

Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.



**SHANGHAI JUNSHI BIOSCIENCES CO., LTD.\***

**上海君實生物醫藥科技股份有限公司**

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

**(Stock code: 1877)**

## **ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED 31 DECEMBER 2024**

The board (the “**Board**”) of directors (the “**Directors**”) of Shanghai Junshi Biosciences Co., Ltd.\* (上海君實生物醫藥科技股份有限公司) (the “**Company**”) hereby announces the audited consolidated annual results of the Company and its subsidiaries (the “**Group**”) for the year ended 31 December 2024 (the “**Reporting Period**”), together with the comparative figures of the year ended 31 December 2023. The consolidated financial statements of the Company for the Reporting Period have been reviewed by the audit committee of the Company (the “**Audit Committee**”) and audited by the Company’s auditors. Unless otherwise specified, financial figures in this announcement are prepared under the International Financial Reporting Standards (“**IFRS**”).

In this announcement, “we”, “us” and “our” refer to the Company and where the context otherwise requires, the Group.

### **FINANCIAL HIGHLIGHTS**

- As at 31 December 2024, total revenue of the Group was approximately RMB1,948 million for the Reporting Period, representing an increase of approximately 30% compared to the corresponding period in 2023, which was mainly due to the increase in revenue from pharmaceutical products, in particular: the domestic sales revenue of our core product TUOYI® (toripalimab) was approximately RMB1,501 million, representing an increase of approximately 66% compared to the corresponding period in 2023.
- Total research and development (“**R&D**”) expenses of the Group were approximately RMB1,275 million for the Reporting Period, representing a decrease of approximately 34% compared to the corresponding period in 2023. The decrease in R&D expenses was mainly due to the Group’s cost control policy and efforts to optimize resource allocation and focus on R&D pipelines with greater potential. In addition, a number of clinical trials of our core product TUOYI® successively met the primary endpoints, which also contributed to natural decline of R&D expenditure.

- Loss attributable to owners of the Company decreased to RMB1,282 million for the Reporting Period, representing a decrease of approximately RMB999 million or approximately 44% compared to the corresponding period in 2023.
- As at 31 December 2024, the aggregate balance of bank balances and cash and financial products of the Group was approximately RMB2,917 million, ensuring a relatively sufficient cash position to support the Group’s development.

## BUSINESS HIGHLIGHTS

During the Reporting Period, focusing on the “unmet medical needs”, we have made original, innovative and breakthrough progress in discovery, R&D and commercialization of innovative therapies and innovative drugs with accelerating international development. The following achievements and milestones were attained:

- Our innovative R&D field has expanded from monoclonal antibodies to the research and development of various drug modalities, including small molecules drugs, polypeptide drugs, antibody drug conjugates (ADCs), bi-specific or multi-specific antibodies, bi-specific antibody drug conjugates, fusion protein and nucleic acid drugs, as well as the exploration of next-generation innovative therapies including cancer and autoimmune diseases. Our product pipelines cover five major therapeutic areas including malignant tumors, autoimmune diseases, chronic metabolic diseases, neurologic diseases and infectious diseases. A total of four drugs (TUOYI<sup>®</sup>, JUNMAIKANG (君邁康<sup>®</sup>), MINDEWEI (民得維<sup>®</sup>) and JUNSHIDA (君適達<sup>®</sup>)) have been commercialized, around 30 assets are undergoing clinical trials, and over 20 drug candidates are at preclinical drug development stage.
  - In January 2024, Coherus BioSciences, Inc. (“**Coherus**”), a partner of the Company, announced that toripalimab was available for access and administration in the United States. Prior to this, toripalimab (U.S. trade name: LOQTORZI<sup>®</sup>) was approved for marketing by the U.S. Food and Drug Administration (the “**FDA**”) in October 2023, and is the first drug for the treatment of nasopharyngeal carcinoma (“**NPC**”) in the United States. At present, it is also the only preferred drug recommended in the *National Comprehensive Cancer Network (“NCCN”) Clinical Practice Guidelines in Oncology for Head and Neck Cancers 2025.V1* for the treatment of recurrent/metastatic NPC across all lines.
  - In January 2024, the new drug application (the “**NDA**”) for toripalimab for the treatment of NPC was accepted by the Singapore Health Sciences Authority (the “**HSA**”). In March 2025, the NDA for toripalimab (Singapore trade name: LOQTORZI<sup>®</sup>) in combination with cisplatin and gemcitabine for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic NPC has been approved by the HSA. Toripalimab has become the first and only approved immuno-oncology treatment for NPC in Singapore.

- In April 2024, the Japanese Pharmaceuticals and Medical Devices Agency (the “**PMDA**”) agreed that the Company may proceed with a randomized, double-blind, placebo-controlled, international multi-regional phase III clinical study of tificemalimab (a recombinant humanized anti-BTLA monoclonal antibody, code: TAB004/JS004) in combination with toripalimab as consolidation therapy for patients with limited-stage small cell lung cancer (“**LS-SCLC**”) without disease progression following chemo-radiotherapy.
- In April 2024, the supplemental new drug application (the “**sNDA**”) for TUOYI® in combination with axitinib for the first-line treatment for patients with medium to high risk unresectable or metastatic renal cell carcinoma (“**RCC**”) was approved by the National Medical Products Administration of China (the “**NMPA**”). This is the first approved immunotherapy for renal carcinoma in China.
- In April 2024, the NDA for toripalimab in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent locally advanced NPC, and for toripalimab, as a single agent, for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy was accepted by the Drug Office, Department of Health, the Government of the Hong Kong Special Administration Region (the “**DO**”), and was approved by the Pharmacy and Poisons Board of Hong Kong (the “**PPB**”) in October 2024, making toripalimab the first and only immunotherapy drug for NPC in Hong Kong SAR, China.
- In June 2024, the primary endpoints of progression free survival (“**PFS**”, based on independent radiographic review) and overall survival (“**OS**”) of a multinational multi-center, randomized, open-label, active controlled phase III clinical study (the HEPATORCH study, NCT04723004) of TUOYI® in combination with bevacizumab for the first-line treatment of advanced hepatocellular carcinoma (“**HCC**”) met the pre-defined efficacy boundary, and the relevant sNDA was accepted by the NMPA in July 2024 and has been approved by the NMPA in March 2025.
- In June 2024, the sNDA for TUOYI® in combination with etoposidein plus platinum as the first-line treatment of extensive-stage small cell lung cancer (“**ES-SCLC**”) was approved by the NMPA.
- In June 2024, the sNDA for TUOYI® in combination with paclitaxel for injection (albumin-bound) for the first-line treatment of recurrent or metastatic triple-negative breast cancer (“**TNBC**”) with a well-validated test to evaluate PD-L1 positive (CPS ≥ 1) was approved by the NMPA.
- In July 2024, the investigational new drug (“**IND**”) application for JS125 (a targeted histone deacetylases (“**HDACs**”) inhibitor) was accepted by the NMPA, and was approved by the NMPA in September 2024.

- In July 2024, a positive opinion from the Committee for Medicinal Products for Human Use (the “CHMP”) of the European Medicines Agency (the “EMA”) was obtained for the marketing authorization application (the “MAA”) of toripalimab (European trade name: LOQTORZI®), which recommends approval for the treatment of two indications: toripalimab in combination with cisplatin and gemcitabine for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic NPC, and toripalimab in combination with cisplatin and paclitaxel for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic esophageal squamous cell carcinoma (“ESCC”). In September 2024, such MAA was approved by the European Commission (the “EC”). The approval is applicable to all 27 member states of the European Union (the “EU”), Iceland, Norway and Liechtenstein, making toripalimab the first and only drug for the treatment of NPC and the only first-line treatment for advanced or metastatic ESCC regardless of PD-L1 status in Europe.
- In August 2024, the sNDA for TUOYI® as the first-line treatment for unresectable or metastatic melanoma was accepted by the NMPA.
- In September 2024 and November 2024, toripalimab was approved for marketing in India and Jordan, respectively, for the treatment of two indications: toripalimab in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent, locally advanced NPC and toripalimab, as a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy. Toripalimab officially commenced commercial sales in India in 2024.
- In October 2024, the NDA for ongericimab injection (a recombinant humanized anti-PCSK9 monoclonal antibody injection, trade name: JUNSHIDA (君適達®)) as the treatment for adult patients with primary hypercholesterolemia (non-familial) and mixed dyslipidemia was approved for marketing by the NMPA.
- In November 2024, toripalimab (UK trade name: LOQTORZI®) obtained the marketing authorisation from the United Kingdom’s (the “UK”) Medicines and Healthcare products Regulatory Agency (the “MHRA”) for the treatment of two indications: toripalimab in combination with cisplatin and gemcitabine for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic NPC, and toripalimab in combination with cisplatin and paclitaxel for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic ESCC. Toripalimab has become the first and only drug for the treatment of NPC and the only first-line treatment for advanced or metastatic ESCC regardless of PD-L1 status in the UK.
- In November 2024, four new indications of TUOYI® were successfully included in Category B of the National Drug List for Basic Medical Insurance, Work-Related Injury Insurance and Maternity Insurance (Year 2024) (the “NRDL”). The ten approved indications of TUOYI® in Chinese mainland were all included in the NRDL, and TUOYI® is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of melanoma, perioperative treatment of non-small cell lung cancer (“NSCLC”), treatment of renal carcinoma and treatment of TNBC.

- **Business operations**
  - In June 2024, the Company convened the 2023 annual general meeting, the 2024 first class meeting of A shareholders and the 2024 first class meeting of H shareholders, and completed the election of the fourth session of the Board of Directors and the board of supervisors of the Company and other matters.
  - In July 2024, Suzhou Union Biopharm Co., Ltd.\* (蘇州眾合生物醫藥科技有限公司), a wholly-owned subsidiary of the Company, received the CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER issued by The Ireland Health Products Regulatory Authority (the “**HPRA**”) in accordance with the relevant regulations of the EMA. This is the first time that the relevant production facilities of toripalimab obtained the GMP certificate of a member state of the EU. According to the GMP mutual recognition system among the EU member states, the obtaining of the GMP certificate indicates that the production facilities with the certificate have met the GMP standards of the EU.
  - In August 2024, the A shares of the Company (“**A Shares**”) were included in the SSE STAR Brand Name Drug Index. The index selects 30 securities of companies listed on the STAR Market with the largest market capitalization and engaged in innovative drugs as constituents, reflecting the overall performance of the securities of the companies listed on the STAR Market and engaged in innovative drugs.
  - As of September 2024, the Company completed the implementation of the A-Share repurchase plan, with a total of 815,871 A Shares repurchased, accounting for 0.0828% of the total share capital of the Company, which will be used for the purpose of share incentives and/or employee stock ownership plan(s) at an appropriate time in the future.
  - In December 2024, the Company’s A Shares were included in the CSI A500 Index. The index selects 500 securities with the largest market capitalization and good liquidity from various sectors as constituents, reflecting the overall performance of the securities of the most representative listed companies across different sectors.

From the end of the Reporting Period to the date of this announcement, in addition to the aforementioned achievements, we have also made significant progress in the R&D and cooperation of several products, including:

- In January 2025, the indication of TUOYI® for the treatment of unresectable or metastatic melanoma after failure of standard systemic therapy has been approved by the NMPA for conversion from conditional approval to regular approval.
- In January 2025, the IND application for JS212 (a recombinant humanized epidermal growth factor receptor (“**EGFR**”) and human epidermal growth factor receptor 3 (“**HER3**”) bispecific antibody-drug conjugate (“**ADC**”)) has been accepted by the NMPA, and has been approved by the NMPA in March 2025.
- In January 2025, the indication of MINDEWEI for the treatment of adult patients with mild to moderate coronavirus disease 2019 (“**COVID-19**”) has been approved by the NMPA for conversion from conditional approval to regular approval.
- In January 2025, the New Chemical Entity (“**NCE**”) application for toripalimab in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent, locally advanced NPC and toripalimab, as a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy has been approved by the Therapeutic Goods Administration of the Australian Government Department of Health and Aged Care (the “**TGA**”). Toripalimab has become the first and only immuno-oncology treatment for NPC in Australia.
- In January 2025, TopAlliance Biosciences Inc. (“**TopAlliance**”), a wholly-owned subsidiary of the Company, has entered into a distribution and marketing agreement with LEO Pharma A/S (“**LEO Pharma**”). TopAlliance will grant LEO Pharma the exclusive right to store, distribute, promote, market and sell toripalimab in all current member states and any future member states of the EU and the European Economic Area (the “**EEA**”), Switzerland as well as the UK (the “**Territory**”). LEO Pharma shall pay TopAlliance an upfront payment of EUR15 million, milestone payment(s) for any subsequent approved indication(s) for toripalimab in the Territory, and a revenue share of a double-digit percentage on the net sales of toripalimab throughout the Territory.
- In February 2025, the IND application for JS213 (a PD-1 and interleukin-2 (“**IL-2**”) bifunctional antibody fusion protein) has been approved by the NMPA.



## MANAGEMENT DISCUSSION AND ANALYSIS

### Overview

#### Business Review

We have all-rounded capabilities in innovative drug discovery and development, clinical research on a global scale, and large-scale production capacity for commercialization across the entire industry chain, with an aim to become an innovative pharmaceutical company that operates “in China, for global”. Adhering to the corporate values of being quality-oriented, realistic and pragmatic, and maintaining integrity and compliance in our pursuit of excellence, we are committed to developing first-in-class or best-in-class drugs by way of original innovation and co-development. With our outstanding capacity for innovative drug discovery, strong biotechnology R&D capability, and large-scale production capacity, we have successfully developed a drug candidate portfolio with tremendous market potential. Multiple products have milestone significance: one of our core products, toripalimab (trade name: TUOYI® (拓益®)/LOQTORZI®, code: JS001), was the first domestic anti-PD-1 monoclonal antibody approved to be marketed in China by the NMPA, with 11 indications approved and also a sNDA accepted in Chinese mainland as of the date of this announcement, many of which are exclusive or leading indications by the Company. Moreover, toripalimab is the first innovative biological drug independently developed and manufactured in China that was approved for marketing by the FDA. As of the date of this announcement, toripalimab has been approved for marketing in various countries and regions including Chinese mainland, Hong Kong SAR, China, the United States, the EU, India, the UK, Jordan, Australia and Singapore. Our independently developed product tificemalimab is the world’s first-in-human anti-tumor anti-BTLA monoclonal antibody, and two phase III registrational clinical studies with several phase Ib/II clinical studies in combination with toripalimab against multiple types of tumors are underway. We also continue to explore early-stage pipelines, and expect to commence pivotal registrational clinical trials for multiple products in 2025.

In 2024, we continued to improve the efficiency of clinical studies and accelerate the registration process. In particular, it took only 36 days for the new indication of TUOYI® in combination with bevacizumab for the first-line treatment of HCC from data readout to NDA acceptance by the NMPA. Throughout the year, we conducted 92 clinical studies, enrolling over 2,100 subjects. The Company’s products were featured in over 145 journal publications in total, with a combined impact factor of over 1,200, and were presented with over 100 reports at international conferences, including 15 oral presentations.

As we continue to expand our product pipeline and further explore drug combination therapies, our innovation field has continued to expand to cover R&D of various drug modalities, including small molecules, polypeptide drugs, ADCs, bi-specific or multi-specific antibodies, bi-specific ADCs, fusion protein and nucleic acid drugs, as well as the exploration of the next-generation innovative therapies including cancer and autoimmune diseases. In 2024, the Company recorded revenue of RMB1,948 million, representing a year-on-year increase of approximately 30%. In particular, the domestic sales revenue of our core product TUOYI® increased by approximately 66% compared with the same period last year, and the loss was significantly narrowed compared with the same period last year. As of the end of the Reporting Period, the aggregate balance of bank balances and cash and financial products of the Company was approximately RMB2,917 million, indicating a relatively sufficient reserve of funds. Centering on our goal of “improving quality, reducing cost and enhancing efficiency”, while controlling different kinds of costs, we made various major achievements in commercialization, R&D of drugs, external collaborations, business operations and other aspects, which are summarized as follows:

***Continued to improve the efficiency of commercialization, and made significant progress in cost reduction and efficiency enhancement***

In recent years, we have continuously optimized the management of the organizational structure of our commercialization team, which greatly improved the efficiency of execution and sales of our commercialization team, and made positive progress in sales. During the Reporting Period, we experienced rapid growth in the revenue from sales of the core product, toripalimab. At the same time, we actively implemented the action plan for “Enhancing Quality and Efficiency with a Focus on Return” by continuously strengthening our control over various expenses, reducing unit production costs and improving the efficiency of sales, and devoted our resources to the R&D projects with greater potential. We recorded a significant decrease in losses as compared to the same period last year. In 2024, the domestic sales revenue of TUOYI® reached approximately RMB1,501 million, representing a year-on-year increase of approximately 66%. As of the end of the Reporting Period, TUOYI® had been sold in around 6,000 medical institutions and more than 3,000 specialty pharmacies and community pharmacies nationwide.

As of the date of this announcement, TUOYI® has 11 indications approved in Chinese mainland, many of which are exclusive or leading indications by the Company. Starting from January 2024, TUOYI® has three new indications, namely the first-line treatment of NPC, the first-line treatment of ESCC and the first-line treatment of NSCLC, included in the NRDL (Year 2023). In November 2024, TUOYI® has four new indications, namely the perioperative treatment of NSCLC, the first-line treatment of advanced TNBC, the first-line treatment of advanced RCC and the first-line treatment of ES-SCLC, included in the NRDL (Year 2024). Currently, 10 of its approved indications have been included in the NRDL, and it is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of melanoma, perioperative treatment of NSCLC, treatment of renal carcinoma and treatment of TNBC. The new edition of the NRDL has been officially implemented since 1 January 2025.

With the improved accessibility by virtue of the inclusion of our approved products and indications in the NRDL, the approvals for marketing of more products and indications in future, as well as continuous commercialization expansion in global markets, our commercialization competitiveness will continue to improve. We will persistently promote cost reduction and efficiency enhancement, optimize resource allocation, and further enhance the efficiency of capital use, thereby strengthening our income-generating capacity.

***Increased number of approved indications of toripalimab, and accelerated the progress of international development***

From the beginning of the Reporting Period to the date of this announcement, we continued to improve the efficiency of clinical studies and accelerate the registration process of toripalimab. Various milestones were achieved in both domestic and overseas markets, further expanding the potential patient population.



From the beginning of the Reporting Period to the date of this announcement, four sNDAs for TUOYI® were approved by the NMPA, with an indication converted from conditional approval to regular approval. As of the date of this announcement, the NMPA approved 11 indications of TUOYI®, and accepted a sNDA, many of which are exclusive or leading indications by the Company and are expected to gain first-mover advantages in the marketing of corresponding indications:

- In April 2024, the sNDA for TUOYI® in combination with axitinib for the first-line treatment for patients with medium to high risk unresectable or metastatic RCC was approved by the NMPA. This is the first approved immunotherapy for renal carcinoma in China.
- In April 2024, the NDA for toripalimab in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent locally advanced NPC, and for toripalimab, as a single agent, for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy was accepted by the DO. In October 2024, such NDA was approved by the PPB, making toripalimab the first and only immunotherapy drug for NPC in Hong Kong SAR, China.
- In June 2024, the primary endpoints of PFS (based on independent radiographic review) and OS of a multinational multi-center, randomized, open-label, active controlled phase III clinical study (the HEPATORCH study, NCT04723004) of TUOYI® in combination with bevacizumab for the first-line treatment of advanced HCC met the pre-defined efficacy boundary. In July 2024, the sNDA for TUOYI® in combination with bevacizumab for the first-line treatment for patients with unresectable or metastatic HCC was accepted by the NMPA. It took only 36 days from data readout to NDA acceptance by the NMPA. In March 2025, such sNDA has been approved by the NMPA.
- In June 2024, the sNDA for TUOYI® in combination with etoposidein plus platinum as the first-line treatment of ES-SCLC was approved by the NMPA.
- In June 2024, the sNDA for TUOYI® in combination with paclitaxel for injection (albumin-bound) for the first-line treatment of recurrent or metastatic TNBC with a well-validated test to evaluate PD-L1 positive (CPS  $\geq$  1) was approved by the NMPA, which is the first immunotherapy approved in the field of TNBC in China.
- In August 2024, the sNDA for TUOYI® as the first-line treatment for unresectable or metastatic melanoma was accepted by the NMPA.
- In January 2025, the indication of TUOYI® for the treatment of unresectable or metastatic melanoma after failure of standard systemic therapy has been approved by the NMPA for conversion from conditional approval to regular approval.

