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GENOR BIOPHARMA HOLDINGS LIMITED

嘉和生物藥業（開曼）控股有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 6998)

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED 31 DECEMBER 2024

The board (the “**Board**”) of directors (the “**Directors**”) of Genor Biopharma Holdings Limited (the “**Company**”, and together with its subsidiaries, the “**Group**”) is pleased to announce the consolidated results of the Group for the year ended 31 December 2024 (the “**Reporting Period**”), together with the comparative figures for the year ended 31 December 2023. The consolidated financial statements of the Group for the Reporting Period have been reviewed by the audit committee of the Company (the “**Audit Committee**”).

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

FINANCIAL HIGHLIGHTS

- **Total revenue** was approximately RMB206.2 million for the Reporting Period, as compared with nil for the year ended 31 December 2023. The increase was primarily due to revenue from license and stock purchase agreements with TRC 2004, Inc.
- **Research and development expenses** were approximately RMB202.8 million for the Reporting Period, as compared with approximately RMB564.3 million for the year ended 31 December 2023. The spending was mainly attributable to (i) our new drugs development fee and ongoing clinical trials expenses; (ii) our employee salary and related benefit costs.
- **Total comprehensive loss** was approximately RMB51.5 million for the Reporting Period, as compared with approximately RMB676.0 million for the year ended 31 December 2023. The decrease was primarily due to increase in revenue and decrease in expenses.
- Under **Non-HKFRS measures**, our adjusted loss⁽¹⁾ was approximately RMB41.3 million for the Reporting Period, as compared with approximately RMB614.3 million for the year ended 31 December 2023.

(1) Adjusted loss is calculated as loss for the years of 2024 and 2023 excluding share-based payment expenses. For details of the reconciliation of the loss for the Reporting Period to the adjusted loss of the Group, please refer to the section headed “Financial Review” in this announcement.

BUSINESS HIGHLIGHTS

The Group has further optimized its structure and adopted various flexible modes of external cooperation during the Reporting Period, successfully achieving the transformation into an enterprise adopting the asset-light model, thereby reducing operating costs. While reducing its costs and increasing its efficiency, the Group actively conducted strategic cooperation, signed merger agreements and reached business development (“**BD**”) cooperation in various pipelines, focusing on promoting the development of core pipelines and new drug approval.

Strategic Cooperation

Proposed Merger with Edding

- On 13 September 2024, the Group entered into the Merger Agreement with Edding whereby the Company will acquire Edding by way of a merger (the “**Proposed Merger**”), and in consideration therefor, the Company will allot and issue Consideration Shares to the shareholders of Edding. Immediately upon completion of the Proposed Merger, the original shareholders of Edding will hold approximately 77%, and the Shareholders will hold approximately 23%, of the issued shares of the Company as enlarged by the allotment and issue of the Consideration Shares (the final issue size is subject to the number of relevant Shares at the time of closing of the Proposed Merger).
- The Group is principally engaged in the development and commercialisation of oncology and autoimmune drugs and has been striving to “provide innovative therapeutics initially for patients in China and gradually for patients globally” through building rich and innovative drug candidates and pipelines. The Directors expects that CDK4/6i will soon be commercialised and the Company has reached a critical development stage which requires strong commercial power to seize all possible market opportunities. Other drug products of the Company are also at clinical development stages, so the Company requires abundant and continuous cash flow to support the relevant R&D work and needs to strengthen their commercialisation capabilities for the subsequent product launch for late-stage products, in order to maintain a leading position in the highly competitive pharmaceutical industry.
- Having evaluated a number of potential target companies, the Board considers that Edding satisfies the above criteria and that it will be in the interest of the Company and the Shareholders as a whole to effect a merger with Edding for the following reasons:
 - Edding has a diversified portfolio of innovative leading patented drugs of immense market potential and originator-branded drugs with competitive market advantages:

Edding has established a diversified product portfolio focusing on the largest and fastest-growing therapeutic areas in China comprising six key products, including three commercialised originator-branded products (namely, Vancocin, Ceclor and FPN) and three innovative leading patented drug products (Vascepa, Mulpleta and Entinostat).

- Edding has a well-developed commercialisation platform supporting robust financial performance:

Gross revenue of Edding from the three key commercialised originator-branded products in aggregate amounted to RMB2,191.9 million for the year ended 31 December 2023. The robust and continuous cash flow of Edding is expected to provide support to the R&D of the Group's pipeline products, including ongoing and planned clinical trials, indication expansion and preparation for registration filings.

- Edding has an industry-leading sales and marketing network in supporting the future commercialisation of synergized pipelines:

Edding has a well-established sales and marketing system with an over-twenty-year proven track record in terms of marketing efficiency and output per capita. As of 30 June 2024, Edding had over 900 sales representatives across 30 provinces in China and covering more than 12,000 hospitals. Edding's Entinostat, an HDAC inhibitor indicated for the treatment of HR+/HER2- breast cancer, is expected to create strong synergies from a commercialisation perspective with CDK4/6i, the Group's core product, also for the treatment of HR+/HER2- advanced breast cancer. Hence, with Edding's established sales and distribution network, and an advanced and comprehensive manufacturing system, the Proposed Merger, if materialises, will significantly enhance the commercialisation success of CDK4/6i.

- Edding has advanced manufacturing platforms and global supply chain system:

Edding has established its own localized manufacturing platform with techniques and know-how meeting international standards for drug manufacturing with unmatched quality, with a deep pool of seasoned management personnel, forming a key competitive moat against its peers. Edding also leverages its cross-regional supply chain management and coordination capabilities to manage an end-to-end global supply chain, and its long-term relationships with suppliers to ensure efficiency and stability of our supply chain. It is expected that these in-house core manufacturing capabilities would be crucial to the commercialisation, production and supply of CDK4/6i and serve as the cornerstone for the future success of the Enlarged Group.

- The consideration of the Proposed Merger is to be wholly settled by way of issuing Consideration Shares and there would be no cash outlay by the Group. The Enlarged Group will have sufficient cash resources to develop and expand its business following the closing of the Proposed Merger.

- The Proposed Merger is a key step for the Company to transform into a developed and fully integrated biopharmaceutical company. The production operation, international supply chain management, the marketing authorization holder (“**MAH**”) management capabilities and commercialisation capabilities possessed by Edding are crucial to the commercialisation and launch of originator-branded drug products. The continuous positive cash flow of Edding is also a core pillar for Edding to maintain its leading position in researching and developing originator-branded drug products. Following the closing of the Proposed Merger, the shortcomings relating to Edding’s R&D facilities can also be resolved. The Proposed Merger is expected to bring complementary and synergetic effects to both the Group and Edding and lay an important foundation for the sustainable development of the Enlarged Group. The Proposed Merger constitutes a very substantial acquisition and a reverse takeover of the Company, and is therefore subject to approval of the Shareholders. The Enlarged Group must be able to meet the basic listing eligibility requirements of the Listing Rules.
- On 24 January 2025, the Group and Edding entered into an amendment agreement to the Merger Agreement to extend the deadline for submitting the new listing application in connection with the Proposed Merger (the “**New Listing Application**”) and the long stop date of the closing of the Proposed Merger. Please refer to the announcement of the Company dated 24 January 2025 for further details.
- As at the date of the announcement, the Company and Edding are in the course of preparing the New Listing Application. The Company currently expects to submit the New Listing Application by the end of April 2025. For further details, please refer to the announcement of the Company dated 25 March 2025.

