

## 榮昌生物製藥(煙台)股份有限公司 RemeGen Co., Ltd.\*

(A joint stock company incorporated in the People's Republic of China with limited liability)

Stock Code: 9995

2021 Environmental, Social and Governance Report

\*For identification purpose only

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# **ABOUT THIS REPORT**

This report is the second Environmental, Social and Governance Report (or "ESG Report") released by RemeGen Co.,Ltd. It is a true reflection of our fulfillment of economic, social and environmental responsibilities and the realization of comprehensive, coordinated and sustainable development.

### Reporting Period

This report covers the period from January 1, 2021, to December 31, 2021. Part of the content is beyond the above period.

# Reporting Scope The object of this report is RemeGen Co., Ltd and its subsidiaries.

Data Source

All data disclosed in this report is from official documents, statistical reports and financial reports of the Company, or is the ESG information collected, summarized and reviewed by the Company. In case of any discrepancy between the Chinese version and the English version of this report, the Chinese version shall prevail. Unless otherwise stated, the currency unit in this report is RMB.

### Basis of Preparation

This report is prepared in accordance with the Environmental, Social and Governance Reporting Guide (the ESG Guide) issued by the Hong Kong Stock Exchange, with appropriate reference to the Sustainability Reporting Guidelines (G4) launched by the Global Reporting Initiative (GRI).

### Reference

For the sake of convenience, "RemeGen", "the Company", "Company", "we", "us" or "our" in this report refer to RemeGen Co., Ltd.

### Statement

The visions contained in this report, including business plans and development strategies, do not constitute any substantial commitment of the Company to investors.

### Report Access

For this report and updates about our sustainability initiatives, please visit the "Investor Relations" Section on the homepage of our official website (http://www.remegen.cn/Invest.aspx ? ClassID=77).

## **1. ABOUT US**

### **1.1. GROUP PROFILE**

RemeGen (HKEX: 09995.HK) was co-founded in 2008 by Mr. Weidong Wang, founder of Rongchang Pharmaceuticals, a leading traditional Chinese medicine company in China, and Dr. Jianmin Fang, a Canadian-American scientist. Headquartered in the coastal city of Yantai, Shandong Province of China, RemeGen has research centers and branches throughout Beijing, Shanghai, San Francisco and Washington, the United States.

On November 9, 2020, RemeGen was listed on the Hong Kong Stock Exchange with a total proceed from the global offering of US\$590 million, becoming the largest biotech IPO in the world in 2020 on record. On March 31, 2022, RemeGen was listed on the STAR Market of the Shanghai Stock Exchange, officially opening the new era of "A+H" dual listing.

Since our inception, we have been committed to the discovery, development and commercialization of antibody drug conjugates, antibody fusion protein, monoclonal antibody and bispecific antibody and other therapeutic antibodies, and have developed a number of biologic drugs of significant clinical value in the key therapeutic areas of autoimmune, oncology and ophthalmic diseases. On such basis, RemeGen has independently built three world-class professional technology platforms of antibody and fusion protein platform, antibody drug conjugates (ADC) platform and HIBODY platform featuring integrated and end-to-end drug development capacity, which made it possible to cover all key biologics development functions.

Currently, there are dozens of innovative drugs in our product pipeline in the R&D and commercialization stage. Specifically, our new biologic Telitacicept, the world's first dual-targeted therapy for systemic lupus erythematosus and Disitamab vedotin, China's first self-developed ADC innovative drug have obtained approval from the NMPA for market entry in China in March and June 2021, respectively and both been approved for inclusion in the national health insurance system. In addition, an innovative fusion protein product RC28, the first-in-class VEGF/FGF dual target product in the field of ophthalmological treatment are in phase IB/II clinical development trial, four drugs are in I/II clinical development trial and several others are in IND preparation.

### **Company Mission:**

Our mission is to discover, develop, and deliver the first-in-class and the best-in-breed biologic drugs for major diseases in the autoimmune, oncology and ophthalmology spaces to create clinical value and fulfill the significant unmet medical needs worldwide, thereby maximizing the value of the Company.

### **Company Vision:**

We aspire to be a Chinese leader within the global biopharmaceutical industry.

# 1. ABOUT US

### 1.2. SUMMARY OF HONORS REMEGEN AWARDED IN 2021

Awards and honors	Sponsors
Top 10 Biomedical Enterprises in China	Menet
Ranking 2nd on the List of Top 20 Asian Biotech Companies	Global investment banking Torreya
Excellent Business Practice Award of China's Pharmaceutical and Biological Industry	JRJ.com
Selected into the TOP 30 List of China's Antibody Drug Enterprise Innovation	Menet
In the first echelon of the Top 100 of China's Pharmaceutical Innovation Enterprises in 2021	E Medicine Manager
Weidong Wang, chairman of RemeGen, was awarded the title of "Yantai Excellent Entrepreneur in 2020"	Yantai Municipal Party Committee and Government
Benchmarking Enterprise for the Best Original Biologics and Gene Cell Therapy	2021 Nanjing International New Medicine and Life Health Industry Innovation Investment Summit
Telitacicept won the "Top 10 Scientific and Technological Achievements" in Shandong in 2020	Department of Science & Technology of Shandong Province
Disitamab vedotin won the "Award for Innovative Drug of the Year"	PharmaDJ
The scientific and technological innovation team led by Dr. Jianmin Fang specializing in the research and development of domestic class 1 biological new drugs for the treatment of serious diseases was awarded the "Excellent Scientific and Technological Innovation Team of Yantai"	Yantai Municipal Party Committee and Government
IPO of the Year	China Healthcare Investment Conference (CHIC)

RemeGen has always adhered to the philosophy of sustainable development, and has taken active approaches to fulfil the corporate responsibility to the environment and society. We have laid stress on the building of ESG governance structure and strived to improve ESG performance step by step by refining the ESG management system. RemeGen has sought to exchange views and communicate with stakeholders to know about their concerns, so as to achieve all-win and sustainable development.

### 2.1. SUSTAINABILITY

### 2.1.1. ESG Management

RemeGen has systematically planned its ESG governance work in accordance with the ESG policies and guidance requirements in the places where it was listed. It continued to improve the ESG governance system, and the Board is responsible for monitoring the ESG strategy and performance of the Company. The ESG working group consisting of the relevant staff of the headquarters and subsidiaries is in charge of assessing, prioritizing and managing important ESG-related work and the promotion and implementation of all works. Moreover, the ESG working group had ESG interviews with relevant departments and sorted corresponding information, effectively increasing the transparency of public disclosure of information, all driving the sustainable development of RemeGen.

### Board's Statement

The Board highly values the ESG performance of RemeGen. As the highest decision-making body, the Board takes full responsibility for the ESG strategy and relevant disclosures of the Company. The Board is responsible for the overall supervision of the Company's ESG-related matters, and the review of the visions, targets, strategies and policies of the ESG. The Board also evaluates and identifies the ESG risks and opportunities involving the Company's business, and monitors and reviews the Company's ESG performance. The Company's ESG working group consists of relevant staff from the headquarters and subsidiaries, which is in charge of the implementation of the Board's requirements for ESG works during the ordinary course of business, the management and carrying-out of ESG related topics and reporting to the Board and management regularly on the progress of the ESG works.

We attach great importance to the decision procedure of ESG material issues, and improve the way stakeholders communicate. We also identify, evaluate and manage the ESG material issues relating to the Company's development and stakeholders concern, so as to determine the material issues matrix for the year.

This report elaborated the progress and achievements of the ESG work of RemeGen for 2021 and took full account of the importance, quantification, consistency and balance of the ESG indicators.

### 2.1.2. Stakeholder Communication

We believe efficient communication and exchange will help us have a better understanding of various stakeholders' expectations and concerns. RemeGen listens to their opinions and suggestions by establishing efficient communication and feedback channels with stakeholders. We respond to demands and expectations of all parties in a targeted manner to comprehensively enhance the corporate social responsibility (CSR) performance.

Stakeholders	Stakeholders' Expectations	Communication Mechanisms
Government and regulators	Law Compliance Compliant Operations Tax Compliance Supporting Local Development	Information Disclosure Daily Communication and Report Government Investigations and Inspections
Shareholders and Investors	Reporting to Shareholders Information Disclosure Risk Management Corporate Governance Business Performance	General Meetings of Shareholders Regular Reports and Announcements Communication Meetings with Investors
Customers	Drug Quality and Safety Protection of Rights and Interests of Consumers Drug Development and Innovation Responsible Marketing	Product Quality Guarantee Customer Satisfaction Surveys Regular Communication Activities with Customers
Employees	Protection of Rights and Interests of Employees Occupational Health and Safety Employee Development	Employee Conferences and Labor Unions Employee Engagement Surveys Performance Management Internal and External Training Employee Care Activities
Partners	Product and Service Quality Win-win Development Sustainability of Supply Chain	Open Tending and Bidding On-site Reviews Supplier Conferences Business Conferences
Community Representatives	Promoting Local Economic Development Local Environmental Impacts of Production and Operations Community Services and Philanthropy	Voluntary Services Supporting Cultural and Sport Activities Popularization of Medical Knowledge Contributing to Epidemic Control Participating in Community Construction
Industry Associations	Fair Competition Promoting Industry Development Technology and Experience Sharing	Industry Exchanges and Seminars

### 2.1.3. Materiality Assessments

In order to ascertain the main focus of ESG practice and information disclosure, we have identified material issues in line with the requirements of the ESG Guide issued by the Hong Kong Stock Exchange, combining with the major focuses of capital markets for the biopharmaceutical industry and peer best practices.

In 2021, in order to ensure the truthfulness, accuracy and completeness of information disclosure, we assessed the material issues identified in 2020 by reference to our counterparts' issues and the change in the ESG development trend. After assessment, we confirmed that no change has occurred in the material issue matrix in 2021, which was in line with the contents reflected in the ESG Report in 2020.



ESG Materiality Matrix of RemeGen in 2021

### 2.2. BUSINESS ETHICS BUILDING

RemeGen put a high value on business ethics building. It took practical measures to uphold the business philosophy of open, transparency, integrity and honesty through rigorous anti-corruption mechanism and accountable marketing strategies, thereby ensuring the sound development of the Company. In addition, we continued to strengthen supply chain management, and took proactive steps to facilitate the harmonious development of upstream and downstream, in a bid to create diversified value for all walks of life.

### 2.2.1. Honest Operations

The Company strictly complies with the *Criminal Law of the People's Republic of China*, the *Anti-Money Laundering Law of the People's Republic of China*, the *Anti-Unfair Competition Law of the People's Republic of China* and other rules and regulations applicable to the regions where it operates. Through a range of internal rules and regulations including the *Fund Management Standards*, the *Provisions on the Administration of Internal Audit*, and the *Provisions on the Administration of Anti-Fraud and Anti-Money Laundering*, we continue to improve the business ethics building within the Company, and eliminate illegal business practices such as corruption, bribery and money laundering. RemeGen did not involve in any corruption cases during the reporting period.

We always encourage our employees and external stakeholders to report on malpractice and material non-compliance behaviors in the process of our operation. We have telephone, E-mail, mail address and other channels for whistle-blowing in place, to ensure that related matters can be dealt with promptly by relevant department. Once the reporting content is verified, we'll strictly treat the related persons according to internal process and offer appropriate reward to whistle-blowers.