In terms of international layout, toripalimab (U.S. trade name: LOQTORZI®) was approved for marketing by the FDA in October 2023, and has been officially marketed in the United States from January 2024. At present, it is the only preferred drug recommended in the *NCCN Clinical Practice Guidelines in Oncology for Head and Neck Cancers 2025.V1* for the treatment of recurrent/metastatic NPC across all lines. We also made sound progress in the marketing applications of toripalimab in other overseas countries and regions:

- In January 2024, the NDA for toripalimab for the treatment of NPC was accepted by the HSA, which was granted a priority review designation by the HSA. In March 2025, the NDA for toripalimab (Singapore trade name: LOQTORZI®) in combination with cisplatin and gemcitabine for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic NPC has been approved by the HSA. Toripalimab has become the first and only approved immuno-oncology treatment for NPC in Singapore. The NDA was submitted under Project Orbis. Project Orbis, initiated and advocated by the Oncology Center of Excellence (OCE) of the FDA, provides a collaborative mechanism and framework among the FDA and regulatory authorities in other countries and regions, allowing different regulatory authorities to jointly review the applications for registration of oncology drugs. Toripalimab was the first domestic oncology drug to be included in Project Orbis.
- In July 2024, a positive opinion from the CHMP was obtained for the MAA of toripalimab (European trade name: LOQTORZI®), which recommends approval for the treatment of two indications: toripalimab in combination with cisplatin and gemcitabine for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic NPC, and toripalimab in combination with cisplatin and paclitaxel for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic ESCC. In September 2024, such MAA was approved by the EC. The approval is applicable to all 27 member states of the EU, Iceland, Norway and Liechtenstein, making toripalimab the first and only drug for the treatment of NPC and the only first-line treatment for advanced or metastatic ESCC regardless of PD-L1 status in Europe.
- In November 2024, toripalimab (UK trade name: LOQTORZI®) obtained the marketing authorisation from the MHRA for the treatment of two indications: toripalimab in combination with cisplatin and gemcitabine for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic NPC, and toripalimab in combination with cisplatin and paclitaxel for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic ESCC. Toripalimab has become the first and only drug for the treatment of NPC and the only first-line treatment for advanced or metastatic ESCC regardless of PD-L1 status in the UK.
- In September 2024 and November 2024, toripalimab was approved for marketing in India and Jordan, respectively, for the treatment of two indications: toripalimab in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent, locally advanced NPC and toripalimab, as a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy. Toripalimab officially commenced commercial sales in India in 2024.
- In January 2025, the NCE application for toripalimab in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent, locally advanced NPC and toripalimab, as a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy has been approved by the TGA. Toripalimab has become the first and only immuno-oncology treatment for NPC in Australia. The NCE application was submitted through Project Orbis. Additionally, the TGA also granted an orphan drug designation to toripalimab for the treatment of NPC, which to some extent accelerated the local review, approval and registration processes for toripalimab.

- In January 2025, TopAlliance has entered into a distribution and marketing agreement with LEO Pharma. TopAlliance will grant LEO Pharma the exclusive right to store, distribute, promote, market and sell toripalimab in all current member states and any future member states of the EU and the EEA, Switzerland as well as the UK (the “**Territory**”). LEO Pharma shall pay TopAlliance an upfront payment of EUR15 million, milestone payment(s) for any subsequent approved indication(s) for toripalimab in the Territory, and a revenue share of a double-digit percentage on the net sales of toripalimab throughout the Territory.

As of the date of this announcement, toripalimab has been approved for marketing in various countries and regions including Chinese mainland, Hong Kong SAR, China, the United States, the EU (including all 27 member states of the EU, Iceland, Norway and Liechtenstein), India, Jordan, the UK, Australia and Singapore, and has its marketing applications submitted/accepted in Brazil, Colombia, South Africa, Chile, Malaysia, Thailand, Indonesia, the Philippines, Vietnam, Canada, Pakistan, the United Arab Emirates, Morocco, Kuwait, and other locations. We have been cooperating on the commercialization with partners including Hikma MENA FZE (“**Hikma**”), Dr. Reddy’s Laboratories Limited (“**Dr. Reddy’s**”), Rxilient Biotech Pte. Ltd. (“**Rxilient Biotech**”) and LEO Pharma in over 80 countries, covering the Middle East and North Africa, Latin America, India, South Africa, Australia, New Zealand, Southeast Asia, the EU, Switzerland, and the UK. We and our partners are actively promoting the marketing application process for toripalimab within their cooperation territories, and actively exploring the possibility of marketing more indications in certain regions.

***Efficiently pushed forward R&D pipelines, and optimized processes to enhance long-term growth forces***

We possess a professional and experienced team in clinical R&D, and the Company has established advanced technology platforms and a comprehensive R&D system. In order to improve the efficiency of R&D, we integrated the laboratories in Wujiang, Suzhou and Zhangjiang, Shanghai to set up the Innovation Research Institute, which concentrated resources and operated in a unified manner to carry out the R&D of innovative drugs, so as to lay the foundation for commercialization expansion and enhance the long-term competitiveness and sustainable development momentum of the Company.

In April 2024, two sNDAs for ongericimab were accepted by the NMPA for the treatment of: (I) heterozygous familial hypercholesterolemia; and (II) primary hypercholesterolemia and mixed dyslipidemia in which statins are not tolerated or contraindicated. In October 2024, the NDA for ongericimab as the treatment for adult patients with primary hypercholesterolemia (non-familial) and mixed dyslipidemia was approved for marketing by the NMPA.

We are accelerating late-stage clinical pipeline R&D and marketing application for tificemalimab (an anti-tumor anti-BTLA monoclonal antibody, code: TAB004/JS004), anti-IL-17A monoclonal antibody (code: JS005), anti-PD-1/VEGF bispecific antibody (code: JS207) and others:

- Our two phase III registrational clinical studies for tificemalimab (an anti-BTLA monoclonal antibody) in combination with toripalimab are underway. We believe that the combination of the two is a promising anti-tumor treatment strategy, which is expected to increase patients’ response to immunotherapy and expand the range of potential beneficiaries.

- A randomized, double-blind, placebo-controlled, international multi-regional phase III clinical study (JUSTAR-001 study, NCT06095583) of tificemalimab in combination with toripalimab as consolidation therapy for patients with LS-SCLC without disease progression following chemo-radiotherapy. As the first confirmatory study of a monoclonal antibody targeting BTLA, this study is led by academician Yu Jinming (於金明) from the Cancer Hospital affiliated to Shandong First Medical University\* (山東第一醫科大學附屬腫瘤醫院) as the global principal investigator, and professor Cheng Ying (程穎) from Jilin Cancer Hospital\* (吉林省腫瘤醫院) as the principal investigator in China. With the plan to be carried out in more than 190 research centers in 17 countries and regions around the world, including China, the United States, and Europe, this study will recruit about 756 subjects. As of the date of this announcement, the study has been carried out in more than 150 centers across 15 countries, and enrollment is underway.
- A randomized, open-label, active controlled, multi-center phase III clinical study (NCT06170489) of tificemalimab in combination with toripalimab for the treatment of classic Hodgkin lymphoma (“cHL”). This study is the first phase III clinical study of drugs targeting BTLA in the field of hematological tumors. It aims to evaluate the efficacy and safety of tificemalimab in combination with toripalimab versus the chemotherapy selected by the investigator for anti-PD-(L)1 monoclonal antibody refractory cHL. Professor Song Yuqin (宋玉琴) from Peking University Cancer Hospital\* (北京大學腫瘤醫院) serves as the principal investigator. It is planned for the study to be carried out in about 60 research centers in China and approximately 185 patients will be recruited, and enrollment is underway.
- For JS005, the phase III registrational clinical study for moderate to severe plaque psoriasis is underway. As of the date of this announcement, all subjects have been enrolled and are being followed up.
- In March 2025, the IND application for a randomized, open-label, active controlled, multi-center phase II/III clinical study of JS207 in combination with etoposide plus platinum for the first-line treatment of ES-SCLC (study no.: JS207-003-II/III-SCLC) has been approved by the NMPA.

We also continue to explore early-stage pipelines. From the beginning of the Reporting Period to the date of this announcement, the IND applications for several products were approved by the NMPA:

- In July 2024, the IND application for JS125 (a targeted HDAC inhibitor) was accepted by the NMPA, and was approved by the NMPA in September 2024. In January 2025, JS125 in combination with JS207 has received an ethics approval for clinical trials in Australia to explore the combination.
- In January 2025, the IND application for JS212 (a recombinant humanized EGFR and HER3 ADC) has been accepted by the NMPA, and has been approved by the NMPA in March 2025.
- In February 2025, the IND application for JS213 (a PD-1 and IL-2 bifunctional antibody fusion protein) has been approved by the NMPA.

With the continuous advancement and improvement of clinical research design and technology, our phase I clinical studies are not limited to dose finding but also include diverse explorations, such as combined cohort investigations and validation of target indications. Once a signal is identified, we may then directly engage with regulatory authorities to communicate and prepare for pivotal registrational studies. We are accelerating the advancement of early-stage pipelines, including the anti-Claudin18.2 ADC (code: JS107), the oral small molecule inhibitor targeting PI3K- $\alpha$  (code: JS105), the CD20/CD3 bispecific antibody (code: JS203), the anti-DKK1 monoclonal antibody (code: JS015) and other products, and plan to push multiple pipelines into pivotal registrational clinical studies in 2025.

We will continue to optimize our clinical R&D processes, and strive to improve R&D efficiency, with the aim of bringing more safe and effective innovative drugs to patients as early as possible.

***Supported business expansion by commercialization capacity, and continued to improve the quality management system***

We have two commercial production bases. With a fermentation capacity of 4,500L (9\*500L), Wujiang production base in Suzhou completed the Pre-License Inspection (PLI) conducted by the FDA and the on-site inspection conducted by the EMA in May 2023 and March 2024, respectively. Wujiang production base in Suzhou received the CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER issued by the HPRA in accordance with the relevant regulations of the EMA in July 2024. According to the GMP mutual recognition system among the EU member states, the obtaining of the GMP certificate indicates that the production facilities with the certificate have met the GMP standards of the EU. Currently, Wujiang production base in Suzhou has obtained GMP certification from the PRC, the United States and the EU, and is responsible for the production of the commercial batches of toripalimab in locations including the United States, India and Hong Kong SAR, China at this stage. As an important support for the Company's commercial production capacity, Shanghai Lingang production base has a production capacity of 42,000L (21\*2,000L), and has obtained GMP certification from the NMPA to produce commercial batches of toripalimab injection jointly with Wujiang production base in Suzhou. By virtue of economies of scale, the expansion of production capacity of the Shanghai Lingang production base will enable the Company to gain the advantage of having more competitive production costs and support the clinical trials of our drug candidates and future production of commercial batches.

In order to strictly control its quality standards, the Company has established and continuously improved the quality audit mechanism which combines both internal and external audits. During the Reporting Period, the Group received external inspections/audits including the GMP on-site inspection by the EMA, the supervision and inspection by the Jiangsu Medical Products Administration, the supervision and inspection (unannounced inspections) by the Shanghai Medical Products Administration, and audits by customers, with a scope covering MAH management system, organizational structure, production management, quality management, laboratory management, supplier management, materials and warehousing management, equipment management, drug safety, and pharmacovigilance. All entities have successfully passed the inspections/audits and are in compliance with the standards of the quality management systems in accordance with the relevant domestic and international pharmaceutical regulatory requirements.

***Balanced talent development and compliance construction, and facilitated the steady progress of corporate development***

As of the end of the Reporting Period, the Group's number of employees was 2,578, among which 620 employees are responsible for R&D of drugs.



Adhering to the basic principle of “harmonious development and continuous symbiosis”, we sustained our current employment policy and signed labour contracts with all employees during the Reporting Period. We adhere to the principle of “equal gender”, with female employees accounting for approximately 52% of our total number of employees in 2024. We adhere to the principle of “being inclusive and diverse”. For employees with different nationalities, ethnicities, races, genders, religious beliefs and cultural backgrounds, the Company adheres to the principle of “equal pay for equal work”, and treats them equally in terms of employee recruitment, compensation and benefits, promotion, dismissal and retirement. We firmly resist the recruitment of child labour and forced labour. We have not had any illegal matters related to the employment of child labour or forced labour.

We attach importance to the career development of our employees, and implemented a unified performance management system that combines competitiveness, fairness and motivation. We protect the rights and interests of our employees in career development by building a job position hierarchy system, and provide a clear and reasonable career path and platform for our employees. At the same time, we improve the management of our training resources by formulating training management measures at the group level, and constantly adjust and improve the training content in a timely manner by collecting training needs from various business departments, so as to form a training system and create a learning culture organization. We also integrate high-quality learning resources from internal and external sources to build training courses for employees that are suitable for different types of needs. We also encourage all employees to participate in industry training and professional certification. For employees who have obtained professional title certificates, we provide them with support in applying for relevant government subsidies or bonuses. Furthermore, for outstanding R&D talents within the Company, we actively apply for national, municipal, and district-level talent programs, helping employees gain more tangible support in various aspects while they diligently dedicate themselves to their work.

Maintaining integrity and compliance is the fundamental rule of our operations. Upholding a corporate culture of operation compliance as always, we are committed to building a comprehensive compliance system at a high standard, strictly complying with relevant national laws and regulations and the regulatory policies of the pharmaceutical industry, and providing patient-centered treatment options which have better efficacy and greater cost-effectiveness. We encourage our employees to comply with laws and regulations related to the products or services of the Company as well as the highest standards of business and personal ethics. Against the backdrop of stringent regulation in the pharmaceutical industry, we will continue to build a compliance culture of “innovation-driven, academic promotion” and optimize our compliance system of “full-process guidance and supervision” to enhance the quality and efficiency of our operations and management, establish a comprehensive compliance management system and facilitate high-quality and sustainable development.

### ***Product Pipelines***

Our products concentrate on self-developed biological products with original innovation. At the same time, through co-development, formation of joint ventures, license-in and other means, we obtained the licenses of drugs or platform technologies that synergized with our own original product pipeline, so as to further expand our product pipeline. After prolonged accumulation of drug development technology, in-depth exploration in the field of translational medicine and the establishment of a new drug type platform, our innovative R&D field has expanded from monoclonal antibodies to the research and development of more drug modalities, including small molecule drugs, polypeptide drugs, ADCs, bi-specific or multi-specific antibodies, bi-specific ADCs, fusion protein and nucleic acid drugs, as well as the exploration of next-generation innovative therapies for cancer and autoimmune diseases. The Company’s product pipelines cover five major therapeutic areas including malignant tumors, autoimmune diseases, chronic metabolic diseases, neurologic diseases and infectious diseases. As of the date of this announcement, a total of four drugs (TUOYI®, JUNMAIKANG (君邁康®), MINDEWEI (民得維®) and JUNSHIDA (君邁達®)) are being commercialized, around 30 drug candidates are undergoing clinical trials, and over 20 drug candidates are at preclinical drug development stage.

# Key Projects Entering the Clinical R&D Stage (As of 27 March 2025)



Phase I/II		Phase III	Approved for marketing
JS213 PD-1×IL2	JS207 PD-1×VEGF	Tifcemalimab BTLA	Toripalimab PD-1
JS212 EGFR×HER3 ADC	JS015 DKK1	JS001sc PD-1	Adalimumab TNF-α
JS006 TIGIT	JS107 Claudin18.2 ADC	JS005 IL-17A	Deuremidevir Hydrobromide Tablets RdRp
JS007 CTLA-4	JS203 CD3×CD20		Ongericimab PCSK9
JS009 CD112R	JS105 PI3K-α		
JS112 Aurora A	JS110 XPO1		
JS214 VEGF x TGF-β	JS111 EGFR exon 20		
JS010 CGRP	JS125 HDACs		
UBP1213sc BLyS	JT002 small nucleic acid immunomodulator		

.....

- Oncology
- Immunology
- Infectious disease
- Metabolism
- Neurologic

# R&D Progress of Toripalimab

Therapeutic Area	Medicine Code	Clinical Trial Number	Indications	Pre-Clinical	Phase I	Phase II	Phase III	NDA	
Oncology	JS001 Toripalimab	NCT03013101	Melanoma (second-line treatment, monotherapy)	NMPA approved on 17 Dec 2018, converted from conditional approval to regular approval in Jan 2025					
		NCT02915432	NPC (second-line and later treatment, monotherapy)	NMPA approved (3rd-line) in Feb 2021, FDA approved in Oct 2023, approved in multiple locations worldwide					
		NCT03113266	UC (second-line treatment, monotherapy)	NMPA approved in Apr 2021					
		NCT03581786	NPC (first-line treatment, combo with chemo)	NMPA approved in Nov 2021, FDA approved in Oct 2023, approved in multiple locations worldwide					
		NCT03829969	ESCC (first-line treatment, combo with chemo)	NMPA approved in May 2022, EMA approved in Sep 2024, MHRA approved in Nov 2024					
		NCT03856411	EGFR-negative NSCLC (first-line treatment, combo with chemo)	NMPA approved in Sep 2022					
		NCT04158440	NSCLC (perioperative treatment)	NMPA approved in Dec 2023					
		NCT04394975	RCC (first-line treatment, combo with axitinib)	NMPA approved in Apr 2024					
		NCT04012606	SCLC (first-line treatment, combo with chemo)	NMPA approved in Jun 2024					
		NCT04085276	TNBC (combo with albumin-bound paclitaxel)	NMPA approved in Jun 2024					
		NCT04723004	HCC (first-line treatment, combo with bevacizumab)	NMPA approved in Mar 2025					
		NCT03430297	Melanoma (first-line treatment, monotherapy)	sNDA accepted by the NMPA					
		NCT03924050	EGFR-mutated TK-failed terminal stage NSCLC (combo with chemo)	Pivotal registered clinical trial					
		NCT04848753	ESCC (perioperative treatment)	Pivotal registered clinical trial					
		NCT04523493	HCC (first-line treatment, combo with lenvatinib)	Pivotal registered clinical trial					
		NCT03859128	HCC (postoperative adjuvant treatment)	Pivotal registered clinical trial					
		NCT05342194	Intrahepatic cholangiocarcinoma (first-line treatment, combo with lenvatinib and chemo)	Pivotal registered clinical trial					
		NCT05302284	UC (first-line treatment, combo with disitamab vedotin)	Pivotal registered clinical trial					
		NCT05180734	Adenocarcinoma of the stomach or gastroesophageal junction (postoperative adjuvant treatment)	Pivotal registered clinical trial					
		NCT06095583	LS-SCLC (consolidation treatment after chemoradiotherapy, combo with BTLA)	Pivotal registered clinical trial					
NCT06170489	Anti-PD-(L)1 mAb Refractory cHL (combo with BTLA)	Pivotal registered clinical trial							

## Our Core Products

### **TUOYI® (toripalimab, code: TAB001/JS001)**

- *Milestones and achievements of commercialization*

During the Reporting Period, TUOYI® recorded domestic sales revenue of approximately RMB1,501 million, representing a year-on-year increase of approximately 66%. The Company's self-developed toripalimab is the first domestic anti-PD-1 monoclonal antibody successfully launched in China, and is also the first innovative biological drug independently developed and manufactured in China that was approved for marketing by the FDA, addressing various malignant tumors. It was granted the "China Patent Gold Award", the highest award in the patent field nationally, and has been supported by two National Major Science and Technology Projects for "Major New Drugs Development" during the "Twelfth Five-Year Plan" and "Thirteenth Five-Year Plan" periods. The Company continued to make positive progress in sales with the increased number of toripalimab's approved indications and NRDL-included indications, improved execution of its commercialization team and international expansion.