International Cooperation of GB261

- On 2 August 2024, the Group has entered into a license agreement (the “**License Agreement**”) and a stock purchase agreement (the “**Stock Purchase Agreement**”) with TRC 2004, Inc. (a company co-founded by Two River, LLC and Third Rock Ventures in Delaware, the United States of America). Under the License Agreement, the Group has agreed, among others, to grant TRC 2004, Inc. an exclusive worldwide license to develop, use, manufacture, commercialize and otherwise exploit GB261 (CD20/CD3, BsAb), excluding mainland China, Hong Kong, Macau and Taiwan. The collaboration between the parties will mainly focus on exploring the potential of GB261 (CD20/CD3, BsAb) in autoimmune diseases.
 - The Group shall receive: (i) a significant equity participation in TRC 2004, Inc.; (ii) a double digit million US dollars upfront payment; (iii) up to 443 million US dollars in milestone payments; and (iv) tiered single to double digits royalty payments on net sales.
- In September 2024, Candid Therapeutics merged with TRC 2004, Inc. It has an experienced management team, which includes Mr. Ken Song as the chief executive officer. The successful international cooperation of GB261 demonstrated the recognition of the world-class biotechnology investment institutions and the management team for the Company’s new drug research and development and innovation pipeline.

Cooperation with Zhongmei Huadong

- On 19 January 2024, the Company entered into an antibody molecules and technology transfer agreement with Zhongmei Huadong, under which an antibody drug and the related IP rights of the Company were transferred to Zhongmei Huadong.

Updates on Pipeline

GB491 (Lerociclib, a differentiated oral CDK4/6 inhibitor) – to provide breast cancer patients a CDK4/6 inhibitor with better efficacy and tolerability

- The Company has completed its patient enrolment for the phase III clinical study of GB491 (Lerociclib) in combination with letrozole as the first-line treatment for the advanced breast cancer and its interim analysis has reached the primary endpoint. The Company submitted the NDA to NMPA for Lerociclib in combination with letrozole for the treatment of locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2-negative (“**HR+/HER2-**”) breast cancer (first-line treatment for advanced breast cancer) that had not received prior systemic antitumor therapy on 28 February 2024. The application was officially accepted on 13 March 2024. The on-site clinical inspection was completed in September 2024. The feedback of NDA queries was submitted in December 2024.
- The Independent Data Monitoring Committee (“**IDMC**”) has reviewed the efficacy and safety data from the interim analysis of the phase III clinical trial of Lerociclib in combination with letrozole as the first-line treatment for the advanced first-line breast cancer. The IDMC recommended that this clinical trial had met the prespecified requirement of statistical significance in efficacy of the interim analysis with good safety and tolerance.
 - Progression-free survival (“**PFS**”) based on the investigator assessment: hazard-ratio (95% CI) and p-value, 0.464 (0.293, 0.733), p=0.0004.
 - PFS based on the Independent Review Committee’s (“**IRC**”) assessment: hazard-ratio (95% CI) and p-value, 0.457 (0.274, 0.761), p=0.0011.
- The results of the interim analysis were presented in the poster discussion session at the American Society of Clinical Oncology (“**ASCO**”) annual meeting held in June 2024.
- On 28 March 2023, the NMPA has officially accepted the NDA of GB491 (Lerociclib) in combination with Fluvestran for the treatment of HR+/HER2- locally advanced or metastatic breast cancer patients (second-line treatment for advanced breast cancer) with disease progression following previous endocrine therapy. On 31 August 2023, clinical on-site inspection was completed. The feedback of NDA queries were submitted in March 2024 and the drug testing at the China National Institutes for Food and Drug Control was completed in May 2024. In September and October 2024, the overseas on-site production Pre-Approval Inspections of the API and the drug product plants were completed, respectively, and the reports for follow-up items of CFDI inspection were submitted to CFDI in December 2024.
- On 13 September 2024, the Company has entered into the CDK4/6i Outsourcing Management Agreement with Edding Group Company Limited (“**Edding**”), pursuant to which the Company agreed to entrust Edding with, and Edding agreed to provide services for, the management of all matters relating to CDK4/6i, including the submission of new drug application(s), manufacturing, supply chain management and any other relevant matters. For further details of the CDK4/6i Outsourcing Management Agreement, please refer to the announcement of the Company dated 7 October 2024.

GB268 (anti-PD-1/VEGF/CTLA-4, TsAb)

- GB268 is another innovative tri-specific antibody solely developed by the Group, specifically targeting PD-1, CTLA-4 and VEGF, with a novel molecular design that balances the activity of different arms of the antibody. The pre-clinical results show that GB268 can substantially enhance the antitumor effect with a better safety profile compared to the combination of three monoclonal antibodies, namely PD-1, CTLA-4 and VEGF, as well as the anti-PD-1/VEGF or anti-PD-1/CTLA-4 BsAb. It has the potential to become an upgraded immune checkpoint inhibitor.

In 2024, GB268 entered the pre-IND enabling stage and conducted the CMC process development and GLP toxicology study. The preliminary results suggest that the tri-specific molecule has a good drug developability and stability, and no significant drug-related toxicity has been observed in the high, medium and low dose groups of the 4-week exploratory toxicological experiment in cynomolgus monkeys.

GB261 (CD20/CD3, BsAb)

- GB261 is the first T-Cell Engager (“TCE”) with low affinity to bind CD3 and has Fc functions (ADCC and CDC), and has potential to be a better and safer TCE. The first-in-human (“FIH”) clinical trials of GB261 were conducted in several clinical research centers in Australia and China, indicating a favorable safety, pharmacokinetic profile and promising clinical antitumor activities, which validated the molecular design mechanism of GB261. The Company completed the phase I/II clinical trial of GB261 for lymphoma in 2024 and completed the clinical study report in July 2024.

GB263T (EGFR/cMET/cMET, TsAb)

- As of 31 December 2023, a total of 15 patients had received at least one GB263T treatment. All patients had received previous third-generation EGFR-TKI and platinum-based chemotherapy and the median number of prior lines of systemic therapy was 3.
- GB263T has shown promising efficacy at the therapeutic dose range (1,260-1,680 mg).
 - The confirmed objective response rate (“ORR”) at the therapeutic dose range of patients with EGFR-sensitive mutations and resistant to the third-generation TKI and progressed after chemotherapy was 28.6 %;
 - Clinical benefit has been observed in three patients (2 PRs, 1 persistent SD) who have cMET alterations after a third-generation TKI treatment.
- At the same time, an advantage of safety profile was also demonstrated.
 - The infusion reaction rate was relatively low and mild;
 - The severity of paronychia and rash were mild (grade 1/2); and only grade 1 diarrhea;
 - No MET target-related peripheral edema were reported.

- These updated research data have been accepted by the ESMO Congress 2024 and were published on 14 September 2024.

Research and Development of the Global Innovative New Drugs

- The Company's R&D team focused on the development of targets and projects with FIC/BIC potential. As at 31 December 2024, a number of preclinical candidate compounds ("PCC") molecules have been developed, all of which are highly innovative and have the potential to become BIC bi-specific/multi-specific antibody projects; among which, research abstracts of two tri-specific antibody molecule projects (GB268 anti-PD-1/VEGF/CTLA-4 and GBD218 CD3/BCMA/GPRC5D) have been accepted for publication at the 2024 Annual Meeting of the AACR.