### Whistle-blowing Channels of RemeGen

Telephone	0535-6383102
E-mail	shenjichu@cnrc.cn
Mail address	58 Middle Beijing Road, Economic and Technological Development Area, Yantai,
	Shandong Province

On that basis, we actively join hands with third-party institutions to organize activities such as legal forums and expert visits, so as to convey the concept of fair competition, exchange ideas with peer companies, and jointly support and improve the ethical standards of pharmaceutical and medical industry in China.



Picture: External exchange activity of RemeGen

We also organize a series of trainings on business ethics and cultural promotion activities such as research projects and departmental trainings for all employees of the Company on a regular basis. We help employees establish the concept of "cannot corrupt, dare not corrupt" to create good corporate culture of integrity, gradually improving the employees' legal awareness.



Picture: Internal trainings of RemeGen and its legal department

### **Case: Research Project**

In 2021, for the purpose of improving the ideological and moral level of employees, the Company organized the study of important provisions such as the Interpretation of the Supreme People's Court on Several Issues Concerning the *Anti-Unfair Competition Law of the People's Republic of China* 《反不正當競爭法司法解釋》, and conducted a series of video lectures such as the Key Points of Dispute Resolution Concerning Personal Injury Arising in the Course of Drug Clinical Trials《藥 物臨床試驗中產生的人身損害爭議解決要點》, How to Crack Down on Counterfeits and Safeguard Rights and Take the Road of Brand Protection 《如何進行打假維權,走好品牌保護之路》 as well as the Latest Trend of Personal Information Protection Compliance 《個人信息保護合規的最新動向》. The Company also organized the employees to carry out relevant research projects and write essays, deepening the corporate spirit of integrity.

### 2.2.2. Responsible Marketing

RemeGen strictly complies with the *Pharmaceutical Administration Law of the People's Republic of China*, the *Regulations for Implementation of the Drug Administration Law of the People's Republic of China* and other rules and regulations. We have formulated and issued internal systems such as the *Management System and Process of Marketing Behavior* (《營銷行為管理制度與流程》) and the *Management System and Process of Target Hospital* 《目標醫院管理制度與流程》). Starting with two aspects, i.e. employees and customers, we implement responsible marketing and develop a trustful relationship with consumers.

### Strengthening Employees' Awareness

To the best knowledge of the Company, the implementation of responsible marketing cannot be separated from the joint efforts of a company and its employees. In 2021, on the basis of existing rules, we formulated the *Marketing Compliance Manual* 《營銷合規手冊》, the *Code of Conduct for Drug-related Academic Promotion* 《藥品學術推廣行為準則》 and its implementation rules. We've established the Marketing Compliance Committee to further assign accountabilities to relevant departments and positions, ensuring that the Company's marketing activities are legal, compliant and efficient.

On the basis of the signing of the *Compliance Pledge* with all employees of the marketing center, we pay close attention to the issuance of new policies and conduct activities of policy interpretation and trainings in a timely manner. Meanwhile, we will also promptly make evaluation and improvements on relevant compliance issues arising in the course of our marketing work, so as to avoid potential compliance risks to the maximum extent.

### Case: Training program of the medical department of the Oncology Division

Since its establishment in 2021, the medical department of the Oncology Division has fully considered the needs of regional colleagues, gradually carrying out more than 40 activities online and offline such as new employees training, department internal training and regional sales training. The activities cover the areas of basic knowledge of diseases, treatment landscape of diseases, interpretation of guidelines, mechanism of action of disitamab vedotin, safety management of disitamab vedotin, interpretation of research progress in diseases fields, etc., which comprehensively enhances the professional marketing capabilities of regional colleagues.



### Improving Service Quality

While building an excellent staff team, the Company has also established standard behavior database of target hospitals, target customers and sales personnel at all levels, which is customer demands-oriented and takes customer satisfaction as principle. The Company continues to regulate the behaviors of sales personnel at all levels through regular evaluation to improve customer service quality. RemeGen did not receive any complaints from customers during the reporting period.

### 2.2.3. Supply Chain Management

The Company is committed to establishing a strategic cooperation relationship with suppliers that is featured with equality, friendliness and win-win situation with mutual benefits. We strictly abide by the *Law of the People's Republic of China on Tendering and Bidding* and other laws and regulations. Based on Supplier Management System, we steadily make efforts for supply risk control and supplier management to drive the development of suppliers at all levels while improving our own quality, so as to achieve a win-win situation in the industry. During the reporting period, all the 376 suppliers under Remegen were located in Mainland China.

The Company always regards the implementation of high-quality supplier management as an important prerequisite for enterprises to provide high-quality products and considerate services. We strictly regulate the management of supplier qualifications, requiring new suppliers to provide complete qualification materials. After confirming their compliance with the requirements, we'll conduct follow-up audit on on-site quality system, production assurance capacity and other qualifications, so as to gradually raise the Company's entry threshold for suppliers.

For suppliers with which we have long-term cooperation, we regularly assess them in strict accordance with relevant rules and regulations, and classify them into four grades of A/B/C/D based on the assessment results. As a result, we can determine the cooperation plan for the next year. For suppliers who fail to pass the assessment or violate the Company's internal regulations, we will impose punishment on them through measures such as warning, suspension of cooperation, and cancellation of the qualification for cooperation.

In 2021, we carried out rigorous and comprehensive risk management and control in terms of risk factors that may affect the stable operation of the supply chain, such as imported materials, key materials, contract terms, organic chemical reagents, etc. By ensuring material supply and environmental compliance to the greatest extent, we provided a safeguard to mass production and business layout prospectively.

Imported materials	For the instability of imported materials, we conduct regular coordination on delivery and organize regular meetings to communicate the dynamics of materials in transit.
Key materials	For key materials, we steadily carry out the development of the second supplier.
Contract terms	We actively perfect the contract terms to clarify and intensify the penalties for breach of contract.
Organic chemical reagents	We improve the packaging methods of organic chemical reagents to effectively reduce their packaging wastes.

### Supply Risk Management and Control Measures of RemeGen

We also actively promote the building of integrity in respect of suppliers and are committed to developing an open and transparent procurement system. We follow rigorous procurement management systems. While entering into annual anti-corruption agreement and Integrity and Mutual Defense Agreement with long-term partner suppliers, we strictly carry out the procurement work in accordance with the relevant systems to effectively avoid malpractice.

RemeGen adheres to quality priority and takes innovation as its driving force. As we continue to enhance our own core competitiveness, we push for scientific research and industry progress, serving the public health in a responsible manner.

### 3.1. PURSUIT OF EXCELLENT QUALITY

RemeGen is always committed to providing consumers with safe and effective drugs, by improving the quality management system, carrying out the entire quality management work, continuously promoting the construction of quality culture, reducing R&D and production quality risk, and improving product quality.

### 3.1.1. Quality Management System

Adhering to the quality policy of "Honest Production, Scientific Management, Continuous Improvement, and Pursuit of Excellence", RemeGen strictly abides by national laws and regulations. In accordance with the *Pharmaceutical Administration Law of the People's Republic of China*, the *Good Manufacturing Practice (2010 Amendment)* and the requirements of its appendices, we develop the quality management system that can cover product life cycle. According to the *Chinese Pharmacopoeia*, USP, EP, national standards and industry standards, the Company has formulated a total of 26 documents on the management of quality assurance and control, 218 on testing methods and 132 on quality standards. With our well-established quality management system, we can ensure our business operation complies with GMP<sup>1</sup> requirements of U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA) and China National Medical Products Administration (NMPA).

Quality document system management	Quality risk management	Corrective action and preventive action (CAPA)	Product quality review
Supplier management	Employee training and evaluation	Unqualified product management	Complaint and recall
Material release and batch release	Production entrustment	Outsourced testing laboratory management	OSS management

### Major Procedures of Quality Management System of RemeGen

### 3.1.2. Full-process Quality Management

RemeGen has conducted full-process quality management on drug pre-clinical stage, non-pivotal clinical stage, clinical trials, drug production and product recall in accordance with international good manufacturing practices and standards.

#### Pre-clinical Stage

Pre-clinical quality management of RemeGen covers compliance management of drug R&D system comprising early-stage drug research, process development, drug synthesis R&D, conjugate development and quality research, review of technical research documents and verification at different stages. In addition, RemeGen has formulated the quality manual, strategy guidance and standard operation procedures to regulate pre-clinical quality management activities, so as to ensure that the R&D and registration of drugs are based on evidence and that the information of R&D and registration is true, complete and in compliance with regulations.

### Non-pivotal Clinical Stage

RemeGen identifies and controls the factors that may affect product quality in non-pivotal clinical stage, and establishes non-pivotal clinical quality management systems, covering six systems in terms of manufacturing, facilities and equipment, laboratory control, materials, packaging and labeling, and quality guarantee, to ensure the effectiveness and safety of products, and protect the safety of subjects in our clinical trials while ensuring the quality of products.

### Manufacturing System

Production activities are required to be organized in accordance with the approved production process and standard operating procedures to effectively prevent contamination, crosscontamination, confusion and errors in the production process.

### Laboratory Control System

Well-equipped inspection equipment is required, to ensure that the necessary inspections are completed before materials and products are released.

### Packaging and Labeling System

It is required to ensure that product information is accurate and traceable.

#### **Facilities and Equipment System**

It is required that the cleanliness grade of the plant should meet the production requirements, the facilities system should be well-equipped, and the key facilities and equipment should be regularly maintained.

#### Materials Control System

The materials used are required to be purchased from approved and qualified suppliers, and the receiving, storage, distribution, use and transportation of materials are carried out in accordance with SOPs.

### **Quality Guarantee System**

It is required to make full use of quality risk assessments on deviations and changes to reduce the quality risks of products, and to regularly evaluate the effectiveness and applicability of the quality guarantee system.

### • Clinical Study Stage

For the clinical study stage, RemeGen has set up four departments, namely the Medical Department, the Project Management Department, the Operation Department, and the Quality and Training Department, to carry out comprehensive and meticulous quality management in clinical trial design, operation management, implementation, and on-site inspection. Each department has prepared comprehensive SOP documents and strictly follows the SOP documents to standardize the work process, so as to guarantee the safety and compliance in the clinical study stage to the greatest extent.

### • Manufacturing Stage

We have formulated relevant regulations for all steps involving the production, striving to standardize operations in every step. An effective and standardized equipment management system has also been established for our production facilities to ensure their effective life cycle control at all stages, namely purchase application, model selection, equipment acceptance, lubrication, spare parts, transfer, idleness, and retirement, while keeping real-time records to minimize the possibility of contamination, cross-contamination and confusion during our pharmaceutical production process. In addition, during the technology transfer of commercializing R&D results, we have formulated the *Management of Technology Transfer*, with a technology transfer team consisting of the R&D Department, Production Department and Quality Department. Multi-party collaboration secures the quality ranging from R&D to commercial production.

### Packaging Material Compatibility

RemeGen has established a research platform for packaging material compatibility and a database for standard packaging materials, and has conducted packaging material research throughout the entire process of drug research and development, to ensure the safety and stability of the quality of pharmaceutical packaging materials. The compatibility research platform mainly conducts research on extractables and leachables, covering container sealing system, disposable components and drug delivery system. The database for standard packaging materials covers 87 elements, more than 100 non-volatiles, dozens of semi-volatiles and volatiles. We have developed testing methods for 39 substances in three major categories of substances, namely nitrosamines, polycyclic aromatic hydrocarbons, and 2-mercaptobenzothiazole, which are of special concern in the regulations, to ensure that packaging materials do not affect the effectiveness and stability of drugs and eliminate safety risks.