As of the date of this announcement, toripalimab has 11 indications approved in Chinese mainland:

- treatment for unresectable or metastatic melanoma after failure of standard systemic therapy (December 2018);
- treatment for recurrent/metastatic NPC after failure of at least two lines of prior systemic therapy (February 2021);
- treatment for locally advanced or metastatic urothelial carcinoma ("UC") that failed platinum-containing chemotherapy or progressed within 12 months of neoadjuvant or adjuvant platinum-containing chemotherapy (April 2021);
- in combination with cisplatin and gemcitabine as the first-line treatment for patients with locally recurrent or metastatic NPC (November 2021);
- in combination with paclitaxel and cisplatin as the first-line treatment for patients with unresectable locally advanced/recurrent or distant metastatic ESCC (May 2022);
- in combination with pemetrexed and platinum as the first-line treatment in EGFR mutation-negative and ALK mutation-negative, unresectable, locally advanced or metastatic non-squamous NSCLC (September 2022);
- in combination with chemotherapy as perioperative treatment and subsequently, monotherapy as adjuvant therapy for the treatment of adult patients with resectable stage IIIA-IIIB NSCLC (December 2023);
- in combination with axitinib for the first-line treatment of patients with medium to high risk unresectable or metastatic RCC (April 2024);
- in combination with etoposidein plus platinum for the first-line treatment of ES-SCLC (June 2024);

- in combination with paclitaxel for injection (albumin-bound) for the first-line treatment of recurrent or metastatic TNBC with a well-validated test to evaluate PD-L1 positive (CPS  $\geq$  1) (June 2024);
- in combination with bevacizumab for the first-line treatment of patients with unresectable or metastatic HCC (March 2025).

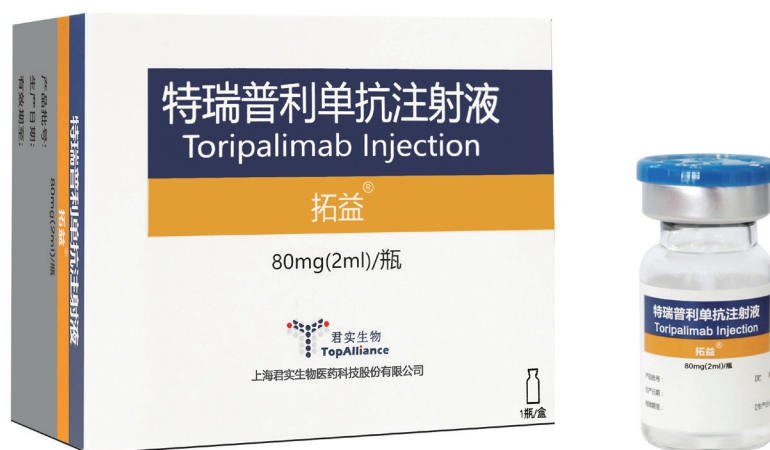
In October 2024, the indication of toripalimab for the treatment of recurrent/metastatic NPC was approved in Hong Kong SAR, China. The sNDA for TUOYI<sup>®</sup> as the first-line treatment for melanoma was accepted by the NMPA. In addition, toripalimab has been recommended and recognized by over ten definitive guidelines both domestically and internationally. It is the first domestic anti-PD-1 monoclonal antibody to be recommended by the three major definitive guidelines: the Chinese Society of Clinical Oncology (CSCO), the National Comprehensive Cancer Network (NCCN), and the European Society for Medical Oncology (ESMO).

Starting from 1 January 2025, TUOYI<sup>®</sup> has four new indications included in the NRDL. Currently, its 10 approved indications have been included in the NRDL, and it is the only anti-PD-1 monoclonal antibody included in the NRDL for the treatment of melanoma, perioperative treatment of NSCLC, treatment of renal carcinoma and treatment of TNBC. The inclusion of new indications of TUOYI<sup>®</sup> in the NRDL will further expand the coverage of patients with various types of cancers who may gain benefits, reduce the medical burden for patients and their families, and improve the affordability and accessibility of TUOYI<sup>®</sup> among patients.

In recent years, we have continuously optimized the management of the organizational structure of our commercialization team, which greatly improved the efficiency of execution and sales of our commercialization team. As of the end of the Reporting Period, TUOYI<sup>®</sup> had been sold in around 6,000 medical institutions and more than 3,000 specialty pharmacies and community pharmacies nationwide.

In terms of international layout, toripalimab had been approved for marketing as the first nasopharyngeal cancer drug in the United States in October 2023, and has been officially marketed in the United States from January 2024. As of the date of this announcement, toripalimab has been approved for marketing in various countries and regions including Chinese mainland, Hong Kong SAR, China, the United States, the EU (including all 27 member states of the EU, Iceland, Norway and Liechtenstein), India, Jordan, the UK, Australia and Singapore, and has its marketing applications submitted/accepted in Brazil, Colombia, South Africa, Chile, Malaysia, Thailand, Indonesia, the Philippines, Vietnam, Canada, Pakistan, the United Arab Emirates, Morocco, Kuwait, and other locations. We have been cooperating on the commercialization with partners including Hikma, Dr. Reddy's, Rxilient Biotech and LEO Pharma in over 80 countries, covering the Middle East and North Africa, Latin America, India, South Africa, Australia, New Zealand, Southeast Asia, the EU, Switzerland, and the UK. We and our partners are actively promoting the marketing application process for toripalimab within their cooperation territories, and actively exploring the possibility of marketing more indications in certain regions.





- *Milestones and achievements of clinical development*

Over 40 clinical studies covering more than 15 indications in respect of toripalimab have been conducted in China, the United States, Europe, Southeast Asia and other regions, involving indications such as lung cancer, nasopharyngeal cancer, esophageal cancer, gastric cancer, bladder cancer, breast cancer, liver cancer, renal cancer and skin cancer. Among the pivotal registered clinical studies, the Company has actively deployed perioperative treatment/postoperative adjuvant treatment for various types of tumors in addition to the extensive layout of toripalimab for the first-line treatment of multiple tumor types, to promote the application of cancer immunotherapy in the early treatment of cancer patients.

Progress of clinical trials in China:

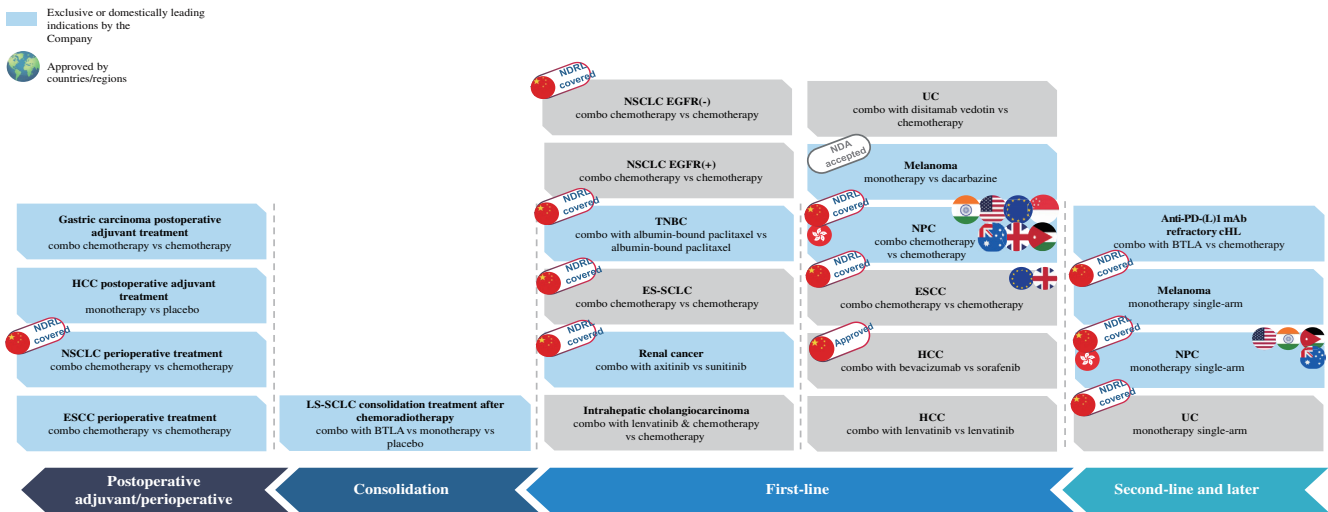
- In April 2024, the sNDA for TUOYI® in combination with axitinib for the first-line treatment for patients with medium to high risk unresectable or metastatic RCC was approved by the NMPA. This is the first approved immunotherapy for renal carcinoma in China.
- In April 2024, the NDA for toripalimab in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent locally advanced NPC, and for toripalimab, as a single agent, for the treatment of adults with recurrent, unresectable, or metastatic NPC with disease progression on or after platinum-containing chemotherapy was accepted by the DO. In October 2024, such NDA was approved by the PPB, making toripalimab the first and only immunotherapy drug for NPC in Hong Kong SAR, China.
- In June 2024, the primary endpoints of PFS (based on independent radiographic review) and OS of a multinational multi-center, randomized, open-label, active controlled phase III clinical study (the HEPATORCH study, NCT04723004) of TUOYI® in combination with bevacizumab for the first-line treatment of advanced HCC met the pre-defined efficacy boundary. In July 2024, the sNDA for TUOYI® in combination with bevacizumab for the first-line treatment for patients with unresectable or metastatic HCC was accepted by the NMPA and has been approved by the NMPA in March 2025.
- In June 2024, the sNDA for TUOYI® in combination with etoposide plus platinum as the first-line treatment of ES-SCLC was approved by the NMPA.

- In June 2024, the sNDA for TUOYI® in combination with paclitaxel for injection (albumin-bound) for the first-line treatment of recurrent or metastatic TNBC with a well-validated test to evaluate PD-L1 positive (CPS ≥ 1) was approved by the NMPA.
- In August 2024, the sNDA for TUOYI® as the first-line treatment for unresectable or metastatic melanoma was accepted by the NMPA.
- In January 2025, the indication of TUOYI® for the treatment of unresectable or metastatic melanoma after failure of standard systemic therapy has been approved by the NMPA for conversion from conditional approval to regular approval.

#### Global registration progress:

- In January 2024, the NDA for toripalimab for the treatment of NPC was accepted by the HSA, which was granted a priority review designation. In March 2025, the NDA for toripalimab (Singapore trade name: LOQTORZI®) in combination with cisplatin and gemcitabine for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic NPC has been approved by the HSA. Toripalimab has become the first and only approved immuno-oncology treatment for NPC in Singapore.
- In July 2024, a positive opinion from the CHMP was obtained for the MAA of toripalimab (European trade name: LOQTORZI®), which recommends approval for the treatment of two indications: toripalimab in combination with cisplatin and gemcitabine for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic NPC, and toripalimab in combination with cisplatin and paclitaxel for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic ESCC. In September 2024, such MAA was approved by the EC. The approval is applicable to all 27 member states of the EU, Iceland, Norway and Liechtenstein, making toripalimab the first and only drug for the treatment of NPC and the only first-line treatment for advanced or metastatic ESCC regardless of PD-L1 status in Europe.
- In November 2024, toripalimab (UK trade name: LOQTORZI®) obtained the marketing authorisation from the MHRA for the treatment of two indications: toripalimab in combination with cisplatin and gemcitabine for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic NPC, and toripalimab in combination with cisplatin and paclitaxel for the first-line treatment of adult patients with unresectable advanced, recurrent, or metastatic ESCC. Toripalimab has become the first and only drug for the treatment of NPC and the only first-line treatment for advanced or metastatic ESCC regardless of PD-L1 status in the UK.
- In September 2024 and November 2024, toripalimab was approved for marketing in India and Jordan, respectively, for the treatment of two indications: toripalimab in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent, locally advanced NPC and toripalimab, as a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy. Toripalimab officially commenced commercial sales in India in 2024.
- In January 2025, the NCE application for toripalimab in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent, locally advanced NPC and toripalimab, as a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy has been approved by the TGA. Toripalimab has become the first and only immuno-oncology treatment for NPC in Australia.

# Pivotal Registration Clinical Trial Layout of Toripalimab



- *Publication of academic results*

Our innovative products have achieved numerous remarkable academic results. During the Reporting Period, the Company’s products were featured in over 145 journal publications in total, with a combined impact factor of over 1,200. In particular, the research findings on toripalimab were published in international authoritative journals and presented at international academic conferences, such as *JAMA* and *Nature Medicine*, for multiple times. Breakthrough progress has been made in the treatment of various cancers, including lung cancer, breast cancer, esophageal cancer, nasopharyngeal carcinoma, liver cancer, and colorectal cancer, setting new records for long-term survival. From the beginning of the Reporting Period to the date of this announcement, the key innovative achievements of toripalimab are as follows:

- International academic conferences

- In May 2024, a number of studies on toripalimab were selected at the 119<sup>th</sup> American Urological Association (AUA) Annual Meeting in 2024 and the European Society for Radiation and Oncology (ESTRO) Annual Meeting in 2024, demonstrating the potential of toripalimab in the field of urinary system tumors and toripalimab in combination with radiotherapy/chemotherapy and other combination therapies in the fields of cervical cancer, colorectal cancer and NPC.
- In June 2024, a total of more than 30 studies on toripalimab were selected at the 2024 American Society of Clinical Oncology (ASCO) annual meeting, covering various fields such as head and neck cancer, lung cancer, gastric/esophageal cancer, liver cancer, colorectal cancer, bladder cancer and melanoma. Being applied in a variety of combination therapies, toripalimab as a cornerstone drug in the immuno-oncology (I-O) field demonstrated its importance and potential for having a diversified product portfolio.
- In September 2024, a number of study results on toripalimab were selected at the 2024 World Conference on Lung Cancer (WCLC).

- In September 2024, 18 studies on toripalimab were selected at the 2024 ESMO annual meeting, covering multiple tumor types such as head and neck cancer, lung cancer, breast cancer, digestive tract tumors and urinary system tumors, and involving a variety of combination therapies, and exploring new directions in immunotherapy.
- In September 2024, a number of study results on toripalimab were selected at the 27<sup>th</sup> National Clinical Oncology Conference and 2024 CSCO Academic Annual Meeting, 7 of which were selected for oral presentations at the meeting, covering multiple tumor types such as head and neck cancer, melanoma, digestive system tumors, breast cancer, urinary system tumors and soft tissue sarcoma.
- In October 2024, 6 study results on toripalimab were presented in the form of oral or poster presentations at the 2024 American Society for Radiation Oncology (ASTRO) 66<sup>th</sup> Annual Meeting, bringing to international scholars the latest cutting-edge results of radiotherapy in combination with toripalimab and other integrated treatments in the field of digestive system tumors and renal cancer.
- In October 2024, a phase II TORCH-E study of short-course radiotherapy (SCRT) in combination with toripalimab and chemotherapy in the neoadjuvant treatment of early rectal cancer was selected for an oral presentation at the 43<sup>rd</sup> Congress of the European Society of Surgical Oncology (ESSO) in 2024.
- In December 2024, a number of study results on toripalimab were selected at the ESMO Asia Congress (ESMO ASIA) and ESMO Immuno-Oncology Congress (ESMO I-O), involving head and neck cancer, lung cancer, digestive tract tumors, urinary system tumors and other fields, and exploring new strategies for immunotherapy.
- In January 2025, the updated data from the phase I/II clinical study of toripalimab in combination with fruquintinib and chemotherapy as the first-line treatment of advanced gastric cancer were presented at the 2025 ASCO Gastrointestinal Cancers Symposium (ASCO GI) with a poster presentation (Abstract No.: #423). The preliminary results of this study were selected at the 2024 ASCO GI Symposium.
- In February 2025, a number of studies on toripalimab were selected at the 2025 ASCO Genitourinary Cancers Symposium (ASCO GU) for oral or poster presentations, focusing on the perioperative treatment of urological tumors, and involving a variety of combination strategies.
- In February 2025, the updated results of the phase II clinical study of toripalimab in combination with surufatinib for the treatment of recurrent ovarian clear cell carcinoma (OCCC) were announced at the 26<sup>th</sup> European Society of Gynaecological Oncology Congress (ESGO) in 2025 (Abstract No.: #381).

➤ Publication in international journals

- In January 2024, the results of the phase III clinical study (TORCHLIGHT study) of toripalimab in combination with paclitaxel (albumin-bound) (nab-P) for the treatment for patients with initial diagnosis of stage IV or recurrent metastatic TNBC were published in *Nature Medicine* (IF: 58.7), a leading international medical journal. This is another international academic recognition of the TORCHLIGHT study following its oral presentation in the fast abstract session at the 2023 ASCO annual meeting in the form of a late-breaking abstracts (LBA). According to the study, toripalimab in combination with nab-P can significantly improve PFS, providing a promising new treatment strategy for patients with PD-L1-positive initial diagnosis of stage IV or recurrent metastatic TNBC.
- In January 2024, the phase III clinical study (NEOTORCH study) of toripalimab in combination with chemotherapy for the perioperative treatment of resectable NSCLC was published in *Journal of the American Medical Association (JAMA)*, (IF: 63.1), a leading international authoritative journal, and became the world's first study for the perioperative immunotherapy of lung cancer (covering neoadjuvant and adjuvant therapy) featured in *JAMA*. Prior to this, the results of the event-free survival (“EFS”) interim analysis of the NEOTORCH study were announced at the April session of the 2023 ASCO Plenary Series and the ASCO annual meeting.
- In July 2024, the results of a randomized, phase II clinical study of TORCH short-course radiotherapy in combination with CAPOX and toripalimab for the total neoadjuvant therapy of locally advanced rectal cancer were published in *Journal of Clinical Oncology (JCO)*, (IF: 42.1), a leading international journal in the field of oncology. TORCH is the first randomized clinical study to report a novel total neoadjuvant chemoradiotherapy in combination with immunotherapy (iTNT) and a selective watch-and-wait (W&W) strategy for pMMR/MSS (proficient mismatch repair/microsatellite-stable) locally advanced rectal cancer (LARC). The study explores the efficacy and safety of iTNT in different combination therapies. Group A first received short-course radiotherapy and then toripalimab in combination with chemotherapy for consolidation treatment, while group B first received two cycles of toripalimab in combination with chemotherapy for induction treatment and then short-course radiotherapy and immunotherapy. The results showed that both groups achieved a complete response rate (CR) of more than 50%, and more than 80% of patients achieved organ preservation.
- In July 2024, the results of a multi-center, randomized, phase II clinical study (NCT04389073) comparing different immune combination therapy regimens for the treatment of advanced HER2-negative breast cancer were published in *Nature Medicine* (IF: 58.7). The study compared the efficacy and safety of conventional chemotherapy, metronomic chemotherapy, anti-angiogenic drugs in combination with toripalimab regimens for advanced HER2-negative breast cancer. The results showed that, compared with conventional chemotherapy, toripalimab in combination with VEX (vinorelbine + cyclophosphamide + capecitabine) metronomic chemotherapy attained higher efficiency and lower toxicity, and can significantly improve the disease control rate (DCR) and PFS.



