third-party Assurance Statement

To readers of SAMSUNG BIOEPIS Sustainability Report 2023

Introduction

Korea Management Registrar (KMR) was commissioned by SAMSUNG BIOEPIS to conduct an independent assurance of its Sustainability Report 2023 (the "Report"). The data and its presentation in the Report is the sole responsibility of the management of SAMSUNG BIOEPIS. KMR's responsibility is to perform an assurance engagement as agreed upon in our agreement with SAMSUNG BIOEPIS and issue an assurance statement.

Scope and Standards

SAMSUNG BIOEPIS described its sustainability performance and activities in the Report. Our Assurance Team carried out an assurance engagement in accordance with the AA1000AS v3 and KMR's assurance standard SRV1000. We are providing a Type 2, moderate level assurance. We evaluated the adherence to the AA1000AP (2018) principles of inclusivity, materiality, responsiveness and impact, and the reliability of the information and data provided using the Global Reporting Initiative (GRI) Index provided below. The opinion expressed in the Assurance Statement has been formed at the materiality of the professional judgment of our Assurance Team.

Confirmation that the Report was prepared in accordance with GRI standards 2021 was included in the scope of the assurance. We have reviewed the topic-specific disclosures of standards which were identified in the materiality assessment process.

- GRI Sustainability Reporting Standards 2021
- Universal standards
- Topic specific standards
  - GRI 205: Anti-Corruption
  - GRI 206: Anti-competitive Behavior
  - GRI 305: Emissions
  - GRI 308: Supplier Environmental Assessment
  - GRI 404: Training and Education
  - GRI 414: Supplier Social Assessment
  - GRI 416: Customer Health and Safety

As for the reporting boundary, the engagement excludes the data and information of SAMSUNG BIOEPIS' partners, suppliers and any third parties.

KMR's Approach

To perform an assurance engagement within an agreed scope of assessment using the standards outlined above, our Assurance Team undertook the following activities as part of the engagement:

- reviewed the overall Report;
- reviewed materiality assessment methodology and the assessment report;
- evaluated sustainability strategies, performance data management system, and processes;
- interviewed people in charge of preparing the Report;
- reviewed the reliability of the Report's performance data and conducted data sampling;
- assessed the reliability of information using independent external sources such as Financial Supervisory Service's DART and public databases.

Limitations and Recommendations

KMR's assurance engagement is based on the assumption that the data and information provided by SAMSUNG BIOEPIS to us as part of our review are provided in good faith. Limited depth of evidence gathering including inquiry and analytical procedures and limited sampling at lower levels in the organization were applied. To address this, we referred to independent external sources such as DART and National Greenhouse Gas Management System (NGMS) and public databases to challenge the quality and reliability of the information provided.

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Third-party Assurance Statement

Conclusion and Opinion
Based on the document reviews and interviews, we had several discussions with SAMSUNG BIOEPIS on the revision of the Report. We reviewed the Report's final version in order to make sure that our recommendations for improvement and revision have been reflected. Based on the work performed, it is our opinion that the Report applied the GRI Standards. Nothing comes to our attention to suggest that the Report was not prepared in accordance with the AA1000AP (2018) principles.

Inclusivity
SAMSUNG BIOEPIS has developed and maintained different stakeholder communication channels at all levels to announce and fulfill its responsibilities to the stakeholders. Nothing comes to our attention to suggest that there is a key stakeholder group left out in the process. The organization makes efforts to properly reflect opinions and expectations into its strategies.

Materiality
SAMSUNG BIOEPIS has a unique materiality assessment process to decide the impact of issues identified on its sustainability performance. We have not found any material topics left out in the process.

Responsiveness
SAMSUNG BIOEPIS prioritized material issues to provide a comprehensive, balanced report of performance, responses, and future plans regarding them. We did not find anything to suggest that data and information disclosed in the Report do not give a fair representation of SAMSUNG BIOEPIS' actions.

Impact
SAMSUNG BIOEPIS identifies and monitors the direct and indirect impacts of material topics found through the materiality assessment, and quantifies such impacts as much as possible.

Reliability of Specific Sustainability Performance Information
In addition to the adherence to AA1000AP (2018) principles, we have assessed the reliability of economic, environmental, and social performance data related to sustainability performance. We interviewed the in-charge persons and reviewed information on a sampling basis and supporting documents as well as external sources and public databases to confirm that the disclosed data is reliable. Any intentional error or misstatement is not noted from the data and information disclosed in the Report.

Competence and Independence
KMR maintains a comprehensive system of quality control including documented policies and procedures in accordance with ISO/IEC 17021·2015 - Requirements for bodies providing audit and certification of management systems. This engagement was carried out by an independent team of sustainability assurance professionals. KMR has no other contract with SAMSUNG BIOEPIS and did not provide any services to SAMSUNG BIOEPIS that could compromise the independence of our work.