### • Product Recall

RemeGen has established strict product recall management procedures, including recall investigation and evaluation, recall application and approval, recall implementation, acceptance of recalled drugs, follow-up of recall process, corrective and preventive measures, handling of recalled drugs, evaluation and conclusion on results of recall implementation. According to the impact of batches of products recalled on patients' health, we classify the recalls into Level 1 recall (within 24 hours), Level 2 recall (within 48 hours) and Level 3 recall (within 72 hours) to recall defective products voluntarily or by order. In addition, the Company organizes a mock recall every two years to evaluate the effectiveness of the recall procedures.

No products have been recalled by RemeGen in 2021.

### 3.1.3. Quality Supervision

RemeGen has established sound quality internal audit and external audit procedures. The internal audit is based on the Good Manufacturing Practices (2010 Amendment) and its appendices, the Pharmacopoeia of the PRC, United States Pharmacopoeia, 21 CFR Part 211<sup>2</sup>, the EU GMP and its appendices, covering organization and staffing, production premises and facilities, equipments, materials and products, recognition and inspection, documentation maintenance, manufacture management, quality control and quality assurance, contractual manufacture and contractual inspection for the products, product delivery and recalls. Meanwhile, the Company has actively cooperated with external supervision agencies according to their inspection requirements, and organized and formulated CAPA<sup>3</sup> for the problems detected in external inspection and completed the rectification and reply reports.

In 2021, RemeGen organized a total of 4 internal audits and completed 3 external inspections.

### 3.1.4. Quality Culture

RemeGen attaches great importance to employees' awareness concerning quality management, and actively prepares targeted training programs according to different positions and product characteristics. The training mainly covers GMP basic knowledge, quality events (deviations, changes, CAPA and quality risk management), audit management, returns/complaints, production processes, aseptic production, cleaning and disinfection of clean areas, pollution control of clean areas, basic knowledge of microbiology, data reliability management, good writing norms, EHS, pest control management, etc.

In 2021, the Company carried out 19 company-level training sessions and 82 department-level training sessions, with more than 11,000 participants in the company-level training and more than 3,800 participants in the department-level training. In addition, the Company has prepared more than 740 annual individual training courses, with 100% of the completion rate.

<sup>&</sup>lt;sup>2</sup> 21 CFR Part 211 refers to Code of Federal Regulations – Title 21 Food and Drug – Part 211 Current Good Manufacturing Practice for Finished Pharmaceuticals

<sup>&</sup>lt;sup>3</sup> CAPA refers to Corrective Action Preventive Action

### 3.2. R&D AND INNOVATION STRENGTHS

RemeGen focuses on the discovery, development and commercialization of first-in-class and best-in-class biologic drugs with proprietary intellectual property rights, and has developed innovative biologic drugs of significant clinical value in the key therapeutic areas of autoimmune, oncology and ophthalmic diseases. Supported by our self-developed professional technology platform, we have carried out R&D and innovation under the premise of complying with the laws and regulations relating to intellectual property and ethical norms, and have produced rich R&D results.

### 3.2.1. Innovation Achievement

The Company is fully aware of the importance of capital investment in innovative research and development. In the past three years, the R&D investment of Remegen increased at a CAGR of 46.70%. In 2021, the Company invested more than RMB710 million in the research and development. In order to continue to promote drug R&D and innovation, we have also established a talented and experienced R&D team. As of the end of 2021, the Company has recruited more than 30 national distinguished experts and other high-level overseas returnees, and the R&D team consists of more than 1,000 members, among whom 55% of the members hold masters or doctorate degrees in life science related majors and seven national technical talent certifications are obtained. The huge R&D investment and the intensive talents development have more effectively promoted the Company to make impressive R&D achievements.

In the process of R&D and innovation, Remegen strictly abides by laws and regulations in the industry, actively applies international standards, guidelines and management systems, and formulates the *Manual of Drug Registration Document* with reference to relevant domestic laws and guidelines to ensure the safety and stability of products.

Supported by its self-developed professional technology platform, Remegen coordinated the R&D centers in Yantai, Shanghai and the United States, striving to surpass the international first-class level in the field of targeted drug research and development. In 2021, the Company obtained two drug registration approvals, one new indication approval, one clinical trial notice, and one breakthrough therapy designation (RC48 BC high-expressing liver metastases), and had two investigational new drug (IND) applications and three supplementary IND applications/filings.

During the Reporting Period, Remegen has developed nearly 20 biologic drug candidates, of which more than 10 biologic drug candidates are in commercialization stage, clinical study stage or IND-enabling stage, and all of them are novel targeted biologics. The Company is carrying out clinical trials for seven products that have entered the clinical trial stage targeting more than 20 indications, including two products that have entered the commercial stage and five products that are in the clinical study stage.

### Case: Telitacicept<sup>®</sup> was approved for marketing

On 12 March 2021, Telitacicept<sup>®</sup>, the world's first "dual targeted" class I biological new drug for the treatment of systemic lupus erythematosus (SLE) independently developed by RemeGen, was approved by the SFDA for marketing. This marks that China is at the forefront of the world in the research and development of new drugs for the treatment of systemic lupus erythematosus.

Due to the characteristics of new targets, new structures and new mechanisms, the invention patent Telitacicept<sup>®</sup> has been authorized by China, the United States, Europe and other countries and regions successively. The R&D project has also been supported by the special major project for technologies of "innovative manufacturing of major new drugs" during the "11th Five-Year Plan", the "Twelfth Five-Year Plan" and the "Thirteenth Five-Year Plan". In addition, Telitacicept<sup>®</sup> also has the potential to be used in other autoimmune indications with a large number of unmet clinical needs. Phase II or Phase III clinical trials have been conducted in China, and global multi-center clinical studies are about to be initiated for many of these indications.



Picture: Press conference on the approval of Telitacicept® for marketing

### Case: Disitamab Vedotin® was approved for marketing

On 9 June 2021, China's first original antibody-drug conjugate (ADC) new drug Disitamab Vedotin<sup>®</sup> independently developed by RemeGen was approved for marketing. The approval of Disitamab Vedotin<sup>®</sup> broke the situation of no original domestic new drugs in the field of ADC drugs, filled the gap in the back-line treatment of gastric cancer patients with HER2 overexpression in the world, and opened up a new path for precise targeted therapy of gastric cancer, which was a milestone in the development history of independent biological drug innovation in China.

Compared with similar ADC drugs in the world, Disitamab Vedotin<sup>®</sup> has specific targeting, higher efficacy and better safety. The Company is actively carrying out global multi-center clinical study and business development activities, and strives to bring the product to the international market as soon as possible so as to benefit patients around the world.



Picture: Press conference on the approval of Disitamab Vedotin® for marketing

# Case: RemeGen was approved for a central government guided local science and technology development project in Shangdong Province

On 7 December 2021, the antibody drug R&D and industrialization innovative system construction project led by RemeGen and jointly carried out by MabPlex and Saipu Biological was approved as a central government guided local science and technology development project in Shandong Province, and was approved with provincial financial funds of RMB1 million. The main goal of the project is to surmount technologies of large-scale cell culture and large-scale purification of antibody fusion proteins. By screening new ADC drug candidates, we continue to optimize core key technologies such as bridging and conjugation of third-generation ADC drugs, preparation of ADC drugs with low toxicity and a high DAR value, and synthesis of small molecule toxins and linkers.

In addition, we also initiated 10 communication meetings with the Center for Drug Evaluation (CDE), 2 meetings with U.S. Food and Drug Administration (FDA), and organized 13 applications on communication with provincial/national bureaus to provide guarantee for the development of products at home and abroad. RemeGen's products also rely on remarkable innovation achievements, with patients enrolled in groups for the first time in Australia and the United States, laying a foundation for developing overseas markets.

### Case: RemeGen and Seattle Genetics entered into a cooperation agreement

In 2021, RemeGen entered into an overseas business licensing and cooperation agreement with Seattle Genetics, a leading biopharmaceutical company in the global oncology and ADC fields to jointly develop the RC48 product through the integration of the advantageous resources of both parties on a global scale to maximize the value and benefits of the product.

This cooperation is a milestone in the transformation of RemeGen from a local company in China to an international company, and has also laid a solid foundation for RemeGen's products to benefit cancer patients around the world.

### 3.2.2. Intellectual Property Protection

RemeGen strictly abides by the *Patent Law of the People's Republic of China*, the *Trademark Law of the People's Republic of China* and other laws and regulations, and strengthens the Company's intellectual property protection system by improving the intellectual property management system, maintaining the patent information database and deploying intellectual property protection measures.

RemeGen has formulated a series of management systems and work guidelines related to patented technologies according to the different product and development stages, and formulated 21 new patent work guidelines in 2021. In addition, the Company has also established the *Administrative Measures for Patent Awards and Rewards* to encourage employees to actively innovate and apply for patents. In order to manage patents and authorized intellectual property information more efficiently, we have set up a patent information database to visualize the patent application process and to facilitate the monitoring of patent status and legitimate benefits more clearly.

In order to comprehensively deploy the intellectual property protection system, we have taken multiple measures to respect the intellectual property rights of others while safeguarding our own legitimate rights and interests.

Safeguarding the Company's intellectual property	Respecting the intellectual property of others
<ul> <li>For important R&amp;D achievements, we have adopted an all-round process and a global multi-region patent layout;</li> </ul>	• For each project, we will conduct intellectual property infringement risk research at all stages from the initiation of the project;
• We have established a standardized business secret protection system and have fully adopted virtual server platform operations to avoid the illegal leakage of important business secrets of the Company;	• When necessary, we will entrust an external third party to conduct a back-to-back internal and external infringement analysis to discover possible infringement risks to the greatest extent.
• When cooperating with external parties, we will strictly review the relevant intellectual property clauses in the contract to maximize the understanding of the relevant intellectual property rights in the cooperation results.	

In 2021, RemeGen applied for a total of 77 patents, including 67 invention patents and 10 utility model patents; and a total of 15 licensed patents, including 10 invention patents and 5 utility model patents.

### 3.2.3. R&D Ethics

In the whole process of drug research and development, RemeGen is guided by the most stringent regulatory requirements, ethics and scientific standards in the world to protect the rights and interests and welfare of patients and experimental animals.

Research and Design Stage	Research and Production Stage
• Declaration of Helsinki	• Biosecurity Law of the People's Republic of China
ICH Guidelines-ICH E(Efficacy Guidelines)	
<i>Guidelines for Human Clinical Studies,</i> including ICH E6(R2) or ICH GCP	• Standards and Procedures for the Expedited Reports of Safety Data during Drug Clinical Trials
• Measures for the Ethical Review of	
Biomedical Research Involving Humans	Guidelines for Drafting "Clinical
• Guidelines for General Considerations for Clinical Trials of Drugs	Risk Management Plans" (for Trial Implementation)
• Good Clinical Practice for Drug Trials	
• Guidelines on Drug Clinical Trial Data Monitoring Committees (for Trial Implementation)	
Relevant laws and regulations for specific drug clinical studies	

### Animal Welfare Guarantee

During non-clinical studies, RemeGen strictly abides by documents such as the guidelines, regulations, standards and operating procedures for the management of experimental animals, such as GB 14925-2010 Laboratory Animal-Requirements of Environment and Housing Facilities, the Guide for the Care and Use of Laboratory Animals (Eighth Edition), etc., to raise, manage and use experimental animals in a scientific, technical and appropriate humane manner, and actively safeguard animal welfare.