- In August 2024, the interim results of a single-center, randomized, controlled phase III clinical study (the HCHTOG1909 study, NCT04280822) were published in *Cancer Communications* (IF: 20.1). The study aims to explore the efficacy and safety of neoadjuvant toripalimab in combination with chemotherapy versus neoadjuvant chemotherapy for the treatment of resectable locally advanced ESCC. The study results showed that toripalimab in combination with paclitaxel + cisplatin as neoadjuvant therapy exhibited a trend of OS benefit. Secondary endpoints such as pathological complete response (pCR) rate, R0 resection rate and major pathological response (MPR) rate also showed certain benefits. The safety profile was consistent with that in previous studies, with no additional surgical risks introduced, suggesting the prospective change to the perioperative treatment landscape of ESCC.
- In September 2024, the full text of the results of the biomarker exploratory analysis of a randomized controlled phase III clinical study (CHOICE-01 study) of toripalimab in combination with chemotherapy for the first-line treatment of advanced NSCLC was published in *Cancer Cell* (IF: 48.8), an internationally renowned journal. Through the integrative analysis of dynamic monitoring of panoramic genomic profiles in the CHOICE-01 study, the study established a peripheral blood-based genomic immune subtypes (bGIS) method based on integrated genomic features of ctDNA, which provides a new strategy for refined stratification of the first-line immuno-chemotherapy for advanced NSCLC and points out the direction for further prospective study based on such stratification strategy in the future.
- In September 2024, the latest data from a phase Ib/II clinical study of toripalimab in combination with surufatinib and chemotherapy (etoposide+cisplatin, EP) for the first-line treatment of advanced SCLC was published in *Signal Transduction and Targeted Therapy (STTT)*, (IF: 40.8), an internationally renowned journal. The results showed that the four-drug, three-therapy regimen of toripalimab in combination with surufatinib and EP for the first-line treatment of ES-SCLC achieved an objective response rate (“**ORR**”) of 97.1%, a DCR of 100%, a median PFS of 6.9 months, and a median OS of 21.1 months, which represented the longest median survival reported in the clinical trials for the first-line treatment of advanced SCLC as of the publication date, setting a new benchmark for improvements in patient survival. Prior to this, the preliminary data from the study was selected at the 2022 ESMO-IO and the 2023 ESMO-IO.
- In October 2024, the results of a phase II NEOTAX study of toripalimab in combination with axitinib for the neoadjuvant treatment of renal cancer with inferior vena cava tumor thrombus were officially published in *Signal Transduction and Targeted Therapy (STTT)*, (IF: 40.8). NEOTAX is the first domestic clinical study targeting the down-staging of venous tumor thrombus. The results showed that toripalimab in combination with axitinib for the neoadjuvant treatment of patients with clear cell RCC and inferior vena cava tumor thrombus achieved a down-staging rate of tumor thrombus of up to 44.0%, which effectively reduced the scope and difficulty of surgery, mitigated perioperative risks, improved the success rate of surgery, and brought better survival and prognosis to patients. Prior to this, the study results were selected at the 2024 ESMO annual meeting.

- In November 2024, the results of the phase III EXTENTORCH study of toripalimab in combination with chemotherapy for the first-line treatment of ES-SCLC were published in *JAMA Oncology* (IF: 22.5), a leading international oncology journal. As the first phase III clinical study of an anti-PD-1 monoclonal antibody that successfully achieved positive results for both pre-specified primary endpoints in the field of ES-SCLC in the world, the EXTENTORCH study also announced the results of its biomarker analysis, providing more evidence-based medical support for the precise treatment of SCLC. Prior to this, the study was selected for an oral presentation in the form of a LBA at the 2023 ESMO Congress.
- In December 2024, the results of a randomized controlled, double-blind phase II study of neoadjuvant and adjuvant toripalimab in combination with concurrent chemoradiotherapy for the treatment of high-risk locoregionally advanced NPC were officially published in *Lancet Oncology* (IF: 41.6), a leading international oncology journal. The study found for the first time that neoadjuvant and adjuvant toripalimab plus concurrent chemoradiotherapy significantly improved the survival rate of patients with high-risk locally advanced NPC and reduced the risk of disease progression or death by 60%. In terms of safety, no new safety signals were identified in the toripalimab combination treatment group, and the incidence of grade  $\geq 3$  treatment-related adverse events was similar in the two groups.

#### ***Tifcemalimab (code: TAB004/JS004)***

Tifcemalimab is the world's first-in-human recombinant humanized anti-tumor anti-BTLA monoclonal antibody specific to B- and T-lymphocyte attenuator (BTLA) independently developed by us. BTLA is expressed in the T lymphocyte, B lymphocyte, and dendritic cell subpopulations. In 2005, the interaction between BTLA and its ligand, Herpes virus entry mediator (HVEM), was discovered. HVEM, a TNF receptor, is extensively expressed in the hematopoietic system and has been confirmed as the ligand of BTLA. By binding with BTLA, tifcemalimab blocks the HVEM-BTLA interaction, thereby obstructing the BTLA-mediated inhibitory signal pathways and activating the tumor-specific lymphocytes.

Tifcemalimab entered phase III clinical stage, with several phase Ib/II clinical studies in combination with toripalimab against multiple types of tumors underway in China and the United States. We believe that the combination of the two is a promising anti-tumor treatment strategy, which is expected to increase patients' response to immunotherapy and expand the range of potential beneficiaries.

- *Milestones and achievements of clinical development*

- The JUSTAR-001 study is a randomized, double-blind, placebo-controlled, international multi-regional phase III clinical study, and is aimed to evaluate the efficacy and safety of tificemalimab in combination with toripalimab compared to toripalimab alone and compared to placebo as consolidation therapy used in LS-SCLC patients without disease progression following chemoradiotherapy. As the first confirmatory study of a monoclonal antibody targeting BTLA, this study is led by academician Yu Jinming (於金明) from the Cancer Hospital affiliated to Shandong First Medical University\* (山東第一醫科大學附屬腫瘤醫院) as the global principal investigator, and professor Cheng Ying (程穎) from Jilin Cancer Hospital\* (吉林省腫瘤醫院) as the principal investigator in China. With the plan to be carried out in more than 190 research centers in 17 countries and regions around the world, including China, the United States, and Europe, this study will recruit about 756 subjects. As of the date of this announcement, the study has been carried out in more than 150 centers across 15 countries, and enrollment is underway;
- The JS004-009-III-cHL study (NCT06170489) is a randomized, open-label, active controlled, multi-center phase III clinical study, and aims to evaluate the efficacy and safety of tificemalimab in combination with toripalimab versus the chemotherapy selected by the investigator for anti-PD-(L)1 monoclonal antibody refractory cHL. This study is the first phase III clinical study of drugs targeting BTLA in the field of hematological tumors. Professor Song Yuqin (宋玉琴) from Peking University Cancer Hospital\* (北京大學腫瘤醫院) serves as the principal investigator. It is planned for the study to be carried out in about 60 research centers in China and approximately 185 patients will be recruited, and enrollment is underway.

In addition, several phase Ib/II clinical studies of tificemalimab in combination with toripalimab against multiple types of tumors are underway in China and the United States. Upon further data collection, we will make plans for subsequent registrational clinical studies based on our clinical data and communication with regulators to promote the application and commercialization of tificemalimab in combination with toripalimab in more tumor types.

- *Publication of academic results*

The preliminary clinical study results of tificemalimab alone or in combination with toripalimab have been presented at various international medical conferences. The combination demonstrated good safety profiles and encouraging efficacy in patients with small cell lung cancer, relapsed/refractory (R/R) lymphoma, and immune-refractory advanced solid tumors who have failed multiple lines of therapy.

- In June 2024, at the 2024 ASCO annual meeting, we displayed a poster (Abstract No.: #8089) containing the preliminary results of the phase I/II clinical study of tificemalimab in combination with toripalimab and chemotherapy as the first-line treatment of ES-SCLC for the first time. The study is a multi-cohort, open-label, multi-center phase Ib/II clinical study (NCT05664971) led by Professor Lu Shun from the Shanghai Chest Hospital, and is designed to evaluate the safety and efficacy of tificemalimab in combination with toripalimab and chemotherapy as the first-line treatment for patients with advanced lung cancer. Preliminary data showed that ES-SCLC patients without previous systemic anti-tumor therapy received tificemalimab (200mg, Q3W) in combination with toripalimab (240mg, Q3W) and standard chemotherapy (etoposide + carboplatin/cisplatin) for 4 cycles, then followed by tificemalimab plus toripalimab maintenance therapy, showing good anti-tumor effect: 1) Among 43 evaluable patients, the ORR of tificemalimab in combination with toripalimab and chemotherapy as first-line treatment was 86.0%, the DCR was 100%, and the median duration of response (DoR) was 4.3 months. PFS was 5.4 months, and the median OS was not reached; 2) Manageable safety profile: 97.7% of patients experienced treatment-emergent adverse events (TEAEs), and 88.6% of patients experienced  $\geq$  grade 3 TEAEs. 29.5% of patients experienced immune-related adverse events (irAEs). Tificemalimab in combination with toripalimab and chemotherapy as the first-line treatment of ES-SCLC showed encouraging clinical response rates with a manageable safety profile. The study will further evaluate patient survival benefit and long-term safety.
  
- In June 2024, at the 2024 ASCO annual meeting, the Company announced the results of the phase I dose-escalation and cohort-expansion study of tificemalimab in combination with toripalimab for American patients with advanced malignancies (Abstract No.: #2596). A total of 16 patients with advanced malignancies who had failed prior standard therapies were enrolled in the dose-escalation phase, and were administered with tificemalimab (20mg, 70mg, 200mg and 500mg, Q3W) in combination with toripalimab (240mg, Q3W). A total of 75 patients were enrolled in the cohort-expansion phase, in which five cohorts (i.e. lymphoma, melanoma, RCC, NSCLC and UC) were selected for the treatment with tificemalimab (200mg, Q3W) in combination with toripalimab (240mg, Q3W). All patients were pretreated with a median of 4 prior lines of therapy, and 75.8% of them had received anti-PD-(L)1 monoclonal antibody treatment. Results showed that: for the melanoma cohort (18 patients with evaluable efficacy), ORR was 17%, and DCR was 39%; for the RCC cohort (11 patients with evaluable efficacy), ORR was 18%, and DCR was 73%; for the NSCLC cohort (17 patients with evaluable efficacy), ORR was 6%, and DCR was 42%; for the UC cohort (9 patients with evaluable efficacy), ORR was 11%, and DCR was 22%. Results showed that tificemalimab in combination with toripalimab showed preliminary efficacy with a manageable safety profile in patients with relapsed/refractory tumors who had failed multiple lines of immunotherapy treatment. Prior to this, the preliminary results of the study on tificemalimab monotherapy for advanced solid tumors were presented at the 2022 ASCO meeting, showing the good anti-tumor activity and safety of tificemalimab.
  
- In September 2024, the updated data from the phase I/II clinical study (NCT05000684) of tificemalimab in combination with toripalimab for the treatment of refractory ES-SCLC were successfully selected at the 2024 WCLC for an oral presentation (No.: #MA17.08). The presentation demonstrated that tificemalimab in combination with toripalimab exhibited good anti-tumor activity and tolerability in the treatment of refractory ES-SCLC, with an ORR of 35.0%, a DCR of 55.0%, a PFS of 2.8 months, and an OS of 12.3 months. Prior to this, the preliminary data related to the study was announced for the first time at the 2023 ASCO meeting.

- In December 2024, the results of the phase Ib/II study of tificemalimab in combination with toripalimab and docetaxel for the second-line treatment for patients with immunotherapy-treated squamous NSCLC (Sq-NSCLC) were selected at the ESMO Asia Congress (ESMO ASIA).
- In March 2025, the latest data from the phase I/II study of tificemalimab in combination with toripalimab in previously treated advanced lung cancer (study no.: JS004-006-I/II-LC) was selected for an oral presentation on lung cancer in the Presidential Session at the 22nd Japanese Society of Medical Oncology (JSMO) Annual Meeting in 2025.

## **Other Products That Have Been Commercialized or Are in Later Stages of Clinical R&D**

### ***MINDEWEI (Deuremidevir Hydrobromide Tablets, code: JT001/VV116)***

MINDEWEI is a new oral nucleoside analog antiviral drug, which can be non-covalently bound to the active center of RdRp of SARS-CoV-2 in the form of nucleoside triphosphate, directly inhibiting the activity of RdRp of the virus and blocking the replication of virus, thus realizing the antiviral effect. Preclinical studies have shown that MINDEWEI exhibited significant antiviral effects against both the original COVID-19 strain and mutant strains, including Omicron, and exhibited no genetic toxicity. MINDEWEI was jointly developed by Shanghai Institute of Materia Medica, Chinese Academy of Sciences\* (中國科學院上海藥物研究所), Wuhan Institute of Virology, Chinese Academy of Sciences\* (中國科學院武漢病毒研究所), Xinjiang Technical Institute of Physics and Chemistry, Chinese Academy of Sciences\* (中國科學院新疆理化技術研究所), Central Asian Center of Drug Discovery and Development of Chinese Academy of Sciences\* (中國科學院中亞藥物研發中心)/China-Uzbekistan Medicine Technical Park (the Belt and Road Joint Laboratory of the Ministry of Science and Technology)\* (中烏醫藥科技城(科技部“一帶一路”聯合實驗室)), Lingang Laboratory\* (臨港實驗室), Suzhou Vigonvita Biomedical Co., Ltd.\* (蘇州旺山旺水生物醫藥有限公司) and the Company.

On 28 January 2023, the marketing of MINDEWEI for the treatment of adult patients with mild to moderate COVID-19 was conditionally approved by the NMPA. In January 2025, such indication has been approved by the NMPA for conversion from conditional approval to regular approval. MINDEWEI was included in the scope of provisional medical insurance reimbursement in January 2023, and has been officially included in the NRDL since January 2024.

After MINDEWEI was being marketed, the Company actively established a commercialization team, continuously explored sales models, and included a new sales promotion model and an internal team for MINDEWEI based on the coverage of its existing internal hospital sales team for TUOYI®. All members of the new sales team have extensive experience in promotion in the field of respiratory infections. We will continue to expand the coverage of MINDEWEI in hospitals and further improve the accessibility of MINDEWEI. As of the end of the Reporting Period, MINDEWEI had been used in more than 2,300 hospitals, including community healthcare service centers, secondary hospitals and tertiary hospitals, covering all provinces in the territory.





**JUNMAIKANG (君邁康®) (adalimumab, code: UBP1211)**

JUNMAIKANG is an adalimumab jointly developed by us, Mabwell (Shanghai) Bioscience Co., Ltd.\* (邁威(上海)生物科技股份有限公司) and its subsidiaries. As our third commercialized product, JUNMAIKANG has received support from the national “Major New Drug Development”, a major scientific and technological project, during the “Twelfth Five-Year Plan”, which brings new treatment options for Chinese patients at large with autoimmune disease after its launch. In March 2022, the marketing of JUNMAIKANG for the treatment of rheumatoid arthritis, ankylosing spondylitis and psoriasis was approved by the NMPA, with the first prescription issued in May 2022. In November 2022, the supplemental application for five additional indications of JUNMAIKANG for the treatment of Crohn’s disease, uveitis, polyarticular juvenile idiopathic arthritis, pediatric plaque psoriasis and pediatric Crohn’s disease was approved by the NMPA. Under the continuous promotion of our commercialization partners, JUNMAIKANG was newly used in 95 hospitals during the Reporting Period. As of the end of the Reporting Period, JUNMAIKANG completed the tendering process on the procurement platform as well as healthcare and insurance connection in 27 provinces, and has been used in 319 hospitals, covering 1,379 pharmacies.



## **JUNSHIDA (君適達®) (ongericimab, code: JS002)**

JUNSHIDA is a recombinant humanized anti-PCSK9 monoclonal antibody independently developed by us. In October 2023, we signed an agreement with Chongqing Bochuang Pharmaceuticals Co., Ltd.\* (重慶博創醫藥有限公司) (“**Bochuang Pharmaceuticals**”), pursuant to which we granted Bochuang Pharmaceuticals an exclusive license to conduct R&D on, manufacture and commercialize JUNSHIDA for the licensed purposes and within Chinese Mainland. Bochuang Pharmaceuticals will be responsible for the subsequent commercialization of JUNSHIDA in Chinese Mainland and will make corresponding milestone payments and sales commissions to the Company.

In October 2024, the NDA for JUNSHIDA as the treatment for adult patients with primary hypercholesterolemia (non-familial) and mixed dyslipidemia was approved for marketing by the NMPA.

In April 2024, two sNDAs for JUNSHIDA were accepted by the NMPA for the treatment of: (I) heterozygous familial hypercholesterolemia; and (II) primary hypercholesterolemia and mixed dyslipidemia in which statins are not tolerated or contraindicated. The aforesaid NDA applications are currently under review.

The significant lipid-lowering effects of ongericimab have been demonstrated in multiple phase III clinical studies, with study results frequently published in international academic journals and presented at international academic conferences. In May 2024, the results of the phase III clinical study of ongericimab for the treatment of primary hypercholesterolemia and mixed hyperlipidemia (study no.: JS002-006) were published in *Nutrition Metabolism And Cardiovascular Diseases*, an international academic journal for endocrinology and metabolism. In June 2024, the results of the phase III clinical study of ongericimab for the treatment of primary hypercholesterolemia and mixed dyslipidemia (study no.: JS002-003) were published in *Journal of the American Heart Association*. In November 2024, the full text of the data from the two clinical pharmacokinetics and pharmacodynamics studies of ongericimab in healthy subjects (phase Ia) and patients with hypercholesterolemia (phase Ib/II) was published in *Clinical and Translational Science*. In February 2025, the full text of the latest data from the phase III clinical study of ongericimab for the treatment for adult patients with heterozygous familial hypercholesterolemia (HeFH) (study no.: JS002-005) was published in *Atherosclerosis*, the official journal of the European Atherosclerosis Society (EAS), which demonstrated the potent lipid-lowering effects and favorable tolerability of ongericimab.



### ***Recombinant humanized anti-IL-17A monoclonal antibody (code: JS005)***

JS005 is a specific anti-IL-17A monoclonal antibody developed independently by us. In preclinical studies, JS005 has shown efficacy and safety comparable to those of anti-IL-17 monoclonal antibodies that have been marketed. Data from preclinical study fully depicts that JS005 has a clear target, definite efficacy, good safety, stable production process, and controllable product quality. At the 2023 annual meeting of the American College of Rheumatology (ACR), we announced the results of the Phase Ib/II clinical study of JS005 for the treatment for patients with moderate to severe psoriasis for the first time. The study results showed that JS005 has a good safety profile in the treatment for patients with moderate to severe plaque psoriasis. Compared with placebo, JS005 significantly improved the psoriasis area and severity index of patients ( $p < 0.0001$ ). The Phase III registrational clinical study of JS005 for moderate to severe plaque psoriasis is underway. As of the date of this announcement, all subjects have been enrolled and are being followed up. Enrollment for the Phase II clinical study of JS005 for the treatment of ankylosing spondylitis has been completed, and follow-up is underway.

### ***PD-1 monoclonal antibody subcutaneous injection formulation (code: JS001sc)***

JS001sc injection is a subcutaneous injection formulation developed by the Company on the basis of TUOYI®, our marketed product. The pre-clinical in vivo pharmacodynamics showed that JS001sc exhibited significant anti-tumor effect in animal models by subcutaneous injection. At the dose level of 0.3mg/kg, the anti-tumor effect of JS001sc administered by subcutaneous injection was comparable to that of toripalimab administered by intravenous injection, with no significant difference. In addition, animals had a good tolerance to JS001sc.

In April 2024, the results of the first-in-human (FIH) study of JS001sc were successfully selected at the 2024 American Association for Cancer Research (AACR) and firstly published with a poster presentation (Abstract Number: #CT113), becoming the first domestic anti-PD-1 monoclonal antibody subcutaneous injection to publish clinical study data. The FIH clinical study (NCT05751486) aims to evaluate the pharmacokinetics (PK) profile of JS001sc in patients with recurrent or metastatic NPC (RM-NPC) and determine the appropriate subcutaneous administration regimen of toripalimab for subsequent clinical trials. The results of the PK analysis showed that, in the first cycle, the exposure of the toripalimab subcutaneous regimen (360mg, Q3W) was comparable to that of the toripalimab intravenous (IV) regimen (240mg, Q3W); the ORR of the 240mg, 360mg, and 480mg subcutaneous injection groups of toripalimab were 100%, 92.3% and 92.3% respectively; in terms of safety, no new safety signals were identified.

As of the date of this announcement, the Company has been conducting a multi-center, open-label, randomized controlled, phase III clinical study to compare the pharmacokinetic profile, efficacy and safety of JS001sc and toripalimab injection in combination with standard chemotherapy for the first-line treatment of recurrent or metastatic non-squamous NSCLC. JS001sc is the first domestic anti-PD-1 monoclonal antibody subcutaneous formulation to enter phase III clinical study, and is expected to bring convenient administration to patients.