Drive Continuous Optimization of CMC Quality and Efficiency

- In accordance with the Company's strategy of "focus and optimization", the CMC team of the Company continued to promote the platform-based construction of the internal and external cooperation workflow of the project.
 - Through the domestic exploration of culture medium, chromatographic filler, disposable products (dispensing bags, storage bags, filling bags and filters) and auxiliary materials, we, without affecting the quantity and quality of products, have significantly reduced production costs, improved the stability of the supply chain, reduced storage costs, and enhanced liquidity efficiency.
 - We continued to promote the establishment and optimization of a molecular developable assessment platform for rapid protein expression, high-throughput purification, full range of characterization and process applicability assessment, and also facilitate the development and application of high-concentration preparation development platform in line with the demand of projects.
 - We further improved the quality control and study platform. We strengthened the construction of applicable quality system and MAH-related quality system and initiated the establishment of the drug variety archive. We supervised the conformity of contract development and manufacturing organization ("CDMO")'s process and method development, production process control and testing process according to the quality manual formulated per Good Manufacturing Practice ("GMP") which was released according to the conformity of the final product, and further optimized the working mode and cooperation efficiency.
 - In addition to solving the industry pain points such as low heterologous pairing rate, high polymer content, removal of homodimer impurities, unstable intermediates, difficulty in activity analysis methods and difficulty in the development of formulations, especially high-concentration formulations, the CMC team of the Company also demonstrated industry-leading strength and rapid execution in the process technology development of GB261 (CD20/CD3, BsAb), GB263T (EGFR/cMET/cMET, TsAb), GB268 (anti-PD-1/VEGF/CTLA-4, TsAb) and other products.

OUR MISSION

Striving to “provide innovative therapeutics initially for patients in China and gradually for patients globally”, the Company presses on with its effort in becoming a biopharmaceutical engine in discovery, research and development of innovative biopharmaceutical drugs.

OVERVIEW

Since its establishment in 2007, the Group is committed to becoming an innovative company capable of drugs innovation, research and development, pre-clinical study, clinical development, registration and chemistry, manufacturing and controls (“**CMC**”) development.

Since the successful implementation of the development strategy of “focus, optimization, acceleration, expansion” in 2022 and the achievement of initial results in 2023, the Group has consistently pushed forward the execution of this strategy in 2024, with a view to achieving stable development and efficient operation as well as creating opportunities under the challenging economic and industry environment.

The Group has further optimized its structure and adopted various flexible modes of external cooperation during the Reporting Period, successfully achieving the transformation into an enterprise adopting the asset-light model, thereby reducing operating costs significantly. While reducing its costs and increasing its efficiency, the Group actively conducted strategic cooperation, signed merger agreements and reached BD cooperation in various pipelines, focusing on promoting the development of core pipelines and new drug approval.

In terms of external cooperation and expansion, the Group entered into a merger agreement (the “**Merger Agreement**”) with Edding Group Company Limited (“**Edding**”) on 13 September 2024, whereby the Company will acquire Edding by way of a merger (the “**Proposed Merger**”), and in consideration therefor, the Company will allot and issue shares (the “**Consideration Shares**”) to the shareholders of Edding. Immediately upon completion of the Proposed Merger, the original shareholders of Edding will hold approximately 77%, and the shareholders of the Company (the “**Shareholders**”) will hold approximately 23%, of the issued shares of the Company as enlarged by the allotment and issue of the Consideration Shares (the final issue size is subject to the number of relevant Shares at the time of closing of the Proposed Merger). The Proposed Merger will bring about complementary advantages from multiple perspectives and create significant synergies, including the complementarity of research and development capabilities and commercialization platforms, the synergy between product pipelines and market expansion, the optimization and integration of financial resources. The Proposed Merger is expected to achieve the two-way empowerment of “research and development-driven” and “product commercialization”, and the in-depth integration between the two parties in areas such as research and development, sales, production and finance is expected to enhance the market competitiveness of the Group. The Proposed Merger constitutes a very substantial acquisition and a reverse takeover of the Company, and is therefore subject to approval of the Shareholders. The Group as enlarged by Edding and its subsidiaries upon the closing of the Proposed Merger (the “**Enlarged Group**”) must be able to meet the basic listing eligibility requirements of the Rules Governing the Listing of Securities (the “**Listing Rules**”) of The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”).

Apart from signing the Merger Agreement with Edding, the Group entered into the License Agreement and the Stock Purchase Agreement with TRC 2004, Inc. on 2 August 2024. Under the License Agreement, the Group has agreed, among others, to grant TRC 2004, Inc. an exclusive worldwide license (excluding mainland China, Hong Kong, Macau and Taiwan) to develop, use, manufacture, commercialize and otherwise exploit GB261 (CD20/CD3, BsAb) (“**GB261**”). The collaboration with TRC 2004, Inc. will mainly focus on exploring the potential of GB261 in autoimmune diseases. This is a recognition for the Company’s independent research and development capabilities. It is also expected that this potential BIC CD20/CD3 bi-specific antibody will be validated by more clinical trial data as soon as possible, which will ultimately demonstrate its promising efficacy and favorable safety profile. The Company expects GB261 to become an “innovative therapeutic for patients in China and globally” and support the Company to achieve its mission. In September 2024, Candid Therapeutics merged with TRC 2004, Inc.

In addition, the Group entered into a technology transfer agreement with Hangzhou Zhongmei Huadong Pharmaceutical Co., Ltd (“**Zhongmei Huadong**”) in January 2024, under which the Group’s anit-FGFR2b molecular sequences, technical data and related intellectual property (“**IP**”) rights were transferred to the latter.

On 2 January 2025, Genor Biopharma Co., Ltd. (“**Genor Biopharma**”), the Company’s wholly-owned subsidiary entered into a cooperative development agreement (the “**Cooperative Development Agreement**”) with Edding in relation to two tri-specific antibodies: GBD218 is a lead molecule of tri-specific antibody targeting CD3/BCMA/GPRC5D, and project GBD220 aims to generate a CD3/CD19/BCMA tri-specific antibody. Both are in the early discovery stage (before preclinical candidate compounds (“**PCC**”)).

In terms of focusing on the development of core pipelines and new drug approval, the interim analysis of the phase III clinical study of Lerociclib (GB491) in combination with letrozole for treatment of the advanced first-line breast cancer has reached the primary endpoint. The Company officially submitted the new drug application (“**NDA**”) of Lerociclib in combination with letrozole for the treatment of locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2-negative (“**HR+/HER2-**”) breast cancer (first-line treatment for advanced breast cancer) that had not received prior systemic antitumor therapy to the China National Medical Products Administration (“**NMPA**”) on 28 February 2024, which was officially accepted on 13 March 2024. The on-site clinical inspection was completed in September 2024, and the feedback of NDA queries was submitted in December 2024.

The NDA of Lerociclib (GB491) in combination with Fluvestran as the second-line treatment for the advanced breast cancer also made a good progress in 2024. The feedback of NDA queries was submitted in March 2024. The drug testing at the China National Institutes for Food and Drug Control was completed in May 2024. The overseas on-site production Pre-Approval Inspections for the active pharmaceutical ingredients (“**API**”) and drug product plants were completed in September and October 2024, respectively, and the reports for follow-up items of the Center for Food and Drug Inspection (“**CFDI**”) inspection were submitted to CFDI in December 2024. On 24 February 2025, the Center for Drug Evaluation (“**CDE**”) formally accepted the overseas on-site production Pre-Approval Inspection follow-up reports and restarted the NDA review for advanced second-line breast cancer.