The Company strictly follows the 3R principles, namely the replacement, reduction and refinement of experimental animals, and makes detailed records of the entry and exit, use and feeding of experimental animals. We regularly clean and disinfect the experimental facilities, and select feed and bedding according to the specifications to ensure a good living environment and food safety. Meanwhile, the Company is equipped with animal welfare toys, such as turntables, cylinders, hemisphere toys, paper silk, etc., to help reduce or eliminate the psychological anxiety of animals. In addition, the Company's biosafety laboratory has BSL-2 laboratory qualifications and the license for the use of experimental animals. It undergoes an environmental test conducted by a third-party test agency every year, and continues to pass the test.

### Protection of the Rights and Interests of Clinical Subjects

At the stage of drug clinical trials, RemeGen strictly protects the personal wishes and rights and interests of clinical subjects, and ensures that subjects are fully informed of the basic information of clinical trials at the stage of signing the informed consent. The Company fully respects the right of subjects to freely withdraw from trials, gains a full understanding of the reasons for withdrawal and makes detailed records when subjects withdraw, and ensures that the subjects' follow-up medical treatment will not be affected or discriminated against.

### 3.3. IMPROVING SERVICE QUALITY

RemeGen takes customer needs as the core, continuously improves the service system, improves the drug complaint and adverse reaction reporting mechanism, meets customer needs with more efficient and better services, ensures information security and customer privacy, reduces patient medical costs, provides high-quality drugs at reasonable prices, and effectively ensures the availability of medicine and health.

#### 3.3.1. Customer Service Management

#### Handling of Complaints

RemeGen attaches great importance to customer opinions and provides customers with smooth feedback channels. It has established complaint handling procedures including complaint reception, handling, feedback, and CAPA formulation and tracking, and promises responding to complaints within the prescribed time limit. After receiving a complaint, the Company will organize relevant departments to conduct a joint investigation. After the investigation, it will form a quality complaint verification conclusion, and make a decision on the handling of the complained product.

In 2021, RemeGen received a total of 1 customer complaint. After investigation, it was determined to be a non-quality complaint (the operation was not carried out in strict accordance with the requirements of the manual). The investigation results have been fed back to the business and marketing staff for rectification. RemeGen will continue to follow up customer opinions and continuously improve customer experience and service quality.

### Handling of Adverse Reaction Reports

RemeGen conducts the collection, evaluation, analysis and feedback of adverse drug reactions in accordance with the requirements of the Good Pharmacovigilance Practice (GVP). Meanwhile, a drug safety committee system has been established to be responsible for major risk judgment, major or emergency drug incident handling, risk control decision-making, and other major matters related to pharmacovigilance.

The Company has established various channels to collect adverse reaction reports. If a serious adverse event occurs during the clinical period, the researcher can fill in the adverse event report form and send it to the relevant department of the Company. In response to adverse reaction events after the product is launched, the Company has set up a dedicated call center and a reporting channel on the Company's official website to receive adverse reaction reports. In addition, we train the operators of the Company's WeChat official account and Weibo official account, and require relevant staff to receive adverse reaction feedback and complaints on this platform.

In 2021, the Company received a total of 215 initial case reports on adverse events, all of which had been recorded, reported, analyzed and evaluated in accordance with regulations and regulatory requirements.

### 3.3.2. Customer Privacy Protection

RemeGen attaches great importance to the protection of information security such as customer privacy, strictly abides by the *Law of the People's Republic of China on the Protection of Consumer Rights and Interests* and other laws and regulations, and has internally formulated and strictly implemented the *Administrative Regulations on Commercial Customer Management*, the *Administrative Regulations on Commercial Customer Management*, the *Administrative Regulations on Commercial Secret Carriers*, the *Business Secret Management System*, the *Administrative Measures for Commercial Secret Carriers*, the *Regulations on the Confidentiality of Secret-Related Meetings*, the *Administrative Measures for Secret-Related Areas*, the *Administrative Regulations on Data Security* and other policies to ensure that user data and privacy are put under institutionalized and systematic protection.

Meanwhile, RemeGen takes seriously the issue of subject privacy protection, has established the *Standard Operating Procedures for Subject Privacy and Data Confidentiality* to regulate subjects' personal information and privacy security, and requires all employees to keep subjects' personal information and privacy, trial data and information confidential. In the documents provided by the research center to the Company or provided by the Company to government authorities, information related to trials is presented in the form of codes, and no personal information of subjects shall be shown. The Company continues to carry out system audits, process audits, employee training and other activities to ensure the integrity of the personal information and privacy of subjects, and to increase employees' awareness of customer privacy protection.

### 3.3.3. Drug Availability

RemeGen has always been committed to promoting the progress of biomedical technology, continuously improving the availability of innovative drugs, and developing advanced biological drugs that can be used and afforded by patients at large, so as to benefit patients at large.

In 2021, both Telitacicept (RC18) and Disitamab Vedotin (RC48), two new biological drugs independently developed by RemeGen, passed the national medical insurance negotiation and were included in the new edition of Part B of the *National Drug Catalogue for Basic Medical Insurance, Work-Related Injury Insurance and. Maternity Insurance (2021 Edition)*. They are used for the treatment of systemic lupus erythematosus and gastric cancer, respectively. The inclusion of Telitacicept and Disitamab Vedotin in the new edition of the Catalogue of Drugs for Basic National Medical Insurance means that patients can use the world's leading new and good drugs at lower costs, which will bring real benefits to patients.

RemeGen attaches great importance to the safety and environmental protection of production and operation. We continue to establish a sound safety management system and environmental management system, coordinate and promote the Company's safety and environmental protection work, fully implement the safety and environmental protection responsibilities of each operation link, and strive to evolve into a safe, stable, environmentally friendly and sustainable developing enterprise.

### 4.1. SAFE OPERATIONS

RemeGen continuously improves the safety management system, implements the safety production responsibility system and the security risk hierarchical management and control mechanism, continues to promote the construction of enterprise safety culture, and comprehensively improves the safety production management level.

### 4.1.1. Safety Management System

The Company strictly abides by the *Production Safety Law of the People's Republic of China* 《中華人民共和國安全生產法》 and *Laws of the People's Republic of China on Prevention and Control of Occupational Diseases* 《中華人民共和國職業病防治法》), and continues to improve the safety management system. In 2021, the Company has formulated the *Safety and Security Management Regulations* 《安全保衛工作管理規定》, *Road Traffic Safety Management Regulations* 《道路交通安全管理規定》, *Fire Prevention and Safety Management Regulations* 《消防安全管理制度》), *Highly Toxic Chemicals Management Regulations* 《《劇毒化學品管理制度》, *Small Molecule Substance Safety Management Regulations* 《環境管理台賬管理規定》), and *Environmental Management Ledger Management Regulations* 《環境管理台賬管理規定》), and has revised the Production Safety Education and Training Management System 《安全全產教育培訓制度》, Safety Inspection and Potential Hazard Control System 《安全檢查和隱患排查治理制度》, Related Party Management system.

The Company established an Environmental Health and Safety (EHS) Committee to strictly implement the safety production responsibility system and actively promote the safety production reward and punishment system, in a bid to effectively improve the Company's safety management level. In 2021, the Company continued to improve the organizational structure of safety management by setting up two second-level departments, namely the Safety Department and the Environmental Protection Department. Safety Production Committee. At the same time, a safety production committee consisting of the main person in charge, the person in charge of safety production, the safety director, the head of each department, the labor union and the employee representatives has been established. In addition, we set up safety management personnel throughout the plant to conduct daily safety inspections, issue inspection reports on a regular basis and make timely rectifications to ensure the safety and compliance of the Company's operations.

#### 4.1.2. Safe Management Measures

RemeGen is committed to creating a safe working environment including laboratories, production sites and office premises. In 2021, the Company invested RMB412,100 in safety production. No safety accident occurred during the production process. The number of lost days due to work-related injuries was zero. In the past three years, there was no fatal incident of employees due to work-related accidents.

#### Safe Management Measures

The Company formulated the *Risk Classification and Control Rules* to improve the risk prevention and control system. We carried out accurate hazard source identification and risk evaluation for each potential risk point during production links, takes special risk control measures and continue to follow up the implementation of rectification. Moreover, we launched regular safety risk supervision campaigns to constantly improve the risk management and control level.

#### Laboratory and Hazardous Chemicals Safety Management

The Company prepared the *Laboratory EHS Management Manual* to require all laboratory personnel to strictly comply with relevant laws and regulations of the Company and follow SOP requirements in experimental operations and wear protective equipment properly. Further, We require new employees to complete a safety education scheme of three levels and laboratory safety training courses, and they will only be allowed to work in the laboratory after passing the examination.

The Company classifies the existing hazardous chemicals in use with strict reference to the *Classification and Code of Dangerous Goods* (GB 6944-2012), sets warning signs for hazardous waste storage facilities, fully ensures the safety in aspects such as transportation, storage, generation and disposal of various types of hazardous chemicals, thus minimizing the potential environmental and safety risks brought by hazardous chemicals.

### Safety Vetting

The Company has established internal systems such as *Safety Inspection and Hazard Investigation and Governance System* and *EHS Internal Audit Control Procedures*, and internal safety inspections and internal and external audits are conducted on a regular basis, including monthly inspections, daily inspections, holiday inspections and special inspections. Additionally, according to the requirements of government departments, we organized and carried out the activities of "Large-Scale Investigation and Rectification", which includes the operation of the safety management system and on-site management. In 2021, more than 290 issues identified during the safety inspection have all been rectified in a timely manner.

In May 2021, the Company implemented internal audit in accordance with the requirements of the Environmental Management System (ISO 14001:2015) and the Occupational Health and Safety Management System (ISO 45001:2018), covering all departments of the Company. A total of five unqualified items were identified in this audit. We have conducted cause analysis, formulated and strictly implemented corrective and preventive measures for non-conforming items. In November 2021, the Company successfully passed the external audit of the system with "zero defects".

### Employees' Occupational Health and Safety

The Company strictly abides by the relevant laws and regulations on occupational health and safety, establishes a series of occupational health management systems and regulations, and regularly carries out knowledge training for occupational health knowledge and labor protection items to effectively enhance employees' awareness and skills of occupational disease prevention. In addition, we regularly invite qualified third parties to monitor and evaluate occupational hazards in various laboratories and workshops. On 19 May 2021, the Company conducted tests on hazard factors of various occupational hazard sites, with a total of 33 points tested, and no occupational hazard factors were found. During the reporting period, no occupational disease cases has occurred in the Company, and the occupational health examination coverage rate of employees was 100%.

In 2021, the Company (headquarter) obtained the ISO 45001 Occupational Health and Safety Management System Certification.



Picture: ISO 45001 Certification

In order to further improve the Company's health management level and better care for the physical and mental health of employees, the Company carried out healthy enterprise construction activities in 2021, and was awarded the title of "Healthy Enterprise" in Yantai in December. Meanwhile, two employees of RemeGen Co., Ltd., Kang Ying and Zhang Shijie, were awarded the honorary titles of provincial-level "Occupational Health Talents".

### Third-party Safety Management

The Company strengthened the safety management of third parties, formulated the *Safety Management System of Related Parties*, and signed safety management agreements with all third parties who entered the factory for construction. In addition, we carried out on-site safety education and training for all personnel entering the factory, including the Company's safety rules and regulations, risk notification, etc., to fully regulate the operation behavior of the construction personnel. In 2021, we conducted the third-party safety education and training for over 500 person-times.