### ***Recombinant humanized anti-PD-1/VEGF bispecific antibody (code: JS207)***

JS207 is a recombinant humanized anti-PD-1/VEGF bispecific antibody self-developed by the Company, mainly used for the treatment of advanced malignant tumors. In view of the co-expression of VEGF and PD-1 in the tumor microenvironment, JS207 can simultaneously bind to PD-1 and VEGFA with high affinity, block the binding of PD-1 to PD-L1 and PD-L2 while blocking the binding of VEGF to the VEGF receptor. JS207 has the efficacy properties of both immunotherapeutic drugs and anti-angiogenic drugs, and can utilize the synergistic effects of immunotherapy and anti-angiogenesis to achieve better anti-tumor activity. Neutralization of VEGF can inhibit the proliferation of vascular endothelial cells, improve the tumor microenvironment, and increase the infiltration of cytotoxic T lymphocytes in the tumor microenvironment. The combination therapy with PD-1 antibody and VEGF blocking agent has shown strong efficacy in a variety of tumor types such as RCC, NSCLC and HCC. Due to the strong correlation between the expression of VEGF-A and PD-1 in the tumor microenvironment, compared with combination therapy, JS207 as a single agent blocking both targets may achieve higher target binding specificity, and enhance anti-tumor activity and safety.

JS207 is designed based on the high-affinity, clinically proven and differentiated anti-PD-1 drug toripalimab as the backbone. The anti-PD-1 moiety of JS207 adopts a Fab structure to maintain binding affinity to PD-1 and thereby target the tumor microenvironment. The anti-VEGF moiety has a binding affinity for human vascular endothelial growth factor that is comparable to that of bevacizumab and has demonstrated similar antitumor efficacy in animal models.

As of the date of this announcement, the IND application for a randomized, open-label, active controlled, multi-center phase II/III clinical study of JS207 in combination with etoposide plus platinum for the first-line treatment of ES-SCLC has been approved by the NMPA. In addition, the exploration of JS207 in combination with chemotherapy, monoclonal antibodies, ADCs and other drugs in NSCLC, colorectal cancer, esophageal cancer, TNBC, liver cancer and other tumor types is underway. Upon further data collection, the Company will make plans for subsequent registrational clinical studies based on the clinical data and its communication with regulators.

### **Other Products in Early Stages of R&D**

#### ***Recombinant humanized anti-CD20/CD3 bispecific antibody (code: JS203)***

JS203 is a recombinant humanized anti-CD20/CD3 bispecific antibody self-developed by the Company. CD20 is a B lymphocyte restricted differentiation antigen and one of the most successful targets for B-cell lymphoma treatment. CD3 is an important marker on the surface of T cell. The main mechanism of T cell engaging bispecific antibodies is using CD3 as a mediator to activate T cells to specifically attack tumor cells. JS203 consists of anti-CD20 segment and anti-CD3 segment. By associating and activating T cells (binding to CD3) and lymphoma cells (binding to CD20), JS203 can enable T cells to kill lymphoma cells effectively. Pre-clinical in vivo pharmacodynamics shows that JS203 has a significant anti-tumor effect. In addition, JS203 is well tolerated by animals. As of the date of this announcement, the phase I/II clinical study of JS203 is underway. It is expected that a pivotal registrational clinical trial will commence in 2025.

### ***PI3K- $\alpha$ inhibitor (code: JS105)***

JS105 is an oral small molecule inhibitor targeting PI3K- $\alpha$  jointly developed by the Company and Risen (Suzhou) Pharma Tech Co., Ltd.\* (潤佳(蘇州)醫藥科技有限公司), and is primarily used in the treatment of female (postmenopausal) and male patients with hormone receptor (HR)-positive, human EGFR 2 (HER-2)-negative, PIK3CA-mutated, advanced breast cancer who are experiencing disease progression during or after treatment with endocrine-based regimens. Preclinical studies have shown that JS105 is effective in animal models of breast cancer, and has better efficacy for patients with other solid tumors such as cervical cancer, renal cancer, colorectal cancer and esophageal cancer. JS105 has also demonstrated good safety. As of the date of this announcement, the phase I/II clinical study of JS105 monotherapy and combination therapy is underway. It is expected that a phase III clinical trial will commence in 2025.

### ***Recombinant humanized anti-Claudin18.2 monoclonal antibody-MMAE conjugate (code: JS107)***

JS107 is a recombinant humanized anti-Claudin18.2 monoclonal antibody-MMAE (Monomethyl auristatin-E) conjugate for injection developed independently by the Company. It is an ADC targeting tumor-related protein Claudin18.2, and is intended to be used for the treatment of advanced malignant tumors, such as gastric cancer and pancreatic cancer. JS107 can bind to Claudin18.2 on the surface of tumor cells, enter into tumor cells through endocytosis, and release the small molecule toxin MMAE, which has demonstrated strong lethality to tumor cells. JS107 also retained antibody-dependent cellular cytotoxicity (ADCC) and complement dependent cytotoxicity (CDC) effects, further killing tumor cells. Furthermore, due to the cell permeability of MMAE, JS107 can mediate indiscriminate killing of other tumor cells by way of its bystander effect, thereby improving the efficacy of treatment and inhibiting tumor recurrence. The preclinical in vivo pharmacodynamics showed that JS107 exhibits significant anti-tumor effect. As of the date of this announcement, the phase I/II clinical trial on the JS107 monotherapy and combination therapy is underway. It is expected that a phase III clinical trial will commence in 2025.

### ***Recombinant humanized anti-DKK1 monoclonal antibody injection (code: JS015)***

JS015 is a recombinant humanized anti-DKK1 monoclonal antibody injection developed independently by the Company that is mainly used for the treatment of advanced malignant solid tumor. DKK1 (Dickkopf-1) is a secreted protein of the DKK family, which is highly expressed in multiple gastric cancer, gastroesophageal junction cancer, myeloma, liver cancer, lung cancer, ovarian cancer and other tumor cells, and can inhibit the canonical Wnt signaling pathway through negative feedback signals. JS015 binds to human DKK1 with high affinity, and can effectively block the interaction between DKK1 and its ligand LRP5/6 and activate the Wnt signaling pathway. JS015 can inhibit the immunosuppressive effect of DKK1 in the tumor microenvironment, thereby improving the ability of immune system to kill tumor cells. The pre-clinical in vivo pharmacodynamics showed that JS015 monotherapy, JS015 in combination with toripalimab, or in combination with paclitaxel, exhibit significant anti-tumor effect. In addition, JS015 is well-tolerated by animals. As of the date of this announcement, the phase II clinical study on the JS015 is underway.



## **Future and Outlook**

With leading R&D capability and standing at the forefront of medical innovation, we see it as our mission to fulfill unmet medical needs and bring cure to the diseased. In respect of R&D of drugs, we will accelerate late-stage pipeline R&D and marketing application. We will also continue to explore early-stage pipelines and closely track relevant clinical trial data, aiming to facilitate the progress of clinical trial registration for more advantageous products and indications, thus creating a sustainable impetus for the future revenue growth of the Company. Meanwhile, we will also invest appropriate resources to explore and develop new drug targets and drug types. Based on independent R&D, we will further enhance cooperation and expand the product pipeline through license-in, formation of joint ventures and other methods to stay on the front line of R&D of innovative drugs. As for production, we plan to further increase the fermentation capacity of macromolecular drugs and explore new production processes to further improve the competitiveness of our production costs. In respect of commercialization, we will continue to improve the establishment of our marketing and commercialization teams while carrying out commercial cooperation with outstanding pharmaceutical companies in the global arena to continuously expand our international business layout. The Company is committed to becoming an innovative pharmaceutical company that operates “in China, for global”, integrating R&D, production and commercialization, and benefiting patients with world-class and trustworthy innovative drugs.

## **Financial Review**

### **1. Revenue**

As at 31 December 2024, total revenue of the Group was approximately RMB1,948 million, representing an increase of approximately 30% compared to the corresponding period in 2023, which includes: (i) revenue from pharmaceutical products of approximately RMB1,640 million, increased by approximately 38% compared to the corresponding period in 2023, which was mainly due to improvement in sales efficiency of the commercialization team and approval of more indications for TUOYI®; (ii) revenue related to out-licensing agreements of approximately RMB235 million; and (iii) revenue from technical services of approximately RMB71 million. During the Reporting Period, the domestic sales revenue of TUOYI® was approximately RMB1,501 million, representing an increase of approximately 66% compared to the corresponding period in 2023.

### **2. R&D Expense**

R&D expenses mainly include clinical research and technical service expenses, staff salary and welfare expenses, depreciation and amortization expenses and other operating expenses.

During the Reporting Period, R&D expenses were approximately RMB1,275 million, which decreased by approximately RMB662 million as compared to the corresponding period in 2023, representing a decrease of approximately 34%. R&D expenses included clinical research and technical service expenses of approximately RMB766 million, staff salary and welfare expenses of approximately RMB370 million, depreciation and amortization expenses of approximately RMB86 million and other operating expenses of approximately RMB53 million, which decreased by approximately 39%, 21%, 31% and 24% as compared to the corresponding period in 2023, respectively. As at 31 December 2023, all expenses related to the restricted share incentive scheme of the Group were recognized, and thus no share-based payment expenses were recognized during the Reporting Period.

The decrease in R&D expenses was mainly due to (i) the Group's cost control policy and efforts to optimize resource allocation and focus on R&D pipelines with greater potential, and (ii) natural decline of R&D expenditure as a number of clinical trials of our core product TUOYI® successively met the primary endpoints.

### **3. *Selling and Distribution Expenses***

Selling and distribution expenses mainly include staff salary and welfare expenses, expenses for marketing and promotion activities and other operating expenses.

During the Reporting Period, selling and distribution expenses amounted to approximately RMB985 million, which increased by approximately RMB140 million as compared to the corresponding period in 2023, representing an increase of approximately 17%. Selling and distribution expenses included staff salary and welfare expenses of approximately RMB492 million, expenses for marketing and promotion activities of approximately RMB460 million and other operating expenses of approximately RMB33 million, which increased by approximately 13%, 21% and 15% as compared to the corresponding period in 2023, respectively. As at 31 December 2023, all expenses related to the restricted share incentive scheme of the Group were recognized, and thus no share-based payment expenses were recognized during the Reporting Period.

The increase in selling and distribution expenses was mainly due to additional demand for market promotion of new indications for TUOYI®, which led to the increase in marketing and promotion expenses, and staff salary and welfare expenses.

### **4. *Administrative expenses***

Administrative expenses mainly include administrative staff cost, depreciation and amortization expenses, ordinary operating expenses and other miscellaneous expenses.

During the Reporting Period, administrative expenses amounted to approximately RMB548 million, which decreased by approximately RMB9 million as compared to the corresponding period in 2023, representing a decrease of approximately 2%. Administrative expenses included administrative staff cost of approximately RMB211 million, depreciation and amortization expenses of approximately RMB140 million, ordinary operating expenses of approximately RMB111 million and other miscellaneous expenses of approximately RMB86 million. In particular, depreciation and amortization expenses and ordinary operating expenses increased by approximately 19% and 11% respectively, while administrative staff cost and other miscellaneous expenses decreased by approximately 13% and 4% as compared to the corresponding period in 2023. As at 31 December 2023, all expenses related to the restricted share incentive scheme of the Group were recognized, and thus no share-based payment expenses were recognized during the Reporting Period.

The decrease in administrative expenses was mainly due to the decrease in administrative staff cost, which reflects the results of the Group's cost control policy. In particular, depreciation and amortization expenses and ordinary operating expenses increased compared to the corresponding period in 2023, mainly due to the transfer of a large amount of construction in progress to fixed assets at the end of 2023.

## **5. *Liquidity and Capital Resources***

As at 31 December 2024, the aggregate balance of bank balances and cash and financial products of the Group was approximately RMB2,917 million, decreased by RMB861 million compared to the balance of 31 December 2023, which ensured that our cash position remained relatively sufficient to support the Group's development. The Group's financial products were investments with original maturities of no more than 3 months and low risk, which were with fair value of approximately RMB431 million.

During the reporting period, net cash inflow from financing activities was approximately RMB1,017 million, and net cash outflow from operating activities was approximately RMB1,443 million, and net cash outflow from investing activities was approximately RMB877 million (including cash outflow in acquisition of the financial products), resulting in a decrease of RMB1,291 million in bank balances and cash from 31 December 2023 after considering the foreign exchange rate change effect.

The Group manages its capital to ensure that entities in the Group will be able to continue as a going concern while maximizing the return to its stakeholders and maintaining an adequate capital structure. The Group's overall strategy remained unchanged throughout the year.

The capital structure of the Group consists of net debts, which includes borrowings, lease liabilities and other financial liabilities, net of bank balances and cash, and equity of the Group, comprising issued share capital, other reserves and non-controlling interests. The management of the Group will regularly review the capital structure on a continuous basis, considering the cost of capital and the risk associated with the capital, so as to better control and reduce the cost of capital.

## **6. *Listing on the STAR Market, Placing of H Shares, Issuance of A Shares and Use of Proceeds***

As approved by the China Securities Regulatory Commission (Zheng Jian Xu Ke [2020] No. 940) (證監許可[2020]940號文), the Company issued 87,130,000 ordinary shares (A Shares) with a nominal value of RMB1.00 to the public in a public offering in July 2020 at the issue price of RMB55.50 per share to allow the Company access a more established platform in the PRC capital market. The gross proceeds amounted to approximately RMB4,836 million. After deducting issuance expenses of approximately RMB339 million in accordance with the related requirements, the net proceeds amounted to approximately RMB4,497 million. The net proceeds from the listing of A Shares have been used and will be used in accordance with the uses disclosed in the Company's A share prospectus dated 8 July 2020.

Committed investment projects	Planned use of proceeds RMB'000	Unutilized proceeds as at 31 December 2023 RMB'000	Proceeds utilized during the Reporting Period RMB'000	Utilized Proceeds as at 31 December 2024 RMB'000	Unutilized Proceeds as at 31 December 2024 RMB'000	Expected timeline for application of the unutilized proceeds
Research and development projects of innovative drugs	1,200,000	-	(16)	1,216,655	-	Was fully utilized by 31 December 2022
Junshi Biotech Industrialization Lingang Project	700,000	-	-	700,000	-	Was fully utilized by 31 December 2020
Repayment of bank loans and replenishment of liquidity	800,000	-	-	824,509	-	Was fully utilized by 30 June 2022
Surplus proceeds	1,796,978	233,768	44,304	1,610,669	190,509	Was fully utilized by 31 January 2025 <sup>(Note 3)</sup>
	<u>4,496,978<sup>(Note 1)</sup></u>	<u>223,768<sup>(Note 2)</sup></u>	<u>44,288<sup>(Note 2)</sup></u>	<u>4,351,833<sup>(Note 1)</sup></u>	<u>190,509<sup>(Notes 1&amp;2)</sup></u>	

*Notes:*

1. The difference between (i) the sum of utilized proceeds and the unutilized proceeds and (ii) the net proceeds from the issuance represents bank charges, foreign exchange gains and interests generated from bank saving accounts.
2. The difference between (i) the sum of proceeds utilized during the Reporting Period and unutilized proceeds as at 31 December 2024 and (ii) unutilized proceeds as at 31 December 2023 represents bank charges, foreign exchange gains and interests generated from bank saving accounts.
3. The proceeds were not utilized by 31 December 2024 due to the protracted regulatory account approval process. The remaining balance has been fully utilized by 31 January 2025.

On 23 June 2021, the Company completed the placing of an aggregate of 36,549,200 new H shares (the “**Placing Shares**”) under general mandate pursuant to a placing agreement dated 16 June 2021 entered into by and among the Company, J.P. Morgan Securities plc (as sole placing agent), Guotai Junan Securities (Hong Kong) Limited (as co-managers) and Caitong International Securities Co., Limited (as co-managers). The Placing Shares were issued to not less than six placees who were professional, institutional and/or other investors and who were independent of, and not connected with the Company and its connected persons (as defined in the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Hong Kong Listing Rules**”)) at a placing price of HK\$70.18 per H share. The market price of the H shares of the Company (“**H Shares**”) on 16 June 2021 was HK\$70.65 per H share. The net cash inflow from the placing was approximately RMB2,104 million. The net proceeds from the placing were intended to be used by the Group towards the R&D of drugs and pipeline expansion, expansion of the commercialization team, domestic and overseas investment, mergers and acquisitions, and business development, and general corporate purposes. The Board considered that the placing was beneficial to the Company for the

following reasons: (a) available funds would be brought by the net proceeds from the placing for the Company's sustainable development to enhance the development and commercialized layout of potential first-in-class drugs in the international market, promote and accelerate the implementation of clinical trials of more first-in-class drugs in international multi-centers, and arrange and expand new-generation platforms and R&D technologies, to further improve the Company's competitiveness; and (b) it could expand the shareholder base of the Company, optimize the shareholding structure and further attract more international renowned investment institutions with long-term strategic values through the platform of The Stock Exchange of Hong Kong Limited. For further details of the placing, please refer to the Company's announcements dated 16 June 2021 and 23 June 2021.

As at 30 June 2024, all of the net proceeds from the placing has been utilized. The following table sets out the intended use and actual usage of the net proceeds from the placing as at 31 December 2024:

Purpose of the proceeds	Intended use of the net proceeds (Approx. RMB million)	Unutilized proceeds as at 31 December 2023 (Approx. RMB million)	Proceeds utilized during the Reporting Period (Approx. RMB million)	Proceeds utilized as at 31 December 2024 (Approx. RMB million)	Unutilized proceeds as at 31 December 2024 (Approx. RMB million)	Expected timeline for application of the unutilized proceeds
R&D of drugs and pipeline expansion	815	2	2	814	–	Was fully utilized by 30 June 2024
Expansion of the commercialization team	1	–	–	1	–	Was fully utilized by 31 December 2022
Domestic and overseas investment, mergers and acquisitions & business development	285	–	–	285	–	Was fully utilized by 30 June 2022
General corporate purpose	1,003	–	–	1,000	–	Was fully utilized by 31 December 2022
	<u>2,104<sup>(Note)</sup></u>	<u>2</u>	<u>2</u>	<u>2,100<sup>(Note)</sup></u>	<u>–<sup>(Note)</sup></u>	

*Note:*

The difference between (i) the sum of proceeds utilized and the unutilized proceeds and (ii) the net proceeds from the Placing represents bank charges, foreign exchange losses and interests generated from bank saving accounts.



As approved by the China Securities Regulatory Commission (Zheng Jian Xu Ke [2022] No. 2616) (證監許可[2022]2616號文), the Company issued 70,000,000 ordinary shares (A Shares) with a nominal value of RMB1.00 to 17 target subscribers (including securities investment fund management companies, securities firms, trust investment companies, finance companies, insurance institutional investors, qualified foreign institutional investors, and other domestic legal persons investors and natural persons, who/which satisfy the relevant requirements of the China Securities Regulatory Commission) on 2 December 2022 at the issue price of RMB53.95 per share. The gross proceeds amounted to approximately RMB3,777 million. After deducting issuance expenses of approximately RMB32 million in accordance with the related requirements, the net proceeds amounted to approximately RMB3,745 million. The net proceeds from the issuance of A Shares have been used and will be used in accordance with the uses disclosed in the Company's circular dated 7 March 2022, announcements dated 7 March 2022, 14 June 2022 and 30 May 2024. The market price of A Shares on 2 December 2022 was RMB61.23 per A share. The Company considered that the projects funded by the proceeds involved in the issuance of A Shares would accelerate the Company's clinical research work and promote the marketing process of relevant products in the PRC and overseas, enhance the synergy between preclinical and clinical research, and relieve tensions in R&D and operation funds of the Company to a certain extent, which are conducive to the realization of the Company's core development strategy and the sustainable and sound development of the production and operation of the Company.