GB268 is another differentiated innovative anti-PD-1/ VEGF/ CTLA-4 tri-specific antibody solely developed by the Group, which specifically targeting PD-1, VEGF and CTLA-4. The pre-clinical results show that GB268 can substantially enhance the anti-tumor effect with a better safety profile compared to the combination of three monoclonal antibodies, targeting PD-1, CTLA-4 and VEGF respectively, as well as the anti-PD-1/VEGF BsAb or anti-PD-1/CTLA-4 BsAb. It has the potential to become an upgraded immune checkpoint inhibitor. GB268 entered the pre-investigational new drug (“**IND**”) enabling stage in 2024, and its Good Laboratory Practice (“**GLP**”) toxicology study in cynomolgus monkeys with weekly dosing for 4 weeks was completed in March 2025, with no serious drug-related adverse effects observed in animals after multiple doses. The preliminary CMC results suggest that the tri-specific molecule has a good drug developability and stability, and the pilot-scale Good Manufacturing Practice (“**GMP**”) production have been completed.

GB261 (CD20/CD3, BsAb) demonstrated a favorable safety, pharmacokinetic profile and promising clinical antitumor activities in the phase I/II clinical trial for lymphoma, which validated the molecular design mechanism of GB261. The Company completed the phase I/II clinical trial of GB261 for lymphoma in 2024, and completed the clinical study report in July 2024.

Developed independently by the Group as the world’s first EGFR/cMET/cMET TsAb, GB263T has shown promising efficacy at the therapeutic dose range (1,260-1,680 mg). It has also shown a favorable safety profile. The updated clinical study results have been accepted by the European Society for Medical Oncology (“**ESMO**”) Congress 2024 and were published on 14 September 2024.

In terms of early-stage research and development, the Company focused on the targets and projects with first-in-class (“**FIC**”)/best-in-class (“**BIC**”) potential. As of 31 December 2024, a number of PCC molecules have been developed, all of which are highly innovative and have the potential to become BIC bi-specific/multi-specific antibody projects. Abstracts of two of the tri-specific antibody molecules (GB268 anti-PD-1/VEGF/CTLA-4 and GBD218 CD3/BCMA/GPRC5D) have been accepted for publication at the 2024 Annual Meeting of the American Association for Cancer Research (“**AACR**”).

THE GROUP’S DRUG CANDIDATES

As at the date of this announcement, the Group relies on the highly specialised departments, the close collaboration between different departments, and its efforts to expand external cooperation to persistently advance the clinical progress of innovative pipeline drugs across the world.

The following chart shows our robust pipeline of drug candidates that are currently under development in China and worldwide across various therapeutic areas and the development status of antibody drug candidates in clinical stage as at the date of this announcement:

Product	Target/MoA (reference drug)	Indication	Classification	Commercial Rights	Discovery	Pre- Clinical	IND Enabling	Phase I	Phase II	Phase III	NDA
GB491 (Lerociclib)	CDK4/6+AI (combo w/ letrozole)	1L HR+/HER2- BC	Novel (In-license)	APAC ex-JP							
	CDK4/6+SERD (combo w/ fulvestrant)	2L HR+/HER2- BC									
GB261	CD20×CD3	NHL	Novel (In-house)	Worldwide ⁽¹⁾	Phase I/II						
GB263T	EGFR×c-Met×c-Met	NSCLC	Novel (In-house)	Worldwide	Phase I/II						
GB242 (Infliximab)	TNF-α (infliximab)	RA, AS, Ps, CD, UC	Biosimilar (In-house)	Worldwide	NDA Approved						
GB226+GB492 (Geptanolimab+ IMSA101)	PD-1 (combo w/ GB226)+STING	Solid Tumours	Novel (In-house)	APAC ex-JP							
GB221 (Coprelotamab)	HER2	HER2+ 1L/2L+ mBC	Novel (In-house)	Worldwide							
GB223	RANKL	GCTB, PMO	Novel (Co-develop)	Worldwide							
GB241 (Rituximab)	CD20 (rituximab)	1L DLBCL	Biosimilar (In-house)	Co-development							
GB251	HER2 ADC	HER2+ 1L/2L+ mBC	Novel (Co-develop)	Worldwide							
GB268	PD-1/VEGF/CTLA-4	Cancers	Novel (In-house)	Worldwide							
GB262	PD-L1/CD55	Cancers	Novel (In-house)	Worldwide							
GB264	Claudin 18.2/CD3	GI Cancers	Novel (In-house)	Worldwide							
GB266	PD-L1/LAG3/LAG3	Cancers	Novel (In-house)	Worldwide							
GB267	CD3/BCMA/GPRC5D	Cancers	Novel (In-house)	Worldwide ⁽²⁾							
***	Undisclosed	Cancers	Novel (In-house)	Worldwide							

Notes:

- (1) Exclusive worldwide license to Candid Therapeutics to develop, use, manufacture, commercialize and otherwise exploit GB261, excluding the mainland China, Hong Kong, Macau and Taiwan.
- (2) Assigned to Edding the rights to develop, manufacture and commercialize GBD218 worldwide.

* Several undisclosed candidate molecules are in discovery stage
Continued internal development of GB226 PD-1 and GB221 have been paused and pending further assessment of development strategy and resource allocation.

BUSINESS REVIEW

During the Reporting Period, on the basis of further organizational optimization, the Group continued to make remarkable progress in strategic cooperation and the development/registration of drug candidates pipelines. The main corporate achievements are as follows:

1. Events during the Reporting Period

Strategic Cooperation and Commercialization

Proposed Merger with Edding

As set out in the section headed “BUSINESS HIGHLIGHTS – Strategic Cooperation – *Proposed Merger with Edding*” above, on 13 September 2024, the Group entered into the Merger Agreement with Edding whereby the Company will acquire Edding by way of a merger. For further details of the Proposed Merger, please refer to the announcement of the Company dated 7 October 2024.

- On 24 January 2025, the Group and Edding entered into an amendment agreement to the Merger Agreement to extend the deadline for submitting the new listing application in connection with the Proposed Merger (the “**New Listing Application**”) and the long stop date of the closing of the Proposed Merger. Please refer to the announcement of the Company dated 24 January 2025 for further details.
- As at the date of the announcement, the Company and Edding are in the course of preparing the New Listing Application. The Company currently expects to submit the New Listing Application by the end of April 2025. For further details, please refer to the announcement of the Company dated 25 March 2025.

International Cooperation of GB261

- As set out in the section headed “BUSINESS HIGHLIGHTS – Strategic Cooperation – *International Cooperation of GB261*” above, on 2 August 2024, the Group has entered into the License Agreement and the Stock Purchase Agreement with TRC 2004, Inc. in respect of GB261. For further details, please refer to the announcement of the Company dated 5 August 2024.

Cooperation with Zhongmei Huadong

As set out in the section headed “BUSINESS HIGHLIGHTS – Strategic Cooperation – *Cooperation with Zhongmei Huadong*” above, on 19 January 2024, the Company entered into an antibody molecules and related technology transfer agreement with Zhongmei Huadong, under which anti-FGFR2b, an antibody drug, and the related IP rights of the Company were transferred to Zhongmei Huadong.

Pipeline Advancement of Drug Candidates

During the Reporting Period, the Company has achieved rapid progress of pre-clinical and clinical trials of product pipelines, which were attributable to the high specialization of and close cooperation across departments:

- Based on in-depth perception of product science, mechanisms and features, the Group has developed its registration and clinical development strategies. The Group has continuously enhanced communication with industry leaders in relevant treatment fields, drug regulatory authorities, drug review agencies, and clinical research centers.
- Relying on rich experience and extensive resources, efficient, high-quality and speedy accomplishment was made in the planning and collaboration with the research centres, project initiating and management, selection and, enrolment of the study participants.