For the daily construction of third parties, we focus on the safe and civilized construction, the management of dangerous operations and the safe use of electricity at the operation site through a combination of weekly inspections and daily safety inspections to ensure that hidden dangers are effectively treated. No major safety accidents and fire accidents occurred in terms of the contractor in 2021.

### 4.1.3. Safety Culture Building

We are committed to improving the construction of the Company's safety culture, proactively carrying out safety production publicity and education and related training activities, enhancing employees' awareness of production safety and skills, and promoting the safe and long-term development of the Company.

### Safety Awareness Promotion

In 2021, the Company carried out a series of safety production month campaigns. Through a variety of activities, we further enhanced employees' emergency awareness and skills, and consolidated the Company's safety production foundation.

Wenjuanxing Q&A Activity	We post 3 questions related to safety, environmental protection, fire prevention, transportation, emergency rescue, special equipment, occupational health, hazardous chemicals, etc. in each company's WeChat group and Ding Talk group with reference to Q&A conducted in a mini app called "Wenjuanxing", to assess the safety capability level of all employees. More than 26,000 person-times participated in the Q&A activity, with a maximum of 1,458 participants in a single day. After the event, we distributed small souvenirs to employees with outstanding performance for encouragement. Through carrying out daily Q&A activities, it effectively stimulated the enthusiasm of employees to learn safety knowledge.
Safe & Entertaining Sport Event	The Safe & Entertaining Sport Event consists of three parts: Answer, Guess and Quick Respond. It not only tests the safety knowledge reserve of the participants, but also tests the team's tacit cooperation. A total of more than 100 employees participated in the activity, which has achieved good results in popularization of science.
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Safety Knowledge Contest	A total of 8 teams and 24 employees participated in the safety knowledge contest. The content of the competition includes knowledge of safety, environmental protection, first aid, fire prevention and other aspects.
Safety Speech Contest	<text></text>

### Safety Training

The Company continues to establish a sound safety training system to promote the overall implementation of safety education. In 2021, the Company organized a large number of health and safety education and training activities, including safety training for new employees, safety training for construction personnel, emergency management training, fire prevention training, special operation and special equipment training, laboratory biology training and so on. All participants have passed the examination. In 2021, the total duration of the Company's safety training was 271 hours.



**Picture: Hazardous Chemicals Training** 

**Picture: Fire Prevention Training** 



Picture: Training on First-aid Knowledge

Furthermore, the Company actively participated in safety training activities organized by external institutions, such as *Training on Biosecurity System Construction organized* by the CCAI, training on *Safety Risk Assessment of Response from Pharmaceutical and Chemical Production Process* organized by the CCEMA and training on *Calculation of OEL*<sup>2</sup> organized by Golder Associates Consulting Limited.

<sup>2</sup> 

Occupational exposure limit values (OELs): It refers to the permissible exposure level that does not cause harmful effects to the health of the vast majority of the workers who have been exposed to them for a long period of time during their occupational activities. It generally divided into occupational exposure limits for chemical hazards and occupational exposure limits for physical agents.

### 4.2. GREEN OPERATIONS

We actively responded to the national call for energy conservation and emission reduction, continued to explore energy conservation and emission reduction technologies, carried out assessment and analysis of risks related to climate change, improved resource utilization efficiency and reduced emissions of three wastes. Meanwhile, we fully advocate green office and fulfill our commitment to green operation demonstrated by our own actions to help achieve the national goal of "carbon peak" and "carbon neutrality".

### 4.2.1. Climate Change

With reference to the framework and recommendations of the Task Force on Climate-related Financial Disclosures (TCFD), RemeGen proactively identified and analyzed the physical risks and transition risks related to climate change affecting the Company, so as to enhance the Company's adaptability to climate change.

Risk Category	Risk Description		
Policy and legal risks	• International and domestic regulatory authorities and the capital market rating index have continuously increased the disclosure requirements of corporate environment-related data. If the environmental data is not disclosed as required, the Company will be exposed to compliance risks from the regulatory authorities;		
	• Extreme weather may cause supply chain disruptions to companies, resulting in litigation risks arising from the inability of companies to perform on time.		
Technology risk	• Facing the carbon peaking and carbon neutrality goals, the Company needs to increase the budget related to the research and development of green chemistry technology in order to reduce the level of carbon emissions, which will lead to an increase in the Company's operating costs.		

### Table: Transition Risks of Climate Change

Risk Category	Risk Description		
Market risk	• In the context of carbon peaking and carbon neutrality goals, customers' preference will change, resulting in more low-carbon green related demand. If the company fails to meet customer demand in a timely manner, it will result in a loss of revenue and market share;		
	• Climate change may lead to the emergence of new diseases, and consumer demands for drugs or other pharmaceutical products may increase;		
	• Extreme weather may cause a decrease in the quantity/quality of raw materials used in the pharmaceutical production, which may lead to an increase in raw material costs and increase the Company's operating costs.		
Reputation risk	<ul> <li>Under the background of widespread concern about climate change, the Company's low-carbon transition work has received close attention from stakeholders such as regulators, investors, customers and the public. Failure to carry out low-carbon transition work in a timely and effective manner and accurately disclose environmental-related data will have a negative impact on the Company's public image and result in a loss of revenue.</li> </ul>		

Risk Category		Risk Description
Acute risks	Typhoon	<ul> <li>Destroying existing equipment and facilities, threatening the safety of employees;</li> </ul>
		• Suppliers may fail to deliver on time, resulting in business interruption, which further leads to a decrease in the Company's operating income.
	Extreme precipitation, floods	<ul> <li>Destroying existing equipment and facilities, threatening the safety of employees;</li> </ul>
		• Suppliers may fail to deliver on time, resulting in business interruption, which further leads to a decrease in the Company's operating income.
Chronic risks	Global warming	• Climate warming may cause a shortage of upstream energy and raw materials, which in turn will lead to increased operating costs.
	Sea level rise	<ul> <li>Destroying existing equipment and facilities, threatening the safety of employees;</li> </ul>
		• Suppliers may fail to deliver on time, resulting in business interruption, which further leads to a decrease in the Company's operating income.

### Table: Physical Risks of Climate Change
#### 4.2.2. Environmental Management System

RemeGen has established the Safety and Environmental Protection Department to improve its environmental management system, and coordinate and fully implement the environmental management actions of the Company. In 2021, RemeGen passed the ISO 14001 Environmental Management System Certification.

We have formulated the *Response Plan for Environmental Emergencies* and regularly carry out emergency drills, aiming to comprehensively enhance the emergency response awareness and skills of all employees and minimize the environmental impact caused by such events. In 2021, there was no environmental pollution incident occurred in the Company.

#### Case: Emergency drill for hazardous waste leakage in warehouse

On June 9, 2021, the Company carried out an emergency drill for hazardous waste leakage in warehouses. The disposal process of the drill was conducted orderly, which enabled employees to understand the correct process to deal with a hazardous waste leakage accident, and improved their emergency awareness and skills. At the same time, the on-site emergency response team responded quickly and used appropriate emergency materials to prevent the spread of leakage, which also verified the applicability and effectiveness of the *Response Plan for Environmental Emergencies*.



Picture: Disposal process during the emergency drill

#### 4.2.3. Emission Management

Adhering to the concept of green development and in strict compliance with the relevant national laws and regulations, we have improved and implemented the internal rules and regulations of the Company, and standardized the emission management process in the daily production to ensure that the air pollution, water pollution and waste generated during the operation are reduced and compliant, so as to mitigate the impact on the ecological environment.

The major pollutants in the Company's exhaust emissions are volatile organic compounds (VOCs). We strictly abide by the relevant standards of exhaust gas emission in the places where we operate, and minimize the air pollution caused by exhaust gas emissions. For volatile solvents generated in laboratories and production workshops, we install professional treatment devices and identify characteristic pollutants based on the process flow, and engage a third party to conduct inspections regularly in accordance with the self-monitoring plan for pollutant discharge permits. For waste gas generated from hazardous waste rooms, we installed professional adsorption devices to ensure the discharge of waste gas in compliance with regulations. For waste gas generated from sewage stations, we upgraded the disposal process and changed the original lye spray + UV photolysis process to a two-stage process including spray of lye spray + sodium hypochlorite spray, ensuring that the odor discharged from the sewage station meets the standard.

Indicators	Unit	2021	2020
	cubic meter(s)	168,906,000.00	13,357,971.00
	tonne(s)	0 23	0.0128

#### Table: Waste gas emissions of RemeGen in 2020 and 2021<sup>3</sup>

The increase in exhaust gas emissions in 2021 is due to the increase in production scale, the expansion of statistical range, and the more accurate and scientific data collection methods.

The wastewater released by the Company mainly includes cell activation wastewater and cleaning wastewater. In 2021, we will dispose of the released wastewater through three processes, so as to ensure that the wastewater discharges up to the standard and prevent the occurrence of water pollution incidents.

- Production wastewater and domestic wastewater: uniformly discharged into the sewage pipeline network of the park, and treated with relevant process at the sewage station in the park until meeting the standard, and then discharged into the municipal sewage pipeline network;
- Protein purification process wastewater: uniformly collected, pre-treated and discharged into the sewage pipeline network of the park;
- Wastewater discharged from the production process: discharged into the reclaimed water reuse pipeline network, and then collected to be used as boiler water.

Indicators	Unit	2021	2020
Wastewater Emissions in total	tonne(s)	187,229	80,594.00
COD	tonne(s)	15.56	12.45
Ammonia nitrogen	tonne(s)	1.76	1.36

#### Table: Wastewater emissions of RemeGen in 2020 and 2021

In 2021, the Company has set a waste reduction target, that is, with sustainable development as the long-term goal. On the basis of meeting production needs, the Company will make full use of materials and consumables to reduce the amount of waste generated.

We adhere to the principle of minimizing, recycling and hazard-free to ensure the compliance of non-hazardous waste. In order to reduce the generation of non-hazardous waste, we have taken the following measures:

- Optimize the filling volume adjustment operation to reduce the consumption of filling;
- Make rational use of surplus rubber stoppers, aluminium caps and vials in production, and reuse them in subsequent testing and partial verification to reduce waste;
- Evaluate the use cycle of filter elements at each point in the preparation workshop, extend their use time and reduce the use of filter elements;
- Reuse of obsolete cleanroom suits: the cleanroom suits eliminated from production can be used for the protection of people engaged in sterilization and disinfection and reduce the use of disposable protective suits;
- Adopt small packages for disposable pipette tips and sterilize it for use after package removal to reduce waste.

Indicators	Unit	2021	2020
Non-hazardous waste	tonne(s)		
emissions in total Density of non-hazardous waste	tonne(s)/revenue of	17.30	17.30
emissions <sup>5</sup>	RMB ten thousand	0.00012	/

#### Table: Non-hazardous waste emissions of RemeGen in 2020 and 2021<sup>4</sup>

<sup>&</sup>lt;sup>4</sup> Non-hazardous waste includes kitchen waste, domestic waste and production waste.

<sup>&</sup>lt;sup>5</sup> Density of non-hazardous waste emissions = total amount of non-hazardous waste discharged during the year/revenue of the Company for the year.

In respect of hazardous waste, we have established a comprehensive hazardous waste treatment process. We have installed anti-leakage collection facilities and ventilation facilities on site to meet the requirements of anti-seepage and anti-leakage; put up warning signs on hazardous waste storage facilities; and cooperated with qualified institutions to carry out compliant disposal of hazardous waste.