Purpose of the proceeds	Intended use of the net proceeds (Approx. RMB million)	Unutilized proceeds as at 31 December 2023 (Approx. RMB million)	Proceeds utilized during the Reporting Period (Approx. RMB million)	Proceeds utilized as at 31 December 2024 (Approx. RMB million)	Unutilized proceeds as at 31 December 2024 (Approx. RMB million)	Expected timeline for application of the unutilized proceeds
R&D projects of innovative drugs	3,464	3,077	345	732	2,733	Expected to be fully utilized by 31 December 2026
Shanghai Junshi Biotech headquarters and R&D base project	281	137	79	223	57	Expected to be fully utilized by 31 December 2026
	<u>3,745</u>	<u>3,214</u>	<u>424</u>	<u>955</u>	<u>2,790</u>	

# CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE YEAR ENDED 31 DECEMBER 2024

	NOTES	Year ended 31 December	
		2024 RMB'000	2023 RMB'000
Revenue	3	1,948,317	1,502,550
Cost of sales and services		<u>(498,861)</u>	<u>(667,290)</u>
Gross profit		1,449,456	835,260
Other income	4	101,509	150,784
Other gains and losses	5	(16,101)	11,523
Impairment losses under expected credit loss model, net of reversal		19,726	(23,484)
Research and development expenses		(1,275,270)	(1,937,470)
Selling and distribution expenses		(984,554)	(844,356)
Administrative expenses		(547,713)	(556,808)
Share of losses of joint ventures		(13,201)	(5,031)
Share of losses of associates		(21,825)	(55,453)
Other expenses		(19,703)	(35,846)
Finance costs		<u>(51,352)</u>	<u>(29,006)</u>
Loss before tax		(1,359,028)	(2,489,887)
Income tax expense	6	<u>(22,552)</u>	<u>(43,995)</u>
Loss for the year		<u>(1,381,580)</u>	<u>(2,533,882)</u>
<b>Other comprehensive (expense) income for the year</b>			
<b>Item that will not be reclassified to profit or loss</b>			
Fair value loss on equity instruments at fair value through other comprehensive income ("FVTOCI")		(21,619)	(83,871)
<b>Item that may be reclassified subsequently to profit or loss</b>			
Exchange differences arising on translation of foreign operations		<u>3,749</u>	<u>10,213</u>
Other comprehensive expense for the year		<u>(17,870)</u>	<u>(73,658)</u>
Total comprehensive expense for the year		<u>(1,399,450)</u>	<u>(2,607,540)</u>
<b>Loss for the year attributable to:</b>			
Owners of the Company		(1,282,398)	(2,281,624)
Non-controlling interests		<u>(99,182)</u>	<u>(252,258)</u>
		<u>(1,381,580)</u>	<u>(2,533,882)</u>

	<i>NOTES</i>	Year ended 31 December	
		2024	2023
		<i>RMB'000</i>	<i>RMB'000</i>
<b>Total comprehensive expense for the year attributable to:</b>			
Owners of the Company		(1,300,268)	(2,355,282)
Non-controlling interests		<u>(99,182)</u>	<u>(252,258)</u>
		<b><u>(1,399,450)</u></b>	<b><u>(2,607,540)</u></b>
<b>Loss per share</b>			
Basic (RMB yuan)	7	<u>(1.30)</u>	<u>(2.32)</u>
Diluted (RMB yuan)		<u>(1.30)</u>	<u>(2.32)</u>

**CONSOLIDATED STATEMENT OF FINANCIAL POSITION**  
**AT 31 DECEMBER 2024**

		<b>At 31 December</b>	
	<i>NOTES</i>	<b>2024</b>	<b>2023</b>
		<b>RMB'000</b>	<b>RMB'000</b>
<b>Non-current assets</b>			
Property, plant and equipment		4,163,872	3,789,409
Right-of-use assets		456,500	463,915
Intangible assets		120,504	134,417
Interests in joint ventures		70,154	74,656
Interests in associates		153,181	167,920
Deferred tax assets		87,045	103,396
Other assets, prepayments and other receivables	<i>10</i>	461,945	188,388
Other financial assets		<u>1,003,070</u>	<u>890,536</u>
		<b>6,516,271</b>	<b>5,812,637</b>
<b>Current assets</b>			
Inventories		584,471	538,053
Trade receivables	<i>9</i>	509,817	479,723
Other assets, prepayments and other receivables	<i>10</i>	256,820	744,388
Other financial assets		430,508	–
Restricted bank deposits		15,522	9,521
Bank balances and cash		<u>2,486,679</u>	<u>3,778,142</u>
		<b>4,283,817</b>	<b>5,549,827</b>
<b>Current liabilities</b>			
Trade and other payables	<i>11</i>	1,548,420	1,706,015
Income tax payable		12,443	18,017
Borrowings	<i>12</i>	894,601	539,391
Deferred income		30,640	2,400
Contract liabilities		8,166	146,298
Provisions and other liabilities		9,567	27,104
Lease liabilities		<u>30,294</u>	<u>35,931</u>
		<b>2,534,131</b>	<b>2,475,156</b>
<b>Net current assets</b>		<u><b>1,749,686</b></u>	<u><b>3,074,671</b></u>
<b>Total assets less current liabilities</b>		<u><b>8,265,957</b></u>	<u><b>8,887,308</b></u>

		<b>At 31 December</b>	
	<i>NOTES</i>	<b>2024</b>	2023
		<b>RMB'000</b>	<b>RMB'000</b>
<b>Non-current liabilities</b>			
Borrowings	<i>12</i>	<b>1,979,680</b>	1,195,794
Deferred income		<b>151,273</b>	181,064
Other financial liabilities		<b>158,434</b>	152,791
Lease liabilities		<b>26,313</b>	17,451
		<u><b>2,315,700</b></u>	<u>1,547,100</u>
<b>Net assets</b>		<u><b>5,950,257</b></u>	<u>7,340,208</u>
<b>Capital and reserves</b>			
Share capital	<i>13</i>	<b>985,690</b>	985,690
Treasury share	<i>14</i>	<b>(30,892)</b>	(26,891)
Reserves		<b>4,923,753</b>	6,212,023
		<u><b>5,878,551</b></u>	<u>7,170,822</u>
Equity attributable to owners of the Company		<b>71,706</b>	169,386
Non-controlling interests		<u><b>5,950,257</b></u>	<u>7,340,208</u>
<b>Total equity</b>		<u><b>5,950,257</b></u>	<u>7,340,208</u>



# NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEAR ENDED 31 DECEMBER 2024

## 1. GENERAL

Shanghai Junshi Biosciences Co., Ltd.\* (the “Company”) was established in the People’s Republic of China (the “PRC”) on 27 December 2012 and converted into a joint stock company with limited liability in May 2015. In August 2015, the Company’s domestic shares became listed on the National Equities Exchange and Quotations (“NEEQ”) (stock code: 833330). On 24 December 2018, the Company’s H shares became listed on the Main Board of The Stock Exchange of Hong Kong Limited (the “Stock Exchange”) (stock code: 1877). The domestic shares of the Company were delisted from NEEQ since 8 May 2020, and were converted to A shares and listed on the STAR Market of the Shanghai Stock Exchange on 15 July 2020 (stock code: 688180). The Company is ultimately controlled by Mr. Xiong Jun, who is also the Chairman, legal representative and executive director of the Company, and Mr. Xiong Fengxiang, father of Mr. Xiong Jun. The respective addresses of the registered office and principal place of business of the Company are Room 1003, Level 10, Building 2, Nos. 36 and 58, Hai Qu Road, China (Shanghai) Pilot Free Trade Zone, the PRC and 5/F, Manulife Place 348 Kwun Tong Road, Kowloon, Hong Kong.

The principal activities of the Company and its subsidiaries (the “Group”) are mainly discovery, development and commercialisation of innovative drugs.

The consolidated financial statements are presented in Renminbi (“RMB”), which is also the functional currency of the Company.

## 2. APPLICATION OF NEW AND AMENDMENTS TO IFRS ACCOUNTING STANDARDS AND CHANGE IN KEY SOURCES OF ESTIMATION UNCERTAINTY

### 2.1 Application of new and amendments to IFRS Accounting Standards

#### *Amendments to IFRS Accounting Standards that are mandatorily effective for the current year*

In the current year, the Group has applied the following amendments to IFRS Accounting Standards issued by the International Accounting Standards Board (the “IASB”) for the first time, which are mandatorily effective for the Group’s annual period beginning on 1 January 2024 for the preparation of the consolidated financial statements:

Amendments to IFRS 16	Lease Liability in a Sale and Leaseback
Amendments to IAS 1	Classification of Liabilities as Current or Non-current
Amendments to IAS 1	Non-current Liabilities with Covenants
Amendments to IAS 7 and IFRS 7	Supplier Finance Arrangements

The application of the amendments to IFRS Accounting Standards in the current year has had no material impact on the Group’s financial positions and performance for the current and prior years and/or on the disclosures set out in these consolidated financial statements.

## ***New and Amendments to IFRS Accounting Standards in issue but not yet effective***

The Group has not early applied the following new and amendments to IFRS Accounting Standards that have been issued but are not yet effective:

Amendments to IFRS 9 and IFRS 7	Amendments to the Classification and Measurement of Financial Instruments <sup>3</sup>
Amendments to IFRS 9 and IFRS 7	Contracts Referencing Nature-dependent Electricity <sup>3</sup>
Amendments to IFRS 10 and IAS 28	Sale or Contribution of Assets between an Investor and its Associate or Joint Venture <sup>1</sup>
Amendments to IFRS Accounting Standards	Annual Improvements to IFRS Accounting Standards — Volume 11 <sup>3</sup>
Amendments to IAS 21	Lack of Exchangeability <sup>2</sup>
IFRS 18	Presentation and Disclosure in Financial Statements <sup>4</sup>

<sup>1</sup> Effective for annual periods beginning on or after a date to be determined.

<sup>2</sup> Effective for annual periods beginning on or after 1 January 2025.

<sup>3</sup> Effective for annual periods beginning on or after 1 January 2026.

<sup>4</sup> Effective for annual periods beginning on or after 1 January 2027.

Except for the new IFRS Accounting Standard mentioned below, the directors of the Company anticipate that the application of all the amendments to IFRS Accounting Standards will have no material impact on the consolidated financial statements in the foreseeable future.

### ***IFRS 18 Presentation and Disclosure in Financial Statements***

IFRS 18 *Presentation and Disclosure in Financial Statements*, which sets out requirements on presentation and disclosures in financial statements, will replace IAS 1 *Presentation of Financial Statements*. This new IFRS Accounting Standard, while carrying forward many of the requirements in IAS 1, introduces new requirements to present specified categories and defined subtotals in the statement of profit or loss; provide disclosures on management-defined performance measures in the notes to the financial statements and improve aggregation and disaggregation of information to be disclosed in the financial statements. In addition, some IAS 1 paragraphs have been moved to IAS 8 and IFRS 7. Minor amendments to IAS 7 *Statement of Cash Flows* and IAS 33 *Earnings per Share* are also made.

IFRS 18, and amendments to other standards, will be effective for annual periods beginning on or after 1 January 2027, with early application permitted. The application of the new standard is expected to affect the presentation of the statement of profit or loss and disclosures in the future financial statements. The Group is in the process of assessing the detailed impact of IFRS 18 on the Group's consolidated financial statements.

## **2.2 Change in key sources of estimation uncertainty**

### ***Useful lives of property, plant and equipment***

Over the years, the Group has developed policies and procedures to regularly maintain and overhaul the property, plant and equipment. The Group's management is of the view that given the current conditions of property, plant and equipment, it is reasonable to revise the estimation of useful lives of property, plant and equipment in order to more objectively and fairly reflect the impact of depreciation on the Group's operating results. This revised estimation is made with reference to the useful lives of property, plant and equipment of similar nature and functions in the industry. The new estimated useful lives are listed as follow with effect from 1 January 2024:

Properties	change from 20 years to 20 to 40 years
Machinery and equipment	change from 10 years to 10 to 15 years
Vehicles	unchanged at 5 years
Furniture fixtures	unchanged at 3 to 5 years
Other equipment	change from 3 to 5 years to 3 to 10 years

The change of estimation will apply prospectively and does not require retrospective adjustment, which had no impact on the Group's financial positions and performance for prior periods.

Based on the revised useful lives, the annual depreciation charge for the year ended 31 December 2024 decreased by approximately RMB49 million.

### 3. REVENUE AND SEGMENT INFORMATION

The Group derives its revenue from the transfer of goods and services over time and at a point in time in the following major revenue sources:

	<b>Year ended 31 December</b>	
	<b>2024</b>	2023
	<b>RMB'000</b>	RMB'000
<b>Timing of revenue recognition</b>		
<i>At a point in time</i>		
Sale of pharmaceutical products	<b>1,640,138</b>	1,190,426
Licensing income	<b>235,446</b>	283,725
Others	<b>1,814</b>	5,046
	<b>1,877,398</b>	1,479,197
<i>Over time</i>		
Service income	<b>70,919</b>	23,353
	<b>1,948,317</b>	1,502,550

#### **Sales of pharmaceutical products**

Revenue is recognised when control of the goods has been transferred, being when the goods have been delivered to the customer's specific location. Transportation and handling activities that occur before customers obtain control are considered as fulfilment activities. Following delivery, the customer bears the risks of obsolescence and loss in relation to the goods. A receivable is recognised by the Group when the goods are delivered to the customer. The normal credit term is ranged from 30 to 60 days (2023: 45 to 60 days) upon delivery.

Under the Group's standard contract terms, customers have a right to return products which are close to expiry dates. The Group uses its accumulated historical experience to estimate the number of return on a portfolio level using the expected value method. Revenue is recognised for sales which are considered highly probable that a significant reversal in the cumulative revenue recognised will not occur. A refund liability is recognised for sales in which revenue has yet to be recognised. The Group's right to recover the product when customers exercise their right is recognised as a right to returned goods asset and a corresponding adjustment to cost of sales.

The transaction price received by the Group is recognised as a contract liability until the goods have been delivered to the customers. All sales of goods are for a period of one year or less. As permitted under IFRS 15, the transaction price allocated to these unsatisfied contracts is not disclosed.

## **Licensing income**

During the years ended 31 December 2024 and 2023, the Group has several exclusive license development and commercialisation agreements, pursuant to which the Group may receive upfront payment, milestone payments and sales-based royalty. The Group recognises non-refundable upfront payments as revenue at a point in time upon the grant of the license, which is the time the customers obtain control on the usage of intellectual property.

For contracts that contain variable consideration in relation to milestone payment and sales-based royalty from license agreement, the Group estimates the amount of consideration to which it will be entitled using the most likely amount, which best predicts the amount of consideration to which the Group will be entitled. The potential milestone payments that the Company is eligible to receive were considered as variable consideration as all milestone amounts were fully constrained due to uncertainty of achievement.

The estimated amount of variable consideration is included in the transaction price only to the extent that it is highly probable that such an inclusion will not result in a significant revenue reversal in the future when the uncertainty associated with the variable consideration is subsequently resolved.

At the end of each reporting period, the Group updates the estimated transaction price (including updating its assessment of whether an estimate of variable consideration is constrained) to represent faithfully the circumstances present at the end of the reporting period and the changes in circumstances during the reporting period.

Notwithstanding the above criteria, the Group shall recognise revenue for a sales-based royalty promised in exchange for a licence of intellectual property only when (or as) the later of the following events occurs:

- the subsequent sale occurs; and
- the performance obligation to which some or all of the sales-based royalty has been allocated has been satisfied (or partially satisfied).

The normal credit term is ranged from 30 to 120 days (2023: 45 days) upon issuance of invoices.

## **Service income**

The Group provides research and development services. Service income is recognised either at a point in time or over time, depending on the type of service provided. Revenue is recognised over time for time-based service income as the Group does not create an asset with an alternative use and the Group has an enforceable right to payment for performance completed to date. For over time revenue recognition, the progress towards complete satisfaction of a performance obligation is measured based on output method. Under the output method, the progress of performance determined based on the goods or services delivered to customers.

The transaction price received by the Group is recognised as a contract liability until the services have been delivered to the customer. All sales of services are for a period of one year or less. As permitted under IFRS 15, the transaction price allocated to these unsatisfied contracts is not disclosed.

The normal credit term is ranged from 15 to 45 days (2023: 45 to 60 days) upon issuance of invoices.

## **Segment information**

For the purpose of resources allocation and performance assessment, the Group's management, being the chief operating decision maker, reviews the consolidated results when making decisions about allocating resources and assessing performance of the Group as a whole. The Group has only one reportable segment.

#### 4. OTHER INCOME

	Year ended 31 December	
	2024	2023
	RMB'000	RMB'000
Bank interest income	43,630	99,426
Government grants related to property, plant and equipment ( <i>Note a</i> )	9,600	2,802
Other subsidies ( <i>Note b</i> )	46,027	48,143
Others	2,252	413
	101,509	150,784
	101,509	150,784

*Notes:*

- (a) Amounts represent subsidies from the PRC government specifically for the capital expenditure incurred for the acquisition of buildings situated on leasehold land in the PRC and machineries, which is recognised as other income over the estimated useful life of the respective assets.
- (b) Amounts mainly represent subsidies from PRC government for research and development activities, which are recognised as other income upon meeting specific conditions and incentives which have no specific conditions attached to the grants.

#### 5. OTHER GAINS AND LOSSES

	Year ended 31 December	
	2024	2023
	RMB'000	RMB'000
Fair value loss of other financial assets measured at FVTPL	(38,620)	(144,942)
Gain on disposal of an associate	–	130,240
Gain on capital reduction of a joint venture and an associate	2,476	–
Loss on disposal of property, plant and equipment	(809)	(2,296)
Other gain ( <i>Note</i> )	14,234	30,598
(Loss) gain on termination of leases	(59)	584
Exchange gains (losses), net	8,266	(2,661)
Others	(1,589)	–
	(16,101)	11,523
	(16,101)	11,523

*Note:*

During the year ended 31 December 2024, the Group transferred certain rights under the license agreement to Excellmab Pte. Ltd. (“**Excellmab**”) in exchange of 40% equity interest in Excellmab and recognised a gain of RMB14,234,000. During the year ended 31 December 2023, the Group transferred certain developing pipelines to Shanghai Anlingke Biopharmaceutical Co., Ltd.\* 上海安領科生物醫藥有限公司 (“**Anlingke**”) in exchange of 9.45% equity interest in Anlingke, a related party of the Group. One of the Company’s non-executive directors who resigned in June 2024 is also the chairman of Anlingke. The transaction results in a gain of RMB30,598,000, representing the fair value of the equity interest in Anlingke on the date of transfer.

## 6. INCOME TAX EXPENSE

	Year ended 31 December	
	2024	2023
	RMB'000	RMB'000
Current tax		
United States Corporate Income Tax	3,021	(88,214)
Singapore Corporate Income Tax	1,634	–
India Corporate Income Tax	1,545	7,178
Others	1	–
	<u>6,201</u>	<u>(81,036)</u>
Deferred tax	16,351	125,031
	<u>22,552</u>	<u>43,995</u>

Under the law of the PRC Enterprise Income Tax (the “**EIT Law**”) and Implementation Regulations of the EIT Law, the tax rate of the Company and its PRC subsidiaries is 25% for both years.

The Company and its certain subsidiaries have been accredited as “High and New Technology Enterprises” for a period of three years starting from 2024 to 2027. Accordingly, the profit derived by the Company and these subsidiaries is subject to 15% Enterprise Income Tax rate for the reporting period.

TopAlliance Biosciences Inc., a wholly-owned subsidiary of the Company, is subject to the US California Corporate Income Tax rate of 8.84% (2023: 8.84%) for the year ended 31 December 2024. Taxation arising in other jurisdictions is calculated at the rates prevailing in the relevant jurisdictions.

During the year ended 31 December 2024, the Company is subject to a United States withholding tax on licensing income received from a US-based customer amounting to RMB2,608,000, a Singapore withholding tax on licensing income received from a Singapore-based customer amounting to RMB1,634,000, and an India withholding tax on licensing income received from an India-based customer amounting to RMB1,545,000. The effective withholding tax rate was 10% (2023: 10%).

During the year ended 31 December 2023, the Company received a refund of United States Corporate Income Tax previously withheld on licensing income from a United States based customer amounting to RMB106,231,000, and the Company is subject to a United States withholding tax on licensing income received from a US-based customer and an India withholding tax on licensing income received from an India-based customer, amounting to RMB18,017,000 and RMB7,178,000, respectively. The effective withholding tax rate was 10%.



## 7. LOSS PER SHARE

### (a) Basic

The calculation of the basic loss per share attributable to owners of the Company is based on the following data:

	Year ended 31 December	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Loss for the year attributable to owners of the Company for the purpose of basic loss per share	<u>(1,282,398)</u>	<u>(2,281,624)</u>

### Number of shares:

	Year ended 31 December	
	2024	2023
Weighted average number of ordinary shares for the purpose of basic loss per share	<u>984,908,447</u>	<u>985,302,166</u>

During the year ended 31 December 2023, the Company repurchased 679,027 ordinary shares (A Shares). During the year ended 31 December 2024, the Company repurchased 136,844 ordinary shares (A Shares) and had accumulated a total of 815,871 treasury shares. The weighted average number of ordinary shares for the purpose of basic loss per share for the year ended 31 December 2024 excludes treasury shares repurchased.