During the Reporting Period, the Group has speedily completed the data cleaning and the interim analysis of the phase III clinical study evaluating efficacy and safety of Lerociclib in combination with letrozole as first-line treatment for HR+/HER2- advanced breast cancer. The Company submitted the corresponding NDA which was accepted by the NMPA.

During the Reporting Period, we have continued our efforts in promoting the clinical pipelines development and achieved milestones as follows:

- 1) The NDA of GB491 (Lerociclib) in combination with letrozole for the treatment of locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2-negative (“**HR+/HER2-**”) breast cancer (first-line treatment for advanced breast cancer) that had not received prior systemic antitumor therapy, has been accepted in March 2024. The on-site clinical inspection was completed in September 2024 and the feedback of NDA queries was submitted in December 2024.
- 2) Regarding the NDA of GB491 (Lerociclib) combined with Fluvestran for the treatment of HR+/HER2- patients with locally advanced or metastatic breast cancer (advanced second-line breast cancer) that have disease progression following previous endocrine therapy, the Company has completed the submission of the feedback of NDA queries and drug testing at China National Institutes for Food and Drug Control in March and May 2024 respectively. In September and October 2024, overseas on-site production Pre-Approval Inspections of the API and drug product plants were completed, respectively, and the reports for follow-up items of CFDI inspection were submitted to CFDI in December 2024.
- 3) GB268 (anti-PD-1/VEGF/CTLA-4, TsAb) entered the pre-clinical pre-IND development stage in 2024 for CMC process development and GLP toxicology studies.
- 4) The Phase I/II clinical trial of GB261 (CD20/CD3, BsAb) for lymphoma ended in 2024, and the clinical study report was completed in July 2024.
- 5) GB263T (EGFR/cMET/cMET, TsAb) Phase I/II clinical trial results have been accepted by ESMO Congress 2024 and were published on 14 September 2024.

GB491 (Lerociclib, a differentiated oral CDK4/6 inhibitor) – to provide breast cancer patients a CDK4/6 inhibitor with better efficacy and tolerability

GB491 (Lerociclib), is a novel, potent, selective oral bioavailable CDK4/6 inhibitor co-developed by the Group and G1 Therapeutics, for use in combination with endocrine therapy in advanced breast cancer.

On 28 March 2023, the NMPA has officially accepted the NDA of GB491 (Lerociclib) in combination with Fluvestrin for the treatment of HR+/HER2- locally advanced or metastatic breast cancer patients (second-line treatment for advanced breast cancer) with disease progression following previous endocrine therapy. On 31 August 2023, clinical on-site inspection was completed. The feedback of NDA queries was submitted in March 2024 and the drug testing at the China National Institutes for Food and Drug Control was completed in May 2024. In September and October 2024, the overseas on-site production Pre-Approval Inspections of the API and the drug product plants were completed, respectively, and the reports for follow-up items of CFDI inspection were submitted to CFDI in December 2024.

On 28 February 2024, the Company has formally submitted the NDA of GB491 (Lerociclib) in combination with letrozole for the treatment of locally advanced or metastatic hormone receptor (HR)-positive, human epidermal growth factor receptor 2-negative (“HR+/HER2-”) breast cancer (first-line treatment for advanced breast cancer) that had not received prior systemic antitumor therapy to the NMPA, and the application was officially accepted on 13 March 2024. The on-site clinical inspection was completed in September 2024. The feedback of NDA queries was submitted in December 2024.

- The Independent Data Monitoring Committee (“**IDMC**”) has conducted efficacy and safety data evaluation on the interim analysis of the phase III clinical trial of Lerociclib in combination with letrozole as the first-line treatment for advanced breast cancer. The IDMC recommended that this clinical trial had met the prespecified requirement of statistical significance in efficacy for the interim analysis with good safety and tolerance.
- The interim analysis results showed that Lerociclib significantly reduced the risk of disease progression in patients by more than 50%. Progression-free survival (“**PFS**”) based on the investigator assessment: for disease progression in the Lerociclib in combination with letrozole group versus the placebo in combination with letrozole group, hazard-ratio (95% CI) and p-value, 0.464 (0.293, 0.733), p=0.0004, respectively; investigator-assessed median PFS was not reached in the Lerociclib group, and was 16.56 months in the placebo group. PFS based on the Independent Review Committee’s (“**IRC**”) assessment: hazard-ratio (95% CI) and p-value, 0.457 (0.274, 0.761), p=0.0011, respectively.
- The safety advantage was reaffirmed: the overall incidence rate of gastrointestinal adverse events (“**AEs**”) was low and mild, with grade 3 diarrhea occurred in only one patient (0.7%). No grade ≥3 nausea or vomiting has occurred, and grade 4 neutropenia occurred in only 5.1%.
- The results of the interim analysis were presented in the poster session at the American Society of Clinical Oncology (“**ASCO**”) annual meeting in June 2024.

The superior efficacy and safety profile of GB491 (Lerociclib) will provide a better treatment option for patients with HR+/HER2- advanced breast cancer:

- HR+/HER2- is the most common subtype of advanced breast cancer, and its treatment has entered the era of targeted therapy. The combination therapy with CDK4/6 inhibitors has been recommended in multiple guidelines as the preferred regimen for patients with advanced breast cancer.
- The innovative molecular structure, targeting specificity and high efficacy, with its unique pharmacokinetics/pharmacodynamics (“**PK/PD**”), has allowed for continuous oral administration of Lerociclib without the need for treatment breaks. It achieves sustained target inhibition and antitumor effects while significantly reduces the common adverse effects of CDK4/6 inhibitors, such as severe myelosuppression and diarrhea.
- GB491 (Lerociclib) demonstrated a superior efficacy with advantages in terms of safety and tolerance profile in two phase III clinical studies, and hence fully demonstrating the differentiation advantage of Lerociclib for clinical purposes.
 - The LEONARDA-1 clinical study has demonstrated that the combination therapy of Lerociclib with Fluvestrin significantly reduce the risk of disease progression and death in HR+/HER2- advanced breast cancer patients following previous endocrine therapy as compared to using Fluvestrin as a monotherapy. The investigator-assessed hazard ratio (“**HR**”) was 0.451 and the Blinded Independent Central Review (“**BICR**”)-assessed HR was 0.353. The median progression free survival (“**mPFS**”) (months) assessed by the investigator and BICR were 11.07 vs. 5.49 and 11.93 vs. 5.75, respectively. Furthermore, the results of all predefined subgroups were consistent with the overall efficacy. The LEONARDA-1 clinical study enrolled a high proportion of refractory patients, including patients with liver metastasis, treated with primary resistance, with four or more metastatic organs, and received first-line chemotherapy at an advanced stage. The use of Lerociclib substantially improved the PFS of the refractory patients. The LEONARDA-1 clinical study showed that, in comparison with other marketed CDK4/6 inhibitors, Lerociclib had significant comprehensive advantages in terms of safety and tolerance profile. It recorded a low incidence rate of diarrhea at 19.7%, which was a relatively low percentage of grade 3/4 myelosuppression, and only a 5.1% incidence rate of grade 4 neutropenia.
 - The LEONARDA-2 clinical study also demonstrated superior efficacy and safety profile in combination with letrozole for the treatment of HR+/HER2- locally advanced or metastatic breast cancer patients who had not received prior systemic antitumor therapy.
 - The interim analysis showed that Lerociclib significantly reduced the risk of disease progression in patients by more than 50%, based on investigator-assessed PFS: hazard ratio (95% CI) and p-value were 0.464 (0.293, 0.733), p=0.0004, respectively; mPFS was not reached in the Lerociclib group, and was 16.56 months in the placebo group. PFS based on IRC assessment: hazard ratio (95% CI) and p-value were 0.457 (0.274, 0.761), p=0.0011, respectively.
 - The safety advantage was reaffirmed: the overall incidence rate of gastrointestinal adverse events (“**AEs**”) was low and mild, with grade 3 diarrhea occurred in only one patient (0.7%). No grade ≥3 nausea or vomiting has occurred, and grade 4 neutropenia occurred in only 5.1% of the patients.