#### Hazardous Waste Treatment Process

- Develop annual hazardous waste management plan, filed on the hazardous waste management platform of Yantai Economic and Technological Development Zone and make production transfer plan;
- The Environmental Protection Department will assign a designated person daily to register and collect the hazardous waste as per the locations of departments generating hazardous waste, and specified the generation department, the type of waste and the detailed name, quantity and other information during the registration process.
- Make registration of hazardous wastes generated by all departments daily and put them into warehouse;
- Contact the disposal company in time according to the storage capacity, carry out the transfer and disposal of hazardous waste on a regular basis, and fill in the Hazardous Waste Transfer Form for each transfer according to the actual situation;
- Calculate the hazardous waste ledger monthly and generate a monthly report, which will be submitted to the hazardous waste management platform of the ecological environment department.

Indicators	Unit	2021	2020
Hazardous waste emissions in total	tonne(s)	77.74	38.06
Density of hazardous waste emissions <sup>7</sup>	tonne(s)/revenue of RMB ten thousand	0.00055	/

#### Table: Hazardous waste emissions of RemeGen in 2021<sup>6</sup>

<sup>&</sup>lt;sup>6</sup> Hazardous wastes include toner cartridges, waste lamps, waste batteries, electronic waste, hazardous waste

<sup>&</sup>lt;sup>7</sup> Density of hazardous waste emissions = total amount of hazardous waste discharged during the year/revenue of the Company for the year.

#### 4.2.4. Resource Management

The Company has established the "Water Measurement Management System" and other internal policies in strict compliance with the Water Law of the People's Republic of China and other relevant laws and regulations as well as national water resource management requirements. In 2021, the Company has set an internal water-saving goal of improving the efficiency of utilizing water resources to a maximum extent.

We have constantly strengthened our actions on water conservation within the company, enhanced water-saving technical innovations and comprehensively improved the efficiency of water use. We also carried out a series of water-saving measures:

- Water conservation campaigns: conducting activities such as collecting good ideas about water and electricity saving, online award-winning water-saving knowledge contest, and water-saving blackboard appraisal to enhance employees' awareness of water conservation.
- Water-saving reconstruction: launching water-saving reconstruction according to the site conditions, and using water-saving appliances as much as possible in the design of the buildings. The Company's water-saving renovation activities have achieved better results;
- Data monitoring: strengthening the monitoring and inspection of water resources data and facilities. Through data analysis, the Company will timely understand the leakage of underground water pipes and carry out emergency repairs in a timely manner to avoid the loss of tap water.

The Company laid more stress on the multiple use of water and cycling use of water to comprehensively improve the efficiency of water resources utilization. We use the reclaimed water reuse device to centrally recycle the wastewater generated from the water production system to the underground secondary reverse osmosis device for re-filtration. The filtered water is re-used to replenish water for cooling towers, ground source heat pumps and other equipment.

#### Table: Water-saving measures/process and effect

Water-saving measures/process	Water-saving effect
Optimization of cleaning process of lyophilizer	Reduced cleaning time led to lower consumption of water for injection. The water saving effect is 8 tonnes/batch, saving about RMB8,000/batch.
Decreasing or increasing the use temperature of injection water cooling point	The water saving effect is 2,036m³/batch

#### Table: Water resource consumption of RemeGen in 2020 and 2021

Indicators	Unit	2021	2020
Consumption of fresh water	tonne(s)	300,600.00	210,224.00
Consumption of reclaimed water	tonne(s)	25,900.00	86,000.00
Density of water consumption <sup>8</sup>	tonne(s)/revenue of RMB ten thousand	2.11	/

The Company is committed to strengthening the reduction of packaging materials at the source, reusing the materials, packaging materials and other resources in the process of testing and verification, so as to improve the recycling efficiency of packaging materials and reduce the waste of resources. Our initiatives are as follows:

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Density of water consumption= Total consumption of fresh water during the year/revenue of the Company for the year

- During the annual re-verification of the preparation filling line equipment, the vials and rubber stoppers are reused to reduce the consumption of packaging materials and maximize the utilization rate of the packaging materials during the verification process.
- During the annual verification process, reduce unnecessary packaging material consumption through the statistics and pre-assessment of the batch data of the current year;
- Employee training was strengthened to improve staff's professional skills, so as to reduce the consumption of wasted packaging materials in the process of equipment commissioning before production.

In 2021, the packaging materials used by the Company amounted to 16.07 tonnes, with use intensity of packaging materials per unit of output of 0.00011 tonnes/revenue of RMB ten thousand.

The Company strictly complies with the *Energy Conservation Law of the People's Republic of China*, and has formulated internal policies such as the *Energy Resource Control Procedures* and the *Interim Provisions on the Management of Energy and Equipment and Facilities in the Park*, and continues to explore energy-saving and emission-reduction technologies to improve the efficiency of energy use. We have established an energy management system, insisting on the scientific management of the use of electricity, natural gas, gasoline and other resources while building special statistical ledgers to record, and adopted special response measures. Meanwhile, we pay attention to energy saving and consumption reduction in the operation process. If there is no production in each workshop for a short period of time, we will turn off the air-conditioning to save power consumption.

The Company has reinforced the use of renewable energy. We adopt ground-source heat pumps as the main energy supply system for refrigeration or heating equipment, and supply air-conditioning system by replacing underground cold and heat energy. Compared with the normal air-conditioning system, the efficiency ratio of this technology can be improved by more than 40% in terms of water and electricity energy, which effectively saves energy consumption. In addition, we have replaced air-cooled chillers with open cooling towers in each of our buildings to reduce the high temperature generated by the operation of the equipment, thereby saving a lot of electricity.

In 2021, the Company has set an energy-saving goal to maximize energy efficiency.

#### Table: Energy consumption of RemeGen in 2020 and 2021

Indicators	Unit	2021	2020
Purchased power <sup>9</sup>	kWh	36,344,609.00	20,128,060.00
Gasoline	tonne(s)	0	3.00
Diesel	tonne(s)	0	1.00
Purchased Heat	MkJ	83,596.55	/
Natural gas	m³	0	1,883,000
Comprehensive energy utilization	tce	7,344.83	4,550.90
Density of comprehensive energy utilization <sup>10</sup>	tce/revenue of RMB ten thousand	0.05	/

In addition, the Company has set a target on greenhouse gas emission reduction, that is, minimizing the Company's carbon emissions through a series of energy saving and emission reduction actions, and actively respond to the national double carbon target.

#### Table: GHG emissions<sup>11</sup> of RemeGen in 2020 and 2021

Indicators	Unit	2021	2020
Scope 1: Direct GHG	tonne(s) of CO <sub>2</sub> e	0	4,136.08
emissions <sup>12</sup> Scope 2: Indirect GHG	tonne(s) of CO <sub>2</sub> e	22,183.04	12,278.12
emissions Total GHG emissions	tonne(s) of CO <sub>2</sub> e	22,183.04	16,414.19
Density of GHG emissions <sup>13</sup>	tonne(s) of CO <sub>2</sub> e/revenue of RMB ten thousand	0.16	/

<sup>&</sup>lt;sup>9</sup> The increase in the consumption of purchased power in 2021 was due to the higher utilization rate of equipment arising from the increased output.

<sup>&</sup>lt;sup>10</sup> The comprehensive energy utilization is calculated based on the *General Principles for the Calculation of Comprehensive Energy Consumption* (GB/T 2589-2020), which is directly converted from the consumption of electricity, purchased heat and other energy. Density of comprehensive energy utilization = total comprehensive energy consumption during the year/ revenue of the Company for the year.

<sup>&</sup>lt;sup>11</sup> Greenhouse gas emissions-Scope 2 from purchased power and purchased heat. The emission factors of purchased power refer to the *Guidelines on Corporate Accounting and Reporting of Greenhouse Gas Emissions* issued by the Ministry of Ecology and Environment of the People's Republic of China in 2015. The emission factors of purchased heat refer to the *Guidelines on Non-industrial Corporate Accounting and Reporting of Greenhouse Gas Emissions* issued by the National Development and Reform Commission on July 6, 2015.

<sup>&</sup>lt;sup>12</sup> In 2021, the Company did not use gasoline, diesel and natural gas, so the Scope 1 GHG emissions were zero.

<sup>&</sup>lt;sup>13</sup> Density of GHG emissions = total GHG emissions during the year/revenue of the Company for the year.

#### 4.2.5. Green Office

RemeGen advocates the concept of green office and focuses on energy saving, water saving, office consumables saving and green travel. It actively carries out green cultural publicity activities to create a low-carbon and green corporate environment.

We are introducing an enterprise asset management system (EAM)<sup>14</sup>, which will enable us to achieve a paperless office. The management of equipment, plant, measurement and others can be realized in the software. We have put an investment of approximately RMB3 million in this system, which effectively saves manpower and management costs, as well as a large amount of paper and printing consumables.

During the daily operation, we put up water-saving signs in toilets, pantries and other places to remind employees to consciously develop good habits of saving water; replace high-efficiency energy-saving lamps if possible, and gradually eliminate regular incandescent bulbs; promote double-sided printing to save paper; advocate green travel and minimize carbon emissions from employee transportation.

<sup>&</sup>lt;sup>14</sup> Enterprise Asset Management. The EAM system is an enterprise resource planning system that used by enterprises with a large proportion of assets to reduce maintenance costs during asset construction and maintenance, improve asset operation efficiency, reduce downtime and increase production capacity through modern information technology.

RemeGen firmly implements its people-oriented employment philosophy to create a fair and equitable, comfortable and friendly working environment where we can grow together with our employers. We also care about the community by actively participating in patient supporting programs, striving to build a premium medical brand that worth the trust from all walks of life.

#### 5.1 TALENT MANAGEMENT

RemeGen always focus on offering employees with diversified employment policies, clear career path as well as industry-leading remuneration and welfare system, making talents become the primary driving force of the Company's sustainable development.

#### 5.1.1 Employees' Rights and Interests

The Company strictly abides by relevant laws and regulations applicable to the places where it operates, such as the Labour Law of the People's Republic of China and Labour Contract Law of the People's Republic of China, formulate and continue to refine the Recruitment and Employment Management Regulations, Resignation Management Regulations, Labour Contract Management Regulations, Labour Management Regulations and other internal systems, through which we can provide institutional guarantees for employees in recruitment, removal, working hours, vacation and other aspects.

In 2021, we actively made response to talent-related policy in Yantai to keep broadening our recruitment channels, therefore, we posted recruitment information in accordance with the demands in each department, so that we can introduce outstanding staff in a scientific, systematic and standard manner. During the Reporting Period, RemeGen has 2,082 employees under the labour contract, representing an increase of 974 employees in 2020. The details are as follows<sup>15</sup>:

Index		Unit	Value
Number of employees in total		Person	2,082
Number of new employees		Person	974
Number of employees by type	Contractor	Person	2,081
	Part-time/Dispatched	Person	1
Number of employees by gender	Male	Person	924
	Female	Person	1,158
Number of employees by age	Below 30	Person	885
	30-50	Person	1,145
	Above 50	Person	52
Number of employees	Chinese mainland	Person	2,046
by geographical region	Ching's Hong Kong Maga		
	China's Hong Kong, Macao,	5	2.6
	Taiwan and overseas	Person	36
Number of employees by rank	Management	Person	105
	Mid-level staff	Person	395
	General staff	Person	1,582

Trainee number is not included for both employee number by category and new added employee number.