The weighted average number of ordinary shares for the purpose of basic loss per share for the year ended 31 December 2023 excludes treasury shares repurchased and has been adjusted for the issuance of 2,818,231 shares upon the exercise of RSUs on 2 February 2023.

### (b) Diluted

The computation of diluted loss per share for the years ended 31 December 2024 and 31 December 2023 do not assume the exercise of the Company's outstanding RSUs as this would be anti-dilutive. Accordingly, diluted loss per share for the years ended 31 December 2024 and 2023 are the same as basic loss per share for the respective year.

## 8. DIVIDENDS

No dividend was paid or proposed by the Company during the years ended 31 December 2024 and 2023, nor has any dividend been proposed since the end of the reporting period.

## 9. TRADE RECEIVABLES

	At 31 December	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Trade receivables	513,899	498,080
Less: Allowance for credit losses	<u>(4,082)</u>	<u>(18,357)</u>
	<u><b>509,817</b></u>	<u><b>479,723</b></u>

The trade receivables are receivables from contracts with customers.

As at 1 January 2023, the trade receivables from contracts with customers amounted to RMB232,725,000, after net of allowance for credit losses RMB18,000.

The aged analysis of the Group's trade receivables net of allowance for credit losses, based on invoice date, at the end of each reporting period are as follows:

	At 31 December	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
0 – 90 days	400,070	462,972
91 – 180 days	18,506	9,484
Over 180 days	<u>91,241</u>	<u>7,267</u>
	<u><b>509,817</b></u>	<u><b>479,723</b></u>

As at 31 December 2024, included in the Group's trade receivables balance are debtors with aggregate carrying amount of RMB113,828,000 (2023: RMB206,151,000) which are past due and the impairment amount is RMB4,082,000 (2023:RMB18,357,000).

Out of the past due balance, RMB108,987,000 (2023: RMB8,388,000) has been past due 90 days or more and is not considered as in default as they are due from customers with good reputation and lower risk of default.

Subsequent to the year end of 2023, the payment schedule for the Group's trade receivables balance amounting to United States dollar (“US\$”) 25,000,000 was revised. Based on the revised payment schedule, US\$12,500,000 will be due in the second quarter of 2024 and the remainder will be due in the first quarter of 2025. The amounts were received based on the revised schedule up to the date of this report.

## 10. OTHER ASSETS, PREPAYMENTS AND OTHER RECEIVABLES

	At 31 December	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Deposits		
– current	38,936	27,139
– non-current	7,705	29,265
Prepayments		
– current (Note a)	199,825	245,217
– non-current (Note b)	195,599	101,175
Amount due from a partner of a joint operation (Note c)	–	3,900
Interest receivables	–	530
Value added tax (“VAT”) recoverable (Note d)		
– current	18,367	134,194
– non-current	258,641	57,948
Consideration receivables arising from equity transfer transactions	–	339,167
	<u>719,073</u>	<u>938,535</u>
Less: Allowance for credit losses	<u>(308)</u>	<u>(5,759)</u>
	<u><b>718,765</b></u>	<u><b>932,776</b></u>
Analysis as		
– current	256,820	744,388
– non-current	461,945	188,388
	<u><b>718,765</b></u>	<u><b>932,776</b></u>

### Notes:

- (a) Prepayments mainly include fee paid for research and development services for the clinical and non-clinical study of the drugs. Prepayments also include other prepaid operating expenses and prepayments for purchase of raw materials. As of 31 December 2024, impairment losses of RMB8,220,000 (2023: RMB27,187,000) were recognised on prepayments relating to purchase of raw materials, due to anticipated decrease of product selling price.
- (b) Amount mainly represents prepayments for construction in progress and acquisition of property, plant and equipment.
- (c) The amount was unsecured, non-interest bearing and repayable on demand.
- (d) Included in VAT recoverable are RMB18,367,000 (2023: RMB134,194,000) presented as current assets as at 31 December 2024 since they are expected to be deducted from future VAT payable arising on the Group’s revenue which are expected to be generated within the next twelve months from the end of the reporting period. The remaining VAT recoverable of RMB258,641,000 (2023: RMB57,948,000) are therefore presented as non-current assets as at 31 December 2024.

## 11. TRADE AND OTHER PAYABLES

	At 31 December	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Trade payables		
– third parties	208,356	247,264
Accrued expenses in respect of:		
– construction costs	465,730	479,284
– research and development expenses ( <i>Note</i> )	310,884	408,516
– selling and distribution expenses	146,565	133,997
– payables under collaboration agreement	10,088	14,947
– others	91,061	97,137
Salary and bonus payables	252,681	234,202
Other tax payables	27,287	41,411
Other payables	35,768	49,257
	<b>1,548,420</b>	<b>1,706,015</b>
	<b>1,548,420</b>	<b>1,706,015</b>

Payment terms with suppliers are mainly with credit term of 0 days to 90 days (2023: 0 days to 90 days) from the time when the goods and services are received from the suppliers.

The following is an aged analysis of trade payables presented based on invoice date at the end of the reporting period:

	At 31 December	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
0 – 30 days	98,434	60,582
31 – 60 days	17,062	33,363
61 – 180 days	14,982	72,400
Over 180 days	77,878	80,919
	<b>208,356</b>	<b>247,264</b>
	<b>208,356</b>	<b>247,264</b>

*Note:* Amounts included service fees payable to outsourced service providers including contract research organisations and clinical trial centres.

## 12. BORROWINGS

	At 31 December	
	2024	2023
	RMB'000	RMB'000
Bank borrowings		
– secured	990,063	868,364
– unsecured	1,884,218	866,821
	<b>2,874,281</b>	1,735,185
The maturity profile of bank borrowings is as follows:		
– within one year	894,601	539,391
– within a period of more than one year but not exceeding two years	623,668	120,135
– within a period of more than two years but not exceeding five years	790,641	700,751
– within a period of more than five years	565,371	374,908
	<b>2,874,281</b>	1,735,185
Less: Amount due within one year shown under current liabilities	<b>(894,601)</b>	(539,391)
Amount shown under non-current liabilities	<b>1,979,680</b>	1,195,794

All bank borrowings are denominated in RMB as at 31 December 2024 and 2023.

## 13. SHARE CAPITAL

	Total number of shares	Amount RMB'000
Registered, issued and fully paid at RMB1.0 per share:		
At 1 January 2023	982,871,640	982,872
Exercise of RSUs	2,818,231	2,818
At 31 December 2023 and 2024	<b>985,689,871</b>	<b>985,690</b>

All the shares rank pari passu with the existing shares in all respects.

Save for disclosed elsewhere, none of the Company's subsidiaries purchased, sold or redeemed any of the Company's listed securities during the year.

#### 14. TREASURY SHARE

During the years ended 31 December 2023 and 2024, the Company repurchased its own ordinary shares (A Shares) through the STAR Market of the Shanghai Stock Exchange as follows:

Month of repurchase	No. of ordinary shares	Price per share		Aggregate consideration paid in 2024 RMB'000
		Highest RMB	Lowest RMB	
March 2024	102,459	29.35	29.21	3,001
June 2024	34,385	29.14	29.03	1,000
	<b>136,844</b>			<b>4,001</b>

Month of repurchase	No. of ordinary shares	Price per share		Aggregate consideration paid in 2023 RMB'000
		Highest RMB	Lowest RMB	
September 2023	388,445	38.99	37.91	15,030
October 2023	171,266	40.49	40.14	6,905
December 2023	119,316	41.69	41.34	4,956
	<b>679,027</b>			<b>26,891</b>



## FINANCIAL STATEMENTS PREPARED UNDER CHINA ACCOUNTING STANDARDS (“CAS”)

The following financial information is extracted from the Company’s 2024 annual report published on the website of the Shanghai Stock Exchange, which is prepared in accordance with the PRC Generally Accepted Accounting Principles.

### CONSOLIDATED BALANCE SHEET

At 31 December 2024

Unit: Yuan Currency: RMB

Item	31 December 2024	31 December 2023
<b>Current assets:</b>		
Cash and bank balances	2,502,201,285.66	3,788,193,376.77
Held-for-trading financial assets	430,508,246.57	–
Notes receivable	–	–
Accounts receivable	509,816,712.45	483,226,004.74
Prepayments	199,787,005.70	238,897,466.48
Other receivables	36,441,479.37	374,008,655.77
Including: Interest receivable	–	–
Dividend receivable	–	–
Inventories	584,470,922.86	538,052,813.07
Non-current assets due within one year	2,187,306.15	8,184,311.36
Other current assets	18,404,148.29	140,512,460.52
	<u>4,283,817,107.05</u>	<u>5,571,075,088.71</u>
<b>Non-current assets:</b>		
Long-term equity investments	223,334,442.32	242,575,715.18
Investments in other equity instruments	62,565,091.14	84,184,097.91
Other non-current financial assets	940,504,669.94	806,351,904.77
Fixed assets	2,281,061,188.57	2,431,855,834.52
Construction in progress	1,858,563,731.17	1,325,356,972.04
Right-of-use assets	55,598,802.53	51,367,618.58
Intangible assets	521,405,365.27	546,964,593.08
Long-term prepaid expenses	6,120,035.12	12,598,552.14
Deferred tax assets	87,045,275.35	103,396,116.17
Other non-current assets	461,944,701.64	167,140,378.23
	<u>6,498,143,303.05</u>	<u>5,771,791,782.62</u>
Total non-current assets	<u>6,498,143,303.05</u>	<u>5,771,791,782.62</u>
Total assets	<u>10,781,960,410.10</u>	<u>11,342,866,871.33</u>

Item	31 December 2024	31 December 2023
<b>Current liabilities:</b>		
Short-term loans	678,106,154.40	452,435,151.72
Notes payable	–	4,672,296.11
Accounts payable	1,232,683,826.19	1,381,144,867.05
Contract liabilities	8,165,732.53	146,298,445.27
Payroll payable	252,681,242.49	234,201,628.25
Taxes payable	39,575,276.61	50,741,556.79
Other payables	35,768,048.63	37,330,788.82
Including: Interest payable	–	–
Dividend payable	–	–
Non-current liabilities due within one year	246,789,095.44	122,886,665.63
Other current liabilities	154,453.34	8,686,175.91
	<u>2,493,923,829.63</u>	<u>2,438,397,575.55</u>
Total current liabilities		
<b>Non-current liabilities:</b>		
Long-term borrowings	1,979,680,277.34	1,195,794,059.52
Lease liabilities	26,313,075.50	17,451,499.85
Provisions	9,566,615.01	27,104,611.58
Deferred income	181,913,109.58	183,463,569.04
Other non-current liabilities	158,433,738.89	160,045,083.81
	<u>2,355,906,816.32</u>	<u>1,583,858,823.80</u>
Total non-current liabilities		
	<u>4,849,830,645.95</u>	<u>4,022,256,399.35</u>
Total liabilities		
<b>Owners' equity:</b>		
Share capital	985,689,871.00	985,689,871.00
Capital reserves	15,406,557,142.12	15,394,559,338.20
Less: Treasury share	30,892,473.08	26,891,299.08
Other comprehensive income	-159,937,004.34	-142,066,958.60
Retained earnings	-10,340,993,199.41	-9,060,066,765.05
Total equity attributable to owners of the Company	5,860,424,336.29	7,151,224,186.47
Minority interests	71,705,427.86	169,386,285.51
	<u>5,932,129,764.15</u>	<u>7,320,610,471.98</u>
Total equity attributable to owners		
	<u>10,781,960,410.10</u>	<u>11,342,866,871.33</u>
Total liabilities and equity attributable to owners		

## CONSOLIDATED INCOME STATEMENT

January-December 2024

Unit: Yuan Currency: RMB

Item	2024	2023
<b>I. Total operating income</b>	<b>1,948,317,315.72</b>	1,502,549,915.75
Including: Operating income	<u>1,948,317,315.72</u>	<u>1,502,549,915.75</u>
<b>II. Total operating costs</b>	<b>3,215,859,236.06</b>	3,811,859,509.40
Including: Operating costs	<b>410,682,338.47</b>	540,976,390.72
Taxes and surcharges	<b>22,293,299.83</b>	19,704,320.97
Selling expenses	<b>984,553,927.36</b>	844,355,927.00
Administrative expenses	<b>523,203,972.13</b>	536,439,566.54
R&D expenses	<b>1,275,270,105.66</b>	1,937,469,544.84
Financial expenses	<b>-144,407.39</b>	-67,086,240.67
Including: Interest expenses	<b>51,351,964.00</b>	23,006,975.29
Interest income	<b>43,630,497.26</b>	99,426,230.82
Add: Other gains	<b>55,626,310.84</b>	47,444,534.82
Investment gains (“-” for losses)	<b>-23,553,900.59</b>	73,990,355.55
Including: Gains from investments in associates and joint ventures	<b>-35,026,266.22</b>	-60,484,681.25
Gains from changes in fair value (“-” for losses)	<b>-47,678,755.74</b>	-149,177,392.25
Credit impairment loss (“-” for losses)	<b>19,724,356.73</b>	-23,483,189.23
Impairment loss of assets (“-” for losses)	<b>-88,178,776.72</b>	-126,313,501.28
Gains from disposal of assets (“-” for losses)	<u>12,777,848.80</u>	<u>29,406,432.28</u>
<b>III. Operating revenue (“-” for losses)</b>	<b>-1,338,824,837.02</b>	-2,457,442,353.76
Add: Non-operating income	<b>2,251,713.09</b>	3,913,286.20
Less: Non-operating expenses	<u>20,984,057.46</u>	<u>38,165,533.03</u>
<b>IV. Total profit (“-” for total losses)</b>	<b>-1,357,557,181.39</b>	-2,491,694,600.59
Less: Income tax expenses	<u>22,551,676.87</u>	<u>43,994,697.26</u>
<b>V. Net profit (“-” for net losses)</b>	<b>-1,380,108,858.26</b>	-2,535,689,297.85
(I) Classified by business continuity		
1. Net profit from continuous operations (“-” for net losses)	<b>-1,380,108,858.26</b>	-2,535,689,297.85
2. Net profit from discontinued operations (“-” for net losses)	-	-
(II) Classified by ownership		
1. Net profit attributable to the shareholders (“-” for net losses)	<b>-1,280,926,434.36</b>	-2,283,431,860.25
2. Profit or loss attributable to minority interests (“-” for net losses)	<u>-99,182,423.90</u>	<u>-252,257,437.60</u>

Item	2024	2023
<b>VI. Other comprehensive income after-tax, net</b>	<b>-17,870,045.74</b>	-73,658,461.53
(I) Other comprehensive income after-tax attributable to owners of the Company, net	<b>-17,870,045.74</b>	-73,658,461.53
1. Other comprehensive income that cannot be reclassified into profit or loss	<b>-21,619,006.77</b>	-83,870,843.12
(1) Changes arising from remeasurement of defined benefit plan	-	-
(2) Other comprehensive income that cannot be reclassified to profit or loss using the equity method	-	-
(3) Changes in fair value of investments in other equity instruments	<b>-21,619,006.77</b>	-83,870,843.12
(4) Change in fair value due to enterprise's own credit risk	-	-
2. Other comprehensive income that can be reclassified to profit or loss	<b>3,748,961.03</b>	10,212,381.59
(1) Other comprehensive income that can be transferred to profit or loss using the equity method	-	-
(2) Changes in fair value of other debt investments	-	-
(3) Financial assets reclassified to other comprehensive income	-	-
(4) Credit impairment provision for other debt investments	-	-
(5) Cash flow hedging reserves	-	-
(6) Difference arising on translation of foreign currency financial statements	<b>3,748,961.03</b>	10,212,381.59
(II) Other net comprehensive income after-tax attributable to minority shareholders	-	-
<b>VII. Total comprehensive income</b>	<b>-1,397,978,904.00</b>	-2,609,347,759.38
(I) Total comprehensive income attributable to owners of the Company	<b>-1,298,796,480.10</b>	-2,357,090,321.78
(II) Total comprehensive income attributable to minority shareholders	<b>-99,182,423.90</b>	-252,257,437.60
<b>VIII. Earnings per share</b>		
(I) Basic earnings per share (RMB/Share)	<b>-1.30</b>	-2.32
(II) Diluted earnings per share (RMB/Share)	<b>-1.30</b>	-2.32

## CONSOLIDATED CASH FLOW STATEMENT

January-December 2024

Unit: Yuan Currency: RMB

Item	2024	2023
<b>I. Cash flows from operating activities:</b>		
Cash receipts from the sale of goods and the rendering of services	1,836,170,338.40	1,474,934,030.73
Receipts of tax refunds	10,546,104.09	143,929,288.86
Other cash receipts relating to operating activities	69,811,541.85	122,669,834.99
Subtotal of cash inflows from operating activities	1,916,527,984.34	1,741,533,154.58
Cash payments for goods purchased and services received	1,732,587,358.04	2,082,560,054.82
Cash payments to and on behalf of employees	1,216,708,662.84	1,254,991,680.89
Payments of various types of taxes	89,149,699.75	78,513,316.85
Other cash payments relating to operating activities	311,923,473.25	330,450,198.99
Subtotal of cash outflows from operating activities	3,350,369,193.88	3,746,515,251.55
Net cash flows from operating activities	<u>-1,433,841,209.54</u>	<u>-2,004,982,096.97</u>
<b>II. Cash flows from investing activities:</b>		
Cash receipts from recovery of investments	1,901,811,816.60	1,246,870,799.38
Cash receipts from investment income	9,430,216.08	4,234,520.55
Net cash received from disposal of fixed assets, intangible assets and other long-term assets	1,865,000.00	4,097,167.34
Other cash receipts relating to investing activities	44,160,556.11	103,189,128.33
Subtotal of cash inflows from investing activities	1,957,267,588.79	1,358,391,615.60
Cash payments to acquire or construct fixed assets, intangible assets and other long-term assets	690,987,533.01	832,574,528.57
Cash payments to acquire investments	2,159,000,000.00	1,459,007,993.15
Other cash payments relating to investing activities	62,189.34	—
Subtotal of cash outflows from investing activities	2,850,049,722.35	2,291,582,521.72
Net cash flows from investing activities	<u>-892,782,133.56</u>	<u>-933,190,906.12</u>
<b>III. Cash flows from financing activities:</b>		
Cash receipts from capital contributions	1,501,566.25	155,594,530.50
Including: cash receipts from capital contributions from minority owners of subsidiaries	1,501,566.25	3,000,000.00
Cash receipts from borrowings	2,306,748,582.68	977,095,079.63
Other cash receipts relating to financing activities	6,350,285.82	207,889,063.78
Subtotal of cash inflows from financing activities	2,314,600,434.75	1,340,578,673.91
Cash repayments of borrowings	1,174,018,295.57	480,915,060.85
Cash payments for distribution of dividends or profits or settlement of interest expenses	73,790,126.93	38,226,802.11
Including: payments for distribution of dividends or profits to minority owners of subsidiaries	—	—
Other cash payments relating to financing activities	43,646,237.27	109,609,030.99
Subtotal of cash outflows from financing activities	1,291,454,659.77	628,750,893.95
Net cash flows from financing activities	<u>1,023,145,774.98</u>	<u>711,827,779.96</u>

Item	2024	2023
<b>IV. Effects of exchange rate fluctuations on cash and cash equivalents</b>	<u>12,014,641.06</u>	<u>7,551,261.18</u>
<b>V. Net increase in cash and cash equivalents</b>	<b>-1,291,462,927.06</b>	-2,218,793,961.95
Add: Opening balance of cash and cash equivalents	<u>3,778,142,035.88</u>	<u>5,996,935,997.83</u>
<b>VI. Closing balance of cash and cash equivalents</b>	<u><b>2,486,679,108.82</b></u>	<u>3,778,142,035.88</u>