May 2024 Seoul, Korea

CEO E. J Hwang

KMR SRV1000 Sustainability Committee Assurance AA1000 Licensed Report 000-129/V3-RHECH

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GHG Verification Report

The Korea Management Registrar Inc. (hereinafter “KMR”) has conducted the verification on the greenhouse gas (hereinafter “GHG”) emission (Scope 1,2) of Samsung Bioepis Co., Ltd (hereinafter “the Company”) in 2023.

SCOPE

Verification of places of business and emission facilities under the control of the company.

STANDARDS

- ISO 14064-1:2018, ISO 14064-3:2019
- IPCC Guidelines for National GHG Inventories
- Guidelines for Reporting and Certification of Emissions under the GHG Emissions Trading System

PROCEDURE

We conducted a risk analysis approach and on-site verification based on data evaluation, and we identified the appropriateness of the data and factors applied to GHG emission calculations based on objective evidence. The verification team verified the GHG emissions during the reporting period in a reasonable way based on the verification guidelines.

INDEPENDENT

KMR does not have any stake in the verified entity and does not conduct verification with biased opinions/views. We have drawn an independent and objective verification conclusion based on the verification standards, and reviewed the every aspect of the verification we performed throughout the entire verification process through internal review.

LIMITATIONS

The verification team verified the related reports, information and data presented by the audited institution by sampling or enumeration methods. As a result, there are many inherent limitations, and there may be disagreements in the interpretation of appropriateness. Although we have tried to faithfully perform verification that meets the verification standards, we suggest that errors, omissions, and false statements that could not be found may be latent as the limitations to the verification.

OPINION

- GHG verification has been performed to meet the limited assurance level according to the verification standards.
- We express that no significant errors were found in the calculation of emissions during the verification process, and that relevant activity data and evidence were appropriately managed and calculated. As a result, we express an “unmodified” opinion.
- Criticality: meets the criterion, which is less than 5%

GHGs Emission	Direct Emission (Scope1)	Indirect Emission (Scope2)	Other indirect Emission (Scope3)	Total (tCO2-eq)
2023	1,209.479	5,085.926	-	6,295.405
Energy Consumption	**Fuel**	**Electricity**	**Steam**	**Total (TJ)**
2023	22.794	98.383	17.016	138.193

※ Note : There is a difference in the total amount of emissions and emissions by greenhouse gas and by workplace.
(Total emissions are cut to a decimal point for each workplace unit and emissions are summed up for each workplace unit.)

RESULTS

We confirm through verification that the emissions from major emission facilities have been calculated and reported without omission.

April 29, 2024
Authorized By

CEO E. J Hwang

KMR KMR ISO 14064-1

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Awards

Date	Award	Host
Oct. 2023	Global Generics & Biosimilars Awards 2023 Company of the Year, Asia Pacific	Citeline
Oct. 2023	Global Generics & Biosimilars Awards 2023 Regulatory Achievement of the year	Citeline
Nov. 2023	Excellence in LMO (Living Modified Organism) safety management	Korean Ministry of Science and ICT

Associations and Sponsorships

Article 31 of Korea's Political Funds Act stipulates that foreigners, corporations and organizations in Korea and abroad are prohibited from contributing any political funds, and that no one should contribute any political funds from any corporation or organization both in Korea and abroad. In accordance with this Act, Samsung Bioepis does not provide any political funds, voting-related election funds, and lobbying funds for political organizations. Yet, we have remained our sponsorship for non-political associations as follows.

(unit: KRW million)

Association	Status	Fees
Korea Biotechnology Industry Organization	Regular member, Chair	35
Korea Biomedicine Industry Association	Regular membe	18
Korea Pharmaceutical and Bio-Pharma Manufacturers Association	Associate member	3
Incheon Chamber of Commerce & Industry	Regular member	108

Certification

Environmental management certification


LRQA
Certificate of Approval
SAMSUNG BIOEPIS CO., LTD.
ISO 14001:2015, ISO 50001:2018

Certification	2022	2023
ISO 14001 (environmental management system)	Certified	Remain certified


LRQA
Certificate of Approval
SAMSUNG BIOEPIS CO., LTD.
ISO 14001:2015, ISO 50001:2018

Certification	2022	2023
ISO 50001 (energy management system)	Certified	Remain certified

Health and safety management certification


LRQA
Certificate of Approval
SAMSUNG BIOEPIS CO., LTD.
ISO 45001:2018

Certification	2022	2023
ISO 45001 (health and safety management system)	-	Certified

Information security management certification


bsi.
Certificate of Registration
INFORMATION SECURITY MANAGEMENT SYSTEM - ISO/IEC 27001:2022
IS 791870
...making excellence a habit.

Certification	2022	2023
ISO 27001 (Information security management system)	-	Certified

SAMSUNG
BIOEPIS

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