On 13 September 2024, the Company has entered into the CDK4/6i Outsourcing Management Agreement with Edding, pursuant to which the Company agreed to entrust Edding with, and Edding agreed to provide services for, the management of all matters relating to CDK4/6i, including the submission of new drug application(s), manufacturing, supply chain management and any other relevant matters. For further details of the CDK4/6i Outsourcing Management Agreement, please refer to the announcement of the Company dated 7 October 2024.

The transfer of technology for local manufacture of GB491 (Lerociclib) has been initiated.

GB268 (anti-PD-1/VEGF/CTLA-4, TsAb)

GB268 is a significantly innovative tri-specific antibody solely developed by the Group that specifically blocks PD-1, VEGF and CTLA-4 signaling pathways. To reduce the CTLA4 inhibition-induced AEs, the CTLA-4 arm only partially blocked the interaction of CTLA4 to its ligands CD80/CD86, and furthermore, the combination of CTLA-4 arm was highly dependent on PD-1 arm. Preclinical data demonstrated the efficient antitumor activities of GB268. At the meantime, immune-related AEs are alleviated. Thus, GB268 may emerge as a promising novel therapy for cancer treatment.

- In multiple PBMC-humanized models including A375 melanoma model, HT29 colorectal cancer model, and NCI-H460 NSCLC model, etc., GB268 exhibited better antitumor efficacy, compared to PD-1/CTLA-4 BsAb and PD-1/VEGF BsAb, or the combination of the three monoclonal antibodies, namely PD-1, CTLA-4 and VEGF.
- In arthritis induction model using hPD1/hCTLA4 KI mice, GB268 had improved tolerance than cadonilimab and at least 20-fold better safety profile than ipilimumab combined with OPDIVO.

GB268(anti-PD-1/VEGF/CTLA-4, TsAb) entered the pre-clinical pre-IND enabling development stage in 2024 for CMC process development and GLP toxicology studies. The preliminary results suggest that the tri-specific molecule has a good drug developability and stability, with no significant drug-related toxicity observed in the high, medium and low dose groups of 4-week exploratory toxicological experiment in the cynomolgus monkeys.

GB261 (CD20/CD3, BsAb)

GB261 (CD20/CD3, BsAb) is the first T-cell engager (“TCE”) with low affinity to bind CD3 and has Fc functions (ADCC and CDC). GB261 significantly inhibits rituximab-resistant cancer cell proliferation in both in vitro assays and in vivo models; meanwhile with T-cell activation, GB261 induces less cytokine release compared with compound in the same class. Thus, GB261 is a highly potent bispecific therapeutic antibody for B-cell malignancies. It has potential to be a better and safer TCE with significant competitive advantages over other CD3/CD20 agents.

The GB261 Phase I/II lymphoma clinical trial was led by Peking University Cancer Hospital, and was completed in 2024 at multiple clinical research centers in Australia and China. The clinical study report was completed in July 2024. Complete and sustained remission was observed in patients with relapsed refractory diffuse large B-cell lymphoma (RR DLBCL) at a low-dose (3mg) conducted in the Australian study center. The favorable safety, pharmacokinetic profile and promising clinical antitumor activities obtained in the trial were consistent with the molecular design mechanism of GB261.

The preliminary results of phase I/II study of GB261 were presented at the annual meeting of the 65th American Society of Hematology in the poster session:

- GB261 is a novel and highly differentiated CD20/CD3 bispecific antibody and is the first clinical stage Fc+ CD20/CD3 TCE. In heavily pretreated BNHL failed patients, GB261 showed a highly advantageous safety/efficacy balance. The safety profile of GB261 is excellent especially for the CRS which is very mild, transient and less frequent as compared with other CD20/CD3 bispecific antibodies. The response after GB261 treatment was early, deep and durable. Additionally, clinical benefit is also seen in other CD20/CD3 failed patients, which provides clinical support to the unique and differentiated mechanism of action of GB261.

GB263T (EGFR/cMET/cMET, TsAb)

GB263T (EGFR/cMET/cMET, TsAb) is the first tri-specific antibody of EGFR/cMET/cMET in the world, targeting EGFR and two different cMET epitopes, so designed to enhance its safety and efficacy profile. With highly differentiated design, GB263T exhibits multiple mechanisms of action to inhibit primary and secondary EGFR mutations and cMET signaling pathway simultaneously.

In pre-clinical studies, GB263T effectively thwarted ligand-induced phosphorylation of EGFR and cMET compared to Amivantamab (JNJ-372) analogue, and demonstrated better dual inhibition of EGFR and cMET signaling pathways. Meanwhile, GB263T effectively induced the endocytosis of EGFR and cMET, and significantly reduced the protein expression levels of EGFR and cMET. GB263T played a significant dosage-dependent role in tumor suppression in several different tumor models including EGFR exon 20 insertions, EGFR exon 19 deletions, C797S mutations and various cMET expression abnormalities. In toxicology studies in cynomolgus monkeys, no significant toxic side effects were observed after 4 weeks of observation, even in the highly-dosed group.

- As of 31 December 2023, a total of 15 patients had received at least one GB263T treatment. All patients had received previous third-generation EGFR-TKI and platinum-based chemotherapy and the median number of prior lines of systemic therapy was 3. These updated research data have been accepted by the ESMO Congress 2024 and were published on 14 September 2024.
- GB263T has shown promising efficacy at the therapeutic dose range (1,260-1,680 mg).
 - The confirmed objective response rate (“**ORR**”) of patients with EGFR-sensitive mutations and resistance to the third-generation TKI treatment and have disease progression at the therapeutic dose range of 1,260/1,680mg was 28.6%;
 - An apparent benefit was observed in three patients (2 PRs and 1 durable SD) who have developed drug-resistant cMET changes after a third-generation TKI treatment. As of the date of relevant data, treatment durations are over 12 months (840mg, SD patients), over 10 months (1,260mg, PR patients), and over 8 months (1,680mg, PR patients), respectively.

- At the same time, an advantage of safety profile was also demonstrated.
 - The infusion reaction rate was relatively low (33.3%) and mild (no ≥ 3 infusion reactions); infusion reactions occurred only in 10% of cases at effective doses and were all grade 1;
 - Other common treatment-related AEs were rash (60%), fatigue (40%), and paronychia (40%), all of which were mild (grade 1/2);
 - No MET target-related peripheral edema toxicity was reported. No venous thrombosis occurred.

Research and Development of the Global Innovative New Drugs

The Company's R&D team focused on developing targets and projects with FIC/BIC potential. As of 31 December 2024, multiple development of bi-poly antibody molecules at or near the PCC stage have been completed, all of which are highly innovative bi-specific/multi-specific antibody projects with the potential to be BIC.