Index		Unit	Value
Employees overall turnover rate		%	19.5
Employees turnover rate by gender	Male	%	22.6
	Female	%	17.0
Employees turnover rate by age	Below 30	%	28.5
	30-50	%	13.3
	Above 50	%	3.8
Employees turnover rate by geographical region	Chinese mainland	%	19.8
	China's Hong Kong, Macao,		
	Taiwan and overseas	%	0

#### Case: Attending "2021 Recruitment Day for Talents from Overseas in Yantai"

In order to promote and introduce the talent-related policies, advantageous industries and working and living environment in Yantai, and to push forward the exchange and cooperation with outstanding personnel from overseas, RemeGen attended the "2021 Recruitment Day for Talents from Overseas in Yantai"(2021 煙台海外高層次人才交流對接會) in October 2021, featuring highlights the company profile, demands for talent and recruitment policy. The Company also exchanged ideas online with overseas talents for the potential cooperation in the future.



Case: Conducting recruitment via livestream themed on "Come to Yantai in Spring for the Wanted Job"

In order to support enterprises in spring recruitment season, and to help college graduates, unemployed personnel, rural migrant workers in cities, the registered poor and other labourers find suitable jobs, RemeGen conducted a Spring Recruitment for the Year 2021 in Yantai themed on "Come to Yantai in Spring for the Wanted Job" (春風送崗,就選煙台) in March 2021.

The recruitment conducted in the form of livestream, aiming to give an introduction on the company profile, job vacancy, and the talent policy that the Company adopted to job seekers, and to offer a large number of positions in R&D, quality and production.



In the process of our recruitment, we managed to strictly comply with *Labour Contract Management Regulations* and other internal systems, to advocate those with diverse backgrounds to join and to firmly prevent the discrimination and excessive competition raised against ethnic, racial, gender, geographical region and other information, so that each employee's rights and interests shall be safeguarded. Also, we rigorously followed the *Law of the People's Republic of China on the Protection of Minors* and other relevant laws and regulations to strictly screen the identity information of employees to protect their rights to work freely, and resolutely opposed the use of child labor and forced labor. The occurrence of relevant incidents will result in our seriously handling in accordance with relevant laws and regulations and the Company's system.

#### 5.1.2 Talent Benefits

The Company regards employees as the most valuable asset and has established and kept improving its internal remuneration and welfare system. We follow the Remuneration Management Regulations and implement the five principles of multi-track development, performance-oriented, fairness and justice, salary going with position, and combination of short-term and long-term incentives, so that employees can devote themselves to their daily work with full enthusiasm.

Multi-track development	To establish a multi-track development path in which the management, professional skills (R&D, function, etc.) and remuneration share the same ranking
Performance-oriented	Work performance appraisal of employees is linked to performance-oriented salary, year-end bonus as well as salary increase and decrease
Fairness and justice	Remuneration is determined based on employees' performance and contribution to achieve internal fairness
Salary going with positions	Employees' salaries are linked to their positions, duties and responsibilities, and the salary goes with positions
Combination of short-term and long-term incentives	Offer share options to employees in certain key positions, taking into account the short-term and long-term interests of employees

#### Five Principles of Compensation Management System in RemeGen

The Company is also committed to creating the most advantageous welfare system for its employees among its peers. On the basis of ensuring that employees are fully entitled to statutory benefits, we also provide employees with special benefits with company characteristics such as paid leave, lunch allowance and apartments, so as to protect the legitimate rights and interests of employees and continue to enhance their sense of happiness.

Statutory benefits	<ul> <li>Social insurance</li> <li>Housing provident fund to facilitate the house purchase and overhaul for employees</li> <li>Statutory leaves for weddings, funerals and childbirth</li> </ul>
Company benefits	<ul> <li>Paid annual leave</li> <li>Provision of fully-equipped apartments for the talents and single employees introduced in the park</li> <li>Lunch allowance</li> <li>Commuter and transportation subsidies</li> <li>Home leave subsidies</li> <li>Personal accident insurance</li> <li>Regular employee physical examinations and establishment of employee health records</li> <li>Presenting exquisite gifts on employees' birthdays</li> <li>Reasonable festivals</li> <li>Long-term incentives</li> </ul>

#### **Employee Benefits in RemeGen**

#### 5.1.3 Communicate with and caring for employee

RemeGen has always been committed to practicing corporate care and making employees feel the warmth like being at home. We attach great importance to the physical and mental health of our employees and focus on improving employees' sense of belonging and identity through effective communication methods and a variety of spare-time activities, so as to help employees achieve a relative balance between work and life.

#### Communication with Employees

The Company always believes that the establishment of diversified communication channels is the most direct way to show the care for employees. We conduct employee representative meetings, set up suggestion boxes, and conduct employee democratic evaluations to extensively collect and provide timely feedback to employees' reasonable demands, so as to effectively involve employees in the daily governance of the Company.

Employee representative meeting	Regularly collect major issues related to the employees' vital interests and concerns of the employees. The employee representative meeting was held after the labor union committee has reviewed and filed the case, to fully solicit the opinions from the labor union representatives and the employee representatives. Unanimous decision will be reached and implemented
Suggestion box	Provide internal communication and whistle-blowing channels to make sure the channels kept open for employees expressing their appeals
Employee democratic evaluations	Fully understand employees' satisfaction and listen to their opinions, and make targeted improvements

#### Diversified Communication Channels in RemeGen

In 2021, in order to relieve the employees' sense of unfamiliar and integrate into their positions as soon as possible, we implemented the departmental guidance system based on the existing system. The head of the department shall designate the key personnel of the department to act as the guide, who are mainly responsible for orienting new employees, preparing work items, accompanying dine in the park, understanding the working environment of the department, introducing the organizational structure of the department, coordinating and hand over work to colleagues assigned by superior leaders, and helping new employees get acquainted with the company quickly.

#### Caring for Employees

The Company focuses on enriching the off-duty life of employees and continues to inject vitality into the Company's development. In 2021, we invested a total of RMB11.16 million in employee caring and held a series of employee caring activities such as new drug launch celebrations, parties for singles, distribute birthday cards and coupons and purchases of baby supplies for those female employees who just gave birth to children, and fully implemented corporate humanistic care.

#### Case: Celebration of New Drug Launch

In 2021, two world-class new biologic drugs of the Company, "Taiai" and Disitamab Vedotin were approved for marketing, respectively. The international collaboration of Disitamab Vedotin refreshed the record of overseas authorized transactions for single category of China pharmaceutical enterprises, representing as a milestone in the process of development of the Company. Therefore, the celebration party for launching products and international collaboration were convened to celebrate the remarkable performance of the Company, and to praise and encourage advanced employees at the same time to further motivate employees' enthusiasm for work.



#### Case: Party for the Singles

In 2021, the activity of "Party for the Singles" was held to provide unmarried employees with a healthy, recreational space to make friends cheerfully, which helped employees to relax themselves and make good friends with each other.



#### Case: Baby Accessories Purchase for Childbearing Female Employees

When practicing employee care, we particularly attached great importance to the basic rights and interests of vulnerable group and female employees. We also carried out several special care activities for female employees, to implement the philosophy of diversified, equal employment with practical actions.



#### Employee Health

RemeGen also greatly emphasizes the physical and mental health of our employees. We ensure our production and operations sites, equipment, firefighting facilities and safety signages are in line with relevant national standards and regulations via established rules and regulations on safety production and work, occupational health management system and emergency plan for accidents. We also organize regular health and safety training for new employees and discuss and study on typical industrial park accident cases with an aim to prevent relevant safety incidents fundamentally. During the reporting period, there were no any work-related fatalities occurred in the Company, and the coverage of medical examinations for employees' occupational diseases reached 100%.

Indicators	Unit	2019	2020	2021
Number of work-related fatalities in the				
past three years	person	0	0	0
Rate of work-related fatalities in the past				
three years	%	0	0	0
Lost days due to work injury	day	/	/	81

In addition, to help employees relieve stress from life and work, we also set up special mental health counseling office to offer employees services including psychological assessment, psychological counseling, educational training.

In 2021, in the context of the unexpected epidemic, besides strictly carrying out related prevention and control work, the Company took full consideration of certain employees who were unable to go home to celebrate the Spring Festival and held activities including New Year's Eve Dinner, New Year's gift packages, lucky draw to send blessings and express gratitude for their efforts to ensure the normal operation of the Company.



#### 5.2. EMPLOYEE CULTIVATION

RemeGen always attaches great importance to development and construction of high quality talents, and continues to consolidate the development base for the Company through effective talent training mechanism and reasonable employee promotion and development channels, so as to build a high end talents with efficient, professional, creative and cohesive attitude.

#### 5.2.1. Employee Promotion

Based on the internal systems including *Provisions on the Management of Promotion, Demotion and Redesignation of Employee* and *Provisions on the Management of Employee Performance Appraisal,* taking into account of actual situation of the Company and the needs of employees from different levels to improve their professional competence and realize their self-value, the Company created a flexible and comprehensive internal promotion system.

In 2021, the Company conducted relevant trainings for newly promoted managements, which was aimed to strengthen their role conversion and recognition, responsibility awareness and assumption, communication and working skills, in order to improve their competence. Based on the response level, learning level and behavior level from above trainings, we shared outstanding performance individual while reviewing results on the training, so as to summarize and improve our working thoughts and methods.

#### 5.2.2 Employee Training

Based on comprehensive employee training system and other factors such as grades of internal employees within the Company and training organizations, we specifically conducted various trainings for them, therefore improving the quality of talents as a whole in a multi and all-round way.

Corporate level	Talent Pool Plan Leadership Improvement	Senior management	Leadership, decision making, influence, personalized needs, cultural seminars
		Middle management	Operation management, team management, understanding and recognition of culture
		Basic management	Competence, role conversion, self-management, employee supervision, understanding and recognition of culture
	General Training Co-cultivation and Internal	All business departments	From solving existing problems as the starting point, human resource department cooperated with each
	Transformation	Competence on core business	department to conduct business system training step by step whenever there is a need, so as to improve competence as a whole
	Improvement on Professional Quality of All Employees	Mainly targeted at basic employees	Conducting trainings on general skills including employee professionalism, professional etiquette, teamwork and time management
	New Employee Training during the Probation	All departments at headquarter	Analyzing system, optimizing and improving procedures, facilitating integration of new employees
	Period	Expatriate employees	Human resource departments at Beijing and Shanghai organized trainings for new employees, and built a useful course system
		Sale and marketing employees	Improving training and management system for new sale and marketing employees

Description	Duefersient		
Department Level	Profession/ Position Skills	Employees from the department	Completing trainings on profession, position skill required by the department and pre-job assessment Trend on industrial regulation/ system and update on the latest knowledge empowerment
		Development plan for new employees	Position responsibility and working procedure Implementing mentor system to provide guidance and experience to new employees
		Improving competence	Integrating quality resources for internal/external sharing, improving competency

#### Employee Training System of RemeGen

In 2021, we successively conducted 6 types of training activities including induction training for new employees, general skill improvement, management competence improvement, cultivation of core talents, external training and training for expatriate departments. We focused on improving competence of managements, empowered them in terms of role conversion and recognition, responsibility awareness and assumption, communication skill and performance management. As at the end of the reporting period, the total number of employees of RemeGen participating in training amounted to 1,467, with training hours of 987, details of which is set out as below:

Metric		Unit	Number
Total number of employees participati	ng in training	Person	1,467
Total training hours		Person	987
Metric		Unit	Number
The percentage of employees trained		%	70.5
The percentage of employees trained by gender	Male	%	72.1
trained by gender	Female	%	69.2
The percentage of employees			
trained by title	Management	%	81.9
	Middle-level employee	%	79.5
	Operational employee	%	67.4
Average training hours per employee			
trained		Hour	0.47
Average training hours per employee			
by gender	Male	Hour	0.58
	Female	Hour	0.39
Average training hours per employee			
by title	Management	Hour	0.13
	Middle-level employee	Hour	1.25
	Operational employee	Hour	0.30

#### **Case: Jingying Program**

In 2021, RemeGen adopted a new cultivation model, and organized a training camp for newly promoted management talents, which was conducted through five stages. As at the end of the reporting period, we had completed total 10 online and offline training courses, after-class summaries and activity plans, with an average training hours per employee of 25.