## CONSOLIDATED STATEMENT OF CHANGES IN OWNERS' EQUITY

January-December 2024

Unit: Yuan Currency: RMB

Item	2024								
	Equity attributable to owners of the Company							Minority interests	Total equity
	Share Capital	Capital reserves	Less: Treasury share	Other comprehensive income	Retained earnings	Subtotal			
I. Closing balance of the preceding year	985,689,871.00	15,394,559,338.20	26,891,299.08	-142,066,958.60	-9,060,066,765.05	7,151,224,186.47	169,386,285.51	7,320,610,471.98	
Add: Changes in accounting policies	-	-	-	-	-	-	-	-	
II. Balance at the beginning of year	985,689,871.00	15,394,559,338.20	26,891,299.08	-142,066,958.60	-9,060,066,765.05	7,151,224,186.47	169,386,285.51	7,320,610,471.98	
III. Changes in the current year ("-" for decreases)	-	11,997,803.92	4,001,174.00	-17,870,045.74	-1,280,926,434.36	-1,290,799,850.18	-97,680,857.65	-1,388,480,707.83	
(I) Total comprehensive income	-	-	-	-17,870,045.74	-1,280,926,434.36	-1,298,796,480.10	-99,182,423.90	-1,397,978,904.00	
(II) Increase of capital from shareholders	-	11,997,803.92	4,001,174.00	-	-	7,996,629.92	1,501,566.25	9,498,196.17	
1. Ordinary shares contributed by shareholders	-	-	-	-	-	-	1,501,566.25	1,501,566.25	
2. Capital contributed by holders of other equity instruments	-	-	-	-	-	-	-	-	
3. Share-based payments recognized in owners' equity	-	-	-	-	-	-	-	-	
4. Others	-	11,997,803.92	4,001,174.00	-	-	7,996,629.92	-	7,996,629.92	
IV. Balance at the end of year	<u>985,689,871.00</u>	<u>15,406,557,142.12</u>	<u>30,892,473.08</u>	<u>-159,937,004.34</u>	<u>-10,340,993,199.41</u>	<u>5,860,424,336.29</u>	<u>71,705,427.86</u>	<u>5,932,129,764.15</u>	

Item	2023							
	Share Capital	Capital reserves	Less: Treasury share	Equity attributable to owners of the Company Other comprehensive income	Retained earnings	Subtotal	Minority interests	Total equity
<b>I. Closing balance of the preceding year</b>	982,871,640.00	15,345,797,913.57	-	-68,408,497.07	-6,776,634,904.80	9,483,626,151.70	292,834,111.52	9,776,460,263.22
Add: Changes in accounting policies	-	-	-	-	-	-	-	-
<b>II. Balance at the beginning of year</b>	<u>982,871,640.00</u>	<u>15,345,797,913.57</u>	<u>-</u>	<u>-68,408,497.07</u>	<u>-6,776,634,904.80</u>	<u>9,483,626,151.70</u>	<u>292,834,111.52</u>	<u>9,776,460,263.22</u>
<b>III. Changes in the current year ("-" for decreases)</b>	2,818,231.00	48,761,424.63	26,891,299.08	-73,658,461.53	-2,283,431,860.25	-2,332,401,965.23	-123,447,826.01	-2,455,849,791.24
(I) Total comprehensive income	-	-	-	-73,658,461.53	-2,283,431,860.25	-2,357,090,321.78	-252,257,437.60	-2,609,347,759.38
(II) Increase of capital from shareholders	2,818,231.00	48,761,424.63	26,891,299.08	-	-	24,688,356.55	128,809,611.59	153,497,968.14
1. Ordinary shares contributed by shareholders	2,818,231.00	153,593,589.50	-	-	-	156,411,820.50	-	156,411,820.50
2. Capital contributed by holders of other equity instruments	-	-	-	-	-	-	-	-
3. Share-based payments recognized in owners' equity	-	23,650,339.24	-	-	-	23,650,339.24	327,107.48	23,977,446.72
4. Others	-	-128,482,504.11	26,891,299.08	-	-	-155,373,803.19	128,482,504.11	-26,891,299.08
<b>IV. Balance at the end of year</b>	<u><u>985,689,871.00</u></u>	<u><u>15,394,559,338.20</u></u>	<u><u>26,891,299.08</u></u>	<u><u>-142,066,958.60</u></u>	<u><u>-9,060,066,765.05</u></u>	<u><u>7,151,224,186.47</u></u>	<u><u>169,386,285.51</u></u>	<u><u>7,320,610,471.98</u></u>

## **RISK FACTORS**

### **1. Risks related to pending profitability**

A long profit cycle is one of the most salient features of the biopharmaceutical industry. It typically takes a relatively long period for a biopharmaceutical company at the R&D stage to grow before it becomes profitable. As an innovative biopharmaceutical company, the Company is currently in an important R&D investment phase, and our R&D investment is expected to increase and consistently in line with the expansion of R&D pipeline and acceleration of domestic and overseas drug clinical trial activities. Our future profitability depends on the pace of the launch and the conditions of post-launch sales of our drug candidates. On the other hand, R&D investments and marketing and operating costs will add uncertainties to the Company's profitability. Therefore, the Company is exposed to the risk of not being able to become profitable in the short term.

A total of four drugs (TUOYI®, JUNMAIKANG, MINDEWEI and JUNSHIDA) are being commercialized by the Company, and various drug candidates in the late stage of research and development close to commercialization. The accelerated development of more and more drug candidates, the successive completion of registrational clinical trials for more indications of the approved products as well as the increased number of products approved for marketing will further improve the Company's financial position and help create conditions for a turnaround in the profitability of the Company as soon as possible.

### **2. Risks related to significant decline in performance or loss**

The Company is committed to the discovery, development and commercialization of innovative therapies. The Company actively deploys a product pipeline that covers various therapeutic areas. In the future, it will maintain a corresponding scale of investment in R&D for the pre-clinical research, global clinical trials and preparation for NDAs of drug candidates and other drug development. Besides, the Company's NDA and registration efforts, post-launch marketing and promotion activities and other aspects will incur expenses, which may result in greater losses for the Company in the short run, thereby adversely affecting the Company's daily operations and financial position. During the Reporting Period, there were no material adverse changes in the principal business and core competitiveness of the Company.

### **3. Risks related to core competitiveness**

Classified as technical innovation, the R&D of new drugs is characterized by long R&D cycles, significant investment, high risks and low success rate. From laboratory research to obtaining approval, new drugs go through a lengthy process with complicated stages, including preclinical study, clinical trial, registration and marketing of new drugs and after-sales supervision. Any of the above stages is subject to the risk of failure. The Company will strengthen its forward-looking strategic research, and determine the direction of new drug R&D according to the needs of clinical drug use. The Company will also formulate reasonable new drug technology solutions, continuously increase the investment in R&D of new drugs, and prudently launch R&D projects for new drugs. In particular, the Company implements phase-based assessment on drug candidates in the course of R&D. If it is found that the expected results cannot be achieved, the subsequent R&D of such product will be terminated immediately, so as to minimize the R&D risks of new drugs.

#### **4. Risks related to operations**

The Company's business operations require certain R&D technical services and raw materials supply. Currently, the relationship between the Company and existing suppliers are stable. If the price of R&D technical services or raw materials increased significantly, the Company's profitability may be adversely affected. At the same time, the Company's suppliers may not be able to keep up with the rapid development of the Company, such that they may have to reduce or terminate the supply of the Company's R&D services or raw materials. If such R&D technical services or the supply of raw materials were disrupted, and thus the Company's business operations may be adversely affected. Furthermore, some of the Company's raw materials, equipment and consumables are directly or indirectly imported. If there are significant changes in the international trade situation, the Company's production and operation may be affected to a certain extent.

The Company's commercialized products toripalimab injection, adalimumab injection and deuremidevir hydrobromide tablets are all included in the NRDL. The reduction in price after being included into the drug list can effectively improve the accessibility and affordability of the Company's products, which is conducive to a significant increase in product sales. However, if the increase in sales is less than expected, it may adversely affect the Company's revenue.

#### **5. Finance risks**

During the Reporting Period, the exchange rate risks of the Company primarily arose from the assets and liabilities held by the Company and its subsidiaries which were denominated in the foreign currencies other than the book-keeping base currency. The Company's exposure to exchange rate risks was mainly related to the items denominated in HKD and USD. If significant fluctuations occur in the exchange rates between these foreign currencies to be kept by the Company and RMB in the future, the Company will continue to experience exchange gains or losses, which could affect the operating performance of the Company.

During the Reporting Period, the net cash outflow from operating activities of the Company was approximately RMB1,443 million. Currently, the Company's capital sources include revenue from sales of marketed products as well as external financing. If the Company is unable to achieve profitability or secure sufficient funds to cover operating expenses within a certain period in the future, the Company may have to delay, reduce or cancel R&D projects, affecting the commercialization progress of its drug candidates, which may in turn have an adverse impact on the business prospects, financial position and operating performance of the Company.

During the Reporting Period, when assessing the risk of inventory impairment, the Company recognized the provisions for inventory impairment upon identifying indications that the estimated net realizable value of the purchased inventories was lower than its carrying value, such as inventory becoming fully or partially obsolete or a decline in selling prices. When estimating the net realizable value of inventories, the Company comprehensively considers factors such as future market competition, pricing, further processing costs and selling expenses to recognize asset impairment losses, thereby accurately reflecting the carrying value of inventories as of the end of the period. In the future, if changes in market conditions or intensified competition occur, the Company may face risks of asset impairment, which may adversely affect its operations.

## **6. Risks related to the industry**

In view of the constant reforms in the medical and health system, encouraging pharmaceutical enterprises to be innovative and reduce prices of drugs have become a trend, and the industry landscape is about to be reshaped. If the Company fails to keep up with industry trends and continue with its innovation in the future, or if there are adverse changes in relevant industry policies, the Company's development may be adversely affected.

The Company's development goal has always been "innovation". Our pipeline focuses on innovative drugs. In response to the above industry and policy risks, the Company will adapt to changes in external policies, continue to improve our innovation capabilities and our ability to continuously discover and develop new products, increase our R&D investments, accelerate the process of innovative drugs entering clinical trial phase and the market, and respond to challenges with innovation. On this basis, the Company will further expand our production capacity, and reduce the unit cost of our products while maintaining the quality of our products, so as to address the possible price reduction of drugs in future. At the same time, we will comply with relevant laws and regulations and adapt our business operations to the changes in regulatory policies to avoid possible policy risks.

## **7. Risks related to the macro environment**

Future changes in the international, political, economic and market environment, especially the uncertainty of trade relations between China and the United States, as well as the additional tariffs or other restrictions that may be imposed by China and the United States on cross-border technology transfer, investment and trade, may have a certain adverse impact on the Company's overseas business operations.

## SUBSEQUENT EVENTS AFTER THE REPORTING PERIOD

- In January 2025, the indication of TUOYI® for the treatment of unresectable or metastatic melanoma after failure of standard systemic therapy has been approved by the NMPA for conversion from conditional approval to regular approval.
- In January 2025, the IND application for JS212 (a recombinant humanized EGFR and HER3 ADC) has been accepted by the NMPA, and has been approved by the NMPA in March 2025.
- In January 2025, the indication of MINDEWEI for the treatment of adult patients with mild to moderate COVID-19 has been approved by the NMPA for conversion from conditional approval to regular approval.
- In January 2025, the NCE application for toripalimab in combination with cisplatin and gemcitabine, for the first-line treatment of adults with metastatic or recurrent, locally advanced NPC and toripalimab, as a single agent, for the treatment of adults with recurrent unresectable or metastatic NPC with disease progression on or after a platinum-containing chemotherapy has been approved by the TGA. Toripalimab has become the first and only immuno-oncology treatment for NPC in Australia.
- In January 2025, TopAlliance, a wholly-owned subsidiary of the Company, has entered into a distribution and marketing agreement with LEO Pharma. TopAlliance will grant LEO Pharma the exclusive right to store, distribute, promote, market and sell toripalimab in all current member states and any future member states of the EU and the EEA, Switzerland as well as the UK (the “**Territory**”). LEO Pharma shall pay TopAlliance an upfront payment of EUR15 million, milestone payment(s) for any subsequent approved indication(s) for toripalimab in the Territory, and a revenue share of a double-digit percentage on the net sales of toripalimab throughout the Territory.
- In February 2025, the IND application for JS213 (a PD-1 and IL-2 bifunctional antibody fusion protein) has been approved by the NMPA.
- In March 2025, the sNDA for TUOYI® in combination with bevacizumab for the first-line treatment for patients with unresectable or metastatic HCC has been approved by the NMPA.
- In March 2025, the NDA for toripalimab in combination with cisplatin and gemcitabine for the first-line treatment of adult patients with recurrent, not amenable to surgery or radiotherapy, or metastatic NPC has been approved by the HSA. Toripalimab has become the first and only approved immuno-oncology treatment for NPC in Singapore.



## **PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES**

During the Reporting Period, the Company repurchased a total of 136,844 A Shares, representing 0.0139% of the total issued shares of the Company, on the Shanghai Stock Exchange. As of the end of the Reporting Period, the Company had repurchased a total of 815,871 A Shares, representing 0.0828% of the total share capital of the Company, which will be used for the purpose of share incentives and/or employee stock ownership plan(s) at an appropriate time in the future. All of such shares have not been cancelled:

<b>Date of repurchase</b>	<b>No. of A shares repurchased</b>	<b>Price per share</b>		<b>Aggregate amount paid RMB</b>
		<b>Highest RMB</b>	<b>Lowest RMB</b>	
7 March 2024	102,459	29.35	29.21	2,999,988.23
19 June 2024	34,385	29.14	29.03	999,982.15

*Note:* The aggregate amount paid excludes transaction fees such as stamp duty and trading commission.

Save as disclosed above, neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the Company's listed securities (including any sale of treasury shares) during the Reporting Period. For details on the changes in treasury shares, please refer to the paragraph headed "Treasury Share" in Note 14 to the financial statements.

## **COMPLIANCE WITH THE MODEL CODE FOR SECURITIES TRANSACTIONS BY DIRECTORS AND SUPERVISORS**

The Company has adopted the Model Code for Securities Transactions by Directors of Listed Issuers in Appendix C3 of Hong Kong Listing Rules as its own code of conduct regarding Directors' securities transactions. Having made specific enquiry with each of the Directors and supervisors of the Company, they have confirmed that they had complied with such code of conduct during the Reporting Period.

## CHANGES IN THE BOARD, ROLES OF DIRECTORS AND CHIEF EXECUTIVE OFFICER DURING THE REPORTING PERIOD

During the Reporting Period, the composition and roles of the Board of Directors and chief executive officer changed as follows:

- Dr. Li Ning
- *elected as the vice chairman of the third session of the Board with effect from 12 January 2024*
  - *ceased from being the general manager and chief executive officer of the Company with effect from 12 January 2024*
  - *retired from his position as a member of the remuneration and appraisal committee of the Company (“**Remuneration and Appraisal Committee**”) and a member of the strategic committee of the Company (“**Strategic Committee**”) with effect from 21 June 2024*
- Dr. Zou Jianjun
- *elected as the general manager and chief executive officer of the Company with effect from 12 January 2024*
  - *became a member of the Remuneration and Appraisal Committee and a member of the Strategic Committee with effect from 21 June 2024*
- Dr. Li Xin
- *re-designated from a non-executive Director to an executive Director with effect from 28 February 2024*
- Dr. Shen Jinggang
- *elected as an independent non-executive Director, a member of the Audit Committee and a member of the Strategic Committee with effect from 21 June 2024*
  - *ceased from being an independent non-executive Director, a member of the Audit Committee and a member of the Strategic Committee in October 2024*
- Dr. Yang Yue
- *elected as an independent non-executive Director, a member of the nomination committee of the Company (“**Nomination Committee**”) and a member of the remuneration and appraisal committee with effect from 21 June 2024*
- Dr. Feng Hui
- *retired from his position as a non-executive Director with effect from 21 June 2024*
- Dr. Roy Steven Herbst
- *retired from his position as an independent non-executive Director and a member of the Strategic Committee with effect from 21 June 2024*

- Mr. Qian Zhi – *retired from his position as an independent non-executive Director, a member of the Audit Committee, a member of the Nomination Committee and a member of the Remuneration and Appraisal Committee with effect from 21 June 2024*
- Mr. Li Zhongxian – *elected as an independent non-executive Director and a member of the Audit Committee with effect from 20 December 2024*
- Ms. Lu Kun – *elected as an independent non-executive Director with effect from 20 December 2024*
- Dr. Wang Gang – *became a member of the Strategic Committee with effect from 20 December 2024*
- Dr. Feng Xiaoyuan – *became a member of the Strategic Committee with effect from 20 December 2024*
- Dr. Meng Anming – *resigned from his position as an independent non-executive Director and a member of the Strategic Committee with effect from 20 December 2024*

## **CORPORATE GOVERNANCE**

The Board is committed to maintaining high corporate governance standards. The Board believes that high corporate governance standards are essential in providing a framework for the Group to safeguard the interests of shareholders, enhance corporate value, formulate its business strategies and policies, and enhance its transparency and accountability.

The Company has applied the principles and code provisions as set out in the Corporate Governance Code (the “**CG Code**”) contained in part 2 of Appendix C1 of the Hong Kong Listing Rules during the Reporting Period. The Board is of the view that, during the Reporting Period, the Company has complied with all code provisions as set out in the CG Code.

## **AUDIT COMMITTEE**

The Audit Committee comprises two independent non-executive Directors, namely Mr. Zhang Chun (chairman of the Audit Committee) and Mr. Li Zhongxian, and one non-executive Director, namely Mr. Tang Yi. The primary duties of the Audit Committee are to assist the Board by providing an independent view of the effectiveness of the financial reporting process, internal control and risk management systems of the Group and overseeing the audit process.

The Audit Committee has reviewed, together with the management and external auditors, the accounting principles and policies adopted by the Group and the condensed consolidated financial statements for the Reporting Period.

## **DISTRIBUTABLE RESERVES**

As at 31 December 2024, the Company did not have any distributable reserves.

## **FINAL DIVIDENDS**

The Directors do not recommend a final dividend for the Reporting Period.

## **ANNUAL GENERAL MEETING AND CLOSURE OF THE REGISTER OF MEMBERS OF H SHARES**

The date of the annual general meeting of the Company and the closure of the register of members of H Shares will be announced in due course.

## **SCOPE OF WORK OF MESSRS. DELOITTE TOUCHE TOHMATSU**

The IFRS figures in respect of the Group's consolidated statement of financial position, consolidated statement of profit or loss and other comprehensive income and the related notes thereto for the year ended 31 December 2024 as set out in the preliminary announcement have been agreed by the Group's auditor, Messrs. Deloitte Touche Tohmatsu, to the amounts set out in the audited consolidated financial statements of the Group for the year prepared in accordance with IFRS as approved by the Board of Directors on 27 March 2025. The work performed by Messrs. Deloitte Touche Tohmatsu in this respect did not constitute an assurance engagement and consequently no opinion or assurance conclusion has been expressed by Messrs. Deloitte Touche Tohmatsu on the preliminary announcement.

## **PUBLICATION OF THE 2024 ANNUAL RESULTS AND 2024 ANNUAL REPORT**

This annual results announcement has been published on the websites of the Company ([www.junshipharma.com](http://www.junshipharma.com)), the Hong Kong Stock Exchange (<http://www.hkexnews.hk>) and the Shanghai Stock Exchange (<http://www.sse.com.cn>). The 2024 Annual Report containing all the information required by the Hong Kong Listing Rules will be published on the respective websites of the Hong Kong Stock Exchange and the Company in due course.

By order of the Board of  
**Shanghai Junshi Biosciences Co., Ltd.\***  
**Mr. Xiong Jun**  
*Chairman*

Shanghai, the PRC, 27 March 2025

*As at the date of this announcement, the Board of Directors of the Company comprises Mr. Xiong Jun, Dr. Li Ning, Dr. Zou Jianjun, Mr. Li Cong, Mr. Zhang Zhuobing, Dr. Yao Sheng, Dr. Wang Gang and Dr. Li Xin as executive Directors; Mr. Tang Yi as a non-executive Director; and Mr. Zhang Chun, Dr. Feng Xiaoyuan, Dr. Yang Yue, Mr. Li Zhongxian and Ms. Lu Kun as independent non-executive Directors.*

\* For identification purpose only