- Abstracts of two TsAb molecule projects have been accepted for publication at the 2024 Annual Meeting of the AACR.
- Topic of "Single Target and Bispecific Antibodies", Number: PO.IM01.06

Title: "Development of GB268, a tri-specific antibody targeting PD-1/CTLA-4/VEGF, with enhanced efficacy and reduced toxicity in pre-clinical studies"

Abstract

- Research background:

Immunotherapy using immune checkpoint modulators such as anti-PD1/PD-L1 have been widely used in cancer therapy. Combination use of anti-PD1 and anti-CTLA4 inhibitors may improve therapeutic efficacy but is also accompanied by severe immune related adverse events ("irAEs") which limited their clinical use. Bi-specific antibody targeting PD-1/CTLA-4 such as cadonilimab has shown improved clinical benefits with reduced irAEs in cervical cancer. Vascular endothelial growth factor ("VEGF") is overexpressed in various solid tumors and anti-VEGF agents inhibit neovascularization. Combined application of bevacizumab and PD-1/PD-L1 blockade displays durable and significant antitumor effects. GB268 is a tri-specific molecule that specifically targets PD-1, CTLA-4 and VEGF. The pre-clinical results show the combined effect of triple targets and good safety.

- Methods:

GB268 is a hexavalent antibody with symmetrical structure, composed of anti-PD-1 VHH antibody, anti-CTLA-4 VHH antibody, and anti-VEGF conventional antibody. The design of molecule and the activity of each arm have been adjusted and explored based on the biological characteristics in order to achieve functional balance. L234A/L235A mutations have been introduced to the FC part.

➤ Results:

GB268 specifically bound to PD-1, VEGF, and CTLA-4 effectively blocked PD-1 and VEGF pathways. To reduce the CTLA4 inhibition-induced AEs, the CTLA-4 arm only partially blocked the interaction of CTLA4 to its ligands CD80/CD86, and furthermore, the combination of CTLA-4 arm was highly dependent on PD-1 arm. GB268 displayed robust antitumor efficacy with attenuated toxicity in murine models. In multiple PBMC-humanized models including A375 melanoma model, HT29 colorectal cancer model, and NCI-H460 NSCLC model, etc., GB268 exhibited better antitumor efficacy, compared to PD-1/CTLA-4 BsAb and PD-1/VEGF BsAb, or in the combination of the three monoclonal antibodies, namely PD-1, CTLA-4 and VEGF. In arthritis induction model using hPD1/hCTLA4 KI mice, GB268 had improved tolerance than cadonilimab and at least 20-fold better safety profile than ipilimumab combined with OPDIVO.

➤ Conclusions:

GB268 is a anti-PD-1/CTLA-4/VEGF tri-specific antibody with innovative design. Preclinical data demonstrated the efficient antitumor responses of GB268. At the meantime, immune-related AEs is alleviated. Thus, GB268 may emerge as a promising novel therapeutics for cancer treatment.

- Topic of “Late-Breaking Research: Immunology 2”, Number: LBPO.IM02

Title: “GBD218 – A tri-specific T cell engager (TCE) targeting BCMA and GPRC5D for treatment of multiple myeloma”

Abstract

➤ Research background:

Multiple myeloma (“MM”) accounts for 10% of all hematologic cancers. Recent advances in MM therapy have greatly increased the overall response and survival rate. However, most of the patients eventually relapse. The prognosis still remains poor. Although CAR-T and T cell engager (“TCE”) targeting BCMA or GPRC5D have been highly efficacious in treating MM patients, resistance still occurs. Since the expression of BCMA and GPRC5D in MM are heterogeneous, to further improve the overall response and survival, the Company has generated a tri-specific TCE, GBD218, targeting both BCMA and GPRC5D.

➤ Methods:

Anti-BCMA and GPRC5D nanobodies were screened from alpaca immune libraries. The format of the tri-specific antibodies was optimized by multiple rounds of in vitro activity and drug physicochemical properties evaluation. The in vivo tumor growth inhibition effects were evaluated in PBMC-humanized xenograft mouse models.

➤ Results:

GBD218 is able to potently bind hBCMA (KD=0.4nM) and hGPC5D (cell binding EC50 ~ 2nM). To reduce CRS and other potential AEs associated with TCEs, anti-CD3 with relatively low affinity was used. In cell-based functional assays, GBD218 showed efficient killing effect against single and double positive MM cell lines with various expression levels of BCMA and GPRC5D. Cell activation and cytokine release are nicely balanced for great killing efficacy and the low risk of CRS. The vitro results showed that GBD218 exhibited superior in vitro killing activity compared to benchmarks, including teclistamab, talquetamab, the combination of teclistamab and talquetamab, suggesting a synergistic effect of GBD218 by targeting both BCMA and GPRC5D. In xenograft models, GBD218 showed excellent antitumor activity, indicating potential for GBD218 as a promising therapeutics for MM.

➤ Conclusions:

GBD218 is a tri-specific antibody that showed potent in vitro and in vivo antitumor activity. GBD218 efficiently kills both BCMA and/or GPRC5D expressing MM cells, which may hold promise to increase response rate and improve survival in MM patients in clinic.

Drive continuous optimization of CMC quality and efficiency

In accordance with the Company's strategy of "focus and optimization", the CMC team of the Company continued to promote the platform-based construction of the internal and external cooperation workflow of the project.

- Through the domestic exploration of culture medium, chromatographic filler, disposable products (dispensing bags, storage bags, filling bags and filters) and auxiliary materials, we, without affecting the quantity and quality of products, have significantly reduced production costs, improved the stability of the supply chain, reduced storage costs, and enhanced liquidity efficiency.
- We continued to promote the establishment and optimization of a molecular developable assessment platform for rapid protein expression, high-throughput purification, full range of characterization and process applicability assessment, and also facilitate the development and application of high-concentration preparation development platform in line with the demand of projects.
- We further improved the quality control and study platform. We strengthened the construction of applicable quality system and MAH-related quality system and initiated the establishment of the drug variety archive. We supervised the conformity of contract development and manufacturing organization ("CDMO")'s process and method development, production process control and testing process according to the quality manual formulated per GMP which was released according to the conformity of the final product, and further optimizing the working mode and cooperation efficiency.

- In addition to solving the industry pain points such as low heterologous pairing rate, high polymer content, removal of homodimer impurities, unstable intermediates, difficulty in activity analysis methods and difficulty in the development of formulations, especially high-concentration formulations, the CMC team of the Company also demonstrated industry-leading strength and rapid execution in the process technology development of GB261 (CD20/CD3, BsAb), GB263T (EGFR/cMET/cMET, TsAb), GB268 (anti-PD-1/VEGF/CTLA-4, TsAb) and other products.