We also built a performance incentive system in association with training system, regularly conducted daily and annual comprehensive appraisal for employees and linked the appraisal results to the salary package and promotion of employees, so as to examine the learning results of employees, inspire their enthusiasm for learning and realize the targets of the Company. We will regularly carry out annual commendation activity for excellent employees to provide incentives and recognition.

#### 5.3 COMMUNITY CARE

RemeGen always adheres to the spirit of being grateful to the society, continues to enhance economic efficiency of the Company and puts sustainable development into practice. We fully integrate our own resources and increasingly make every effort to patient assistance and rare diseases aiding from pharmaceutical industry. During the reporting period, RemeGen had funded RMB194.13 million to patient assistance, with numbers of person times for volunteer services amounting to 40.

#### **Case: Patient Assistance Project of Telitacicept**

In 2021, RemeGen cooperated with Beijing Public Health Foundation to conduct "Specific Project for Telitacicept Assistance". The Project covered 69 prefecture-level cities across 30 provinces, assisted a total of 2,299 patients, donating a total of 28,844 drugs, with a total value of approximately RMB74,590,584. The Company was awarded "2021 Charitable Unit" by Beijing Public Health Foundation in December 2021 for the wide range of beneficiaries and great feedbacks.

#### **Case: Patient Assistance Project of Disitamab Vedotin**

In 2021, RemeGen cooperated with Beijing Health Alliance Charitable Foundation to conduct "Patient Assistance Project for Disitamab Vedotin". The Project covered 86 cities across 29 provinces, assisted a total of 1,818 patients, donating a total of 8,855 drugs, with a total value of approximately RMB119,542,500.

#### Case: Repost for Love, Focusing on Rare Diseases

In February 2021, on the 14th International Day for Rare Diseases, RemeGen actively responded to the theme of "Rare is many, rare is strong, rare is proud!", propagated and educated common rare diseases in China. At the same time, RemeGen advocated everyone to repost for love to the society, caring patients with rare disease with action.



### 6.1. ESG REPORTING GUIDANCE INDEX

		Disclosure Plans and Statements	
		General Disclosure:	4.2. GREEN OPERATIONS
	<ul> <li>(a) the policies; and</li> <li>(b) compliance with relevant laws and regulations that have a significant impact on the issuer</li> </ul>		
		relating to air and greenhouse gas emissions, discharges into water and land, and generation of hazardous and non-hazardous waste	
		A1.1 The types of emissions and respective emissions data	4.2. GREEN OPERATIONS
Environmental A1 Emissions	A1.2 Total greenhouse gas emissions (tonnes) and, where appropriate, intensity (e.g. per unit of production volume, per facility)	4.2. GREEN OPERATIONS	
		A1.3 Total hazardous waste produced (tonnes) and, where appropriate, intensity (e.g. per unit of production volume, per facility)	4.2. GREEN OPERATIONS
	A1.4 Total non-hazardous waste produced (tonnes) and, where appropriate, intensity (e.g. per unit of production volume, per facility)	4.2. GREEN OPERATIONS	
		A1.5 Description of measures to mitigate emissions and results achieved	4.2. GREEN OPERATIONS
		A1.6 Description of how hazardous and non-hazardous wastes are handled, reduction initiatives and results achieved	4.2. GREEN OPERATIONS

		Metric	Disclosure Plans and Statements
		General Disclosure:	4.2. GREEN OPERATIONS
		Policies on the efficient use of resources, including energy, water and other raw materials	
		A2.1 Direct and/or indirect energy consumption by type (e.g. electricity, gas or oil) in total (kWh in '000s) and intensity (e.g. per unit of production volume, per facility)	4.2. GREEN OPERATIONS
	A2 Use of Resources	A2.2 Water consumption in total and intensity (e.g. per unit of production volume, per facility)	4.2. GREEN OPERATIONS
		A2.3 Description of energy use efficiency initiatives and results achieved	4.2. GREEN OPERATIONS
	A2.4 Description of whether there is any issues in sourcing water that is fit for purpose, water efficiency initiatives and results achieved	4.2. GREEN OPERATIONS	
		A2.5 Total packaging material used for finished products (tonnes) and, if applicable, with reference to per unit produced	4.2. GREEN OPERATIONS
		General Disclosure:	4.2. GREEN OPERATIONS
	A3 The Environment and Natural Resources	Policies on minimizing the issuer's significant impacts on the environment and natural resources	
		A3.1 Description of the significant impacts of activities on the environment and natural resources and the actions taken to manage them	4.2. GREEN OPERATIONS

		Metric	Disclosure Plans and Statements
		General Disclosure: Information on:	5.1. TALENT MANAGEMENT 5.2. EMPLOYEE CULTIVATION
B1 Employment	<ul> <li>(a) the policies; and</li> <li>(b) compliance with relevant laws and regulations that have a significant impact on the issuer</li> <li>relating to compensation and dismissal, recruitment and promotion, working hours, rest periods, equal opportunity,</li> </ul>		
		diversity, anti-discrimination, and other benefits and welfare B1.1 Total workforce by gender, employment type (e.g. full time or part time), age group and geographical region	5.1. TALENT MANAGEMENT
	Social	B1.2 Employee turnover rate by gender, age group and geographical region	5.1. TALENT MANAGEMENT
Social		General Disclosure: Information on:	4.1. SAFE OPERATIONS 5.1. TALENT MANAGEMENT
		<ul><li>(a) the policies; and</li><li>(b) compliance with relevant laws and regulations that</li></ul>	
B2 Health and Safety		have a significant impact on the issuer relating to providing a safe working environment and protecting employees from occupational hazards	
		B2.1 Number and rate of work-related fatalities occurred in each of the past three years including the reporting year	5.1. TALENT MANAGEMENT
		B2.2 Lost days due to work injury	5.1. TALENT MANAGEMENT
	B2.3 Description of occupational health and safety measures adopted, and how they are implemented and monitored	4.1. SAFE OPERATIONS 5.1. TALENT MANAGEMENT	

		Metric	Disclosure Plans and Statements
		General Disclosure:	5.2. EMPLOYEE CULTIVATION
		Policies on improving employees' knowledge and skills for discharging duties at work. Description of training activities	
B3 Devel and Trair	· ·	Note: Training refers to vocational training. It may include internal and external courses paid by the employer	
	_	B3.1 The percentage of employees trained by employee category (e.g. senior management, middle management)	5.2. EMPLOYEE CULTIVATION
		B3.2 The average training hours completed per employee by employee category	5.2. EMPLOYEE CULTIVATION
		General Disclosure:	5.1. TALENT MANAGEMENT
		Information on:	
		(a) the policies; and	
B4 Devel and Trair		(b) compliance with relevant laws and regulations that have a significant impact on the issuer	
	-	relating to preventing child and forced labour	
	_	B4.1 Description of measures to review employment practices to avoid child and forced labour	5.1. TALENT MANAGEMENT
		B4.2 Description of steps taken to eliminate such practices when discovered	5.1. TALENT MANAGEMENT
		General Disclosure:	2.2. BUSINESS ETHICS BUILDING
		Policies on managing environmental and social risks of the supply chain	
	-	B5.1 Number of suppliers by geographical region	2.2. BUSINESS ETHICS BUILDING
B5 Supply ChainManagement	-	B5.2 Description of practices relating to engaging suppliers, number of suppliers where the practices are being implemented, and how they are implemented and monitored	2.2. BUSINESS ETHICS BUILDING
	-	B5.3 Description of practices used to identify environmental and social risks along the supply chain, and how they are implemented and monitored	2.2. BUSINESS ETHICS BUILDING
		B5.4 Description of practices used to promote environmentally preferable products and services when selecting suppliers, and how they are implemented and monitored	2.2. BUSINESS ETHICS BUILDING

		Metric	Disclosure Plans and Statements
		General Disclosure: Information on: (a) the policies; and (b) compliance with relevant laws and regulations that	3.1. PURSUIT OF EXCELLENT QUALITY
Operation Practices	B6 Product Responsibility	(b) compliance with relevant laws and regulations that have a significant impact on the issuer relating to health and safety, advertising, labelling and privacy matters relating to products and services provided and methods of redress	
		B6.1 Percentage of total products sold or shipped subject to recalls for safety and health reasons	3.1. PURSUIT OF EXCELLENT QUALITY
		B6.2 Number of products and service-related complaints received and how they are dealt with	3.3. IMPROVING SERVICE QUALITY
		B6.3 Description of practices relating to observing and protecting intellectual property rights	3.2. R&D AND INNOVATION STRENGTHS
		B6.4 Description of quality assurance process and recall procedures	3.1. PURSUIT OF EXCELLENT QUALITY

		Metric	Disclosure Plans and Statements
		General Disclosure:	2.2. BUSINESS ETHICS BUILDING
		Information on: (a) the policies; and	
	B7 Anti-corruption	(b) compliance with relevant laws and regulations that have a significant impact on the issuer relating to bribery, extortion, fraud and money laundering	
	B7 Anti-corruption	B7.1 Number of concluded legal cases regarding corrupt practices brought against the issuer or its employees during the reporting period and the outcomes of the cases	2.2. BUSINESS ETHICS BUILDING
		B7.2 Description of preventive measures and whistle-blowing procedures, and how they are implemented and monitored	2.2. BUSINESS ETHICS BUILDING
		B7.3 Description of anti-corruption training provided to directors and staff	2.2. BUSINESS ETHICS BUILDING
		General Disclosure:	5.3. COMMUNITY CARE
B8 Community	Policies on community engagement to understand the needs of the communities where the issuer operates and to ensure its activities take into consideration the communities' interests		
Community	Investment	B8.1 Focus areas of contribution (e.g. education, environmental concerns, labour needs, health, culture, sport)	5.3. COMMUNITY CARE
		B8.2 Resources contributed (e.g. money or time) to the focus area	5.3. COMMUNITY CARE

### FEEDBACK FROM READERS

#### Dear readers:

Thank you for your interest and support for the sustainable development of RemeGen Co., Ltd. In order to provide more professional and valuable environmental, social and governance report and further improve its quality, we are eager to hear your valuable voice for the following questions.

- 1. Are you satisfied with the Report? Please give your comments.
- 2. Do you think we have completely disclosed our performance in fulfilling our social responsibility?
- 3. Have the information you want to know been disclosed completely?
- 4. Do you have any suggestions to improve the Report?

	Your Information
Name	
Company	
Title	
Fax	
Tel	
E-mail	