2. Events after the Reporting Period

- On 2 January 2025, Genor Biopharma and Edding entered into the Cooperative Development Agreement in relation to two tri-specific antibodies: GBD218 is a lead molecule of tri-specific antibody targeting CD3/BCMA/GPRC5D with therapeutic potential for treating multiple myeloma, and project GBD220 aims to generate a CD3/CD19/BCMA tri-specific antibody with potential for treating autoimmune diseases. Both are in the early discovery stage (before PCC). Pursuant to the Cooperative Development Agreement, Genor Biopharma has agreed, among others, to assign to Edding all rights to develop, manufacture and commercialize GBD220 and GBD218 worldwide and in all fields (i.e. treatment, mitigation, diagnosis or prevention of human or animal diseases). For details, please refer to the announcement of the Company dated 24 January 2025.
- With effect from 10 January 2025, the address of the principal place of business in Hong Kong of the Company has been changed to Room 1920, 19/F, Lee Garden One, 33 Hysan Avenue, Causeway Bay, Hong Kong. For details, please refer to the announcement of the Company dated 9 January 2025.
- On 24 January 2025, the Group and Edding entered into an amendment agreement to the Merger Agreement to extend the deadline for submitting the New Listing Application and the long stop date of the closing of the Proposed Merger. For details, please refer to the announcement of the Company dated 24 January 2025.
- On 16 January 2025, the Nature Communications published the phase 3 study (LEONARDA-1) results titled “GB491 (Lerociclib) combined with fulvestrant for the treatment of HR+/HER2- patients with locally advanced or metastatic breast cancer that have disease progression following previous endocrine therapy: LEONARDA-1 a phase III randomized trial”. LEONARDA-1 Phase III study (ClinicalTrials.gov identifier, NCT05054751) was led by the lead author Prof. Binghe Xu, MD, PhD, the academician of the Chinese Academy of Engineering, the Head of Medical Oncology at Cancer Hospital affiliated with Chinese Academy of Medical Sciences.
- On 19 February 2025, the Company convened an extraordinary general meeting to approve the removal of PricewaterhouseCoopers and the appointment of Ernst & Young as the auditor of the Company. Each of the said proposed removal and proposed appointment was approved by the Shareholders by way of an ordinary resolution. Accordingly, with effect from 19 February 2025, PricewaterhouseCoopers has been removed as the auditor of the Company, and Ernst & Young has been appointed as the new auditor of the Company and to hold office until the conclusion of the next annual general meeting of the Company. For details, please refer to the announcements of the Company dated 22 January 2025 and 19 February 2025, the circular of the Company dated 4 February 2025.

- On 24 February 2025, the CDE formally accepted the overseas on-site production Pre-Approval Inspection reports and restarted the NDA review for advanced second-line breast cancer.
- The GLP toxicology studies in cynomolgus monkeys of GB268 (anti-PD-1/VEGF/CTLA-4) with repeated administration for 4 weeks was completed in March 2025, with no serious drug-related adverse effects observed in animals after multiple doses, and the pilot-scale GMP production has been completed.

Cautionary Statement required by Rule 18A.08(3) of the Listing Rules of the Stock Exchange:

Apart from Jiayoujian 佳佑健® (GB242, Infliximab Biosimilar), the Company cannot guarantee that it will be able to develop, and ultimately market, any of the other drug candidates successfully. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

Shareholders and potential investors should note that the closing of the Proposed Merger is subject to the fulfillment or waiver (as the case may be) of the conditions precedent to the obligations of the Company and/or Edding to consummate the Proposed Merger (the “Merger Conditions Precedent”). In addition, the Listing Committee of the Stock Exchange may or may not approve the New Listing Application to be made by the Company. In the event that approval of the New Listing Application is not granted, the Merger Agreement will not become unconditional and the Proposed Merger will not proceed.

The Executive of the Securities and Futures Commission of Hong Kong (the “Executive”) may or may not grant the whitewash waiver in connection with the Proposed Merger (the “Whitewash Waiver”). It is one of the Merger Conditions Precedent that the Whitewash Waiver has been granted. In the event that the Whitewash Waiver is not granted by the Executive or the Whitewash Waiver and the Proposed Merger are not approved at the extraordinary general meeting by the independent Shareholders, the Merger Agreement will not become unconditional and the Proposed Merger will not proceed.

As the Merger Closing may or may not take place, Shareholders and potential investors are reminded to exercise caution when dealing in the Shares.

BUSINESS OUTLOOK

The Group will further concentrate its efforts on potential global FIC and BIC innovation pipelines for tumors and autoimmune diseases, optimize and maximize its existing product portfolio by developing and executing a comprehensive strategy to conduct research on molecules with the best potential to become clinically beneficial and commercially viable drugs, with a view to achieving the mission of addressing unmet medical needs in China and globally.

During the Reporting Period, the Group further optimized its structure and successfully realized the enterprise's asset-light model through various flexible forms of external cooperation, thus significantly reducing operating costs. While reducing costs and enhancing efficiency, we actively carried out strategic cooperation, signed a merger agreement, and reached BD cooperations for several pipelines, focusing on promoting the development of core pipelines and new drug approvals.

With a focus on high-quality and original innovation, the Group is actively exploring its highly differential research and development platforms, technologies and development projects for early discovery on an ongoing basis. After successfully realizing the enterprise's transformation into asset-light model, not only will the Group reduce costs and enhance efficiency, but it will also continue to focus on promoting key projects of tumours and autoimmune diseases and exploration of FIC/BIC potential in multi-dimensions to achieve an effective balance between efficiency and costs. The Group actively carried out strategic cooperation and spared no effort to advance the Proposed Merger process with Edding, and the approval of GB491 (Lerociclib) for marketing, and IND and FIH clinical trials for GB268.

The Proposed Merger is expected to be filed with the Stock Exchange in the first half of 2025 and its closing is expected to be completed in the second half of 2025. The NDA for GB491 (Lerociclib) in combination with Fluvestran for the treatment of HR+/HER2- locally advanced or metastatic breast cancer patients (second-line treatment for advanced breast cancer) with disease progression following previous endocrine therapy and the NDA for GB491(Lerociclib) in combination with letrozole for the treatment of HR+/ HER2- locally advanced or metastatic breast cancer (first-line treatment for advanced breast cancer) that had not received prior systemic antitumor therapy are expected to be approved in 2025. The transfer of technology for local production of GB491 (Lerociclib) has been initiated simultaneously. The Company will also proactively advance the FIH clinical trial for GB268 this year. On the basis of the clinical proof-of-concept data for GB263T (EGFR/cMET/cMET, TsAb), the Group will actively seek international cooperation.

FINANCIAL REVIEW

The Reporting Period compared to year ended 31 December 2023

	<i>Notes</i>	Year ended 31 December 2024 RMB'000	Year ended 31 December 2023 RMB'000
Revenue	2	206,229	–
Cost of revenue	3	(1,341)	–
Gross profit		204,888	–
Administrative expenses	4	(71,707)	(125,237)
Research and development expenses	5	(202,778)	(564,278)
Impairment losses on financial assets		(31,588)	(8,922)
Other income – net	6	37,107	5,649
Other loss – net		(8,475)	(18,408)
Operating loss		(72,553)	(711,196)
Finance income	7	37,703	34,739
Finance costs	7	(282)	(1,039)
Finance income – net		37,421	33,700
Loss before tax		(35,132)	(677,496)
Income tax (expense)/credit		(17,842)	2,280
Loss for the Reporting Period	8	(52,974)	(675,216)

1. Overview

During the Reporting Period, the revenue of the Group was RMB206.2 million, as compared to nil for the year ended 31 December 2023, and the loss for the Reporting Period were RMB53.0 million, as compared to a loss of RMB675.2 million for the year ended 31 December 2023.

Research and development expenses of the Group were RMB202.8 million for the Reporting Period, as compared to RMB564.3 million for the year ended 31 December 2023. Administrative expenses were RMB71.7 million for the Reporting Period, as compared to RMB125.2 million for the year ended 31 December 2023.

2. Revenue

Revenue for the Reporting Period was RMB206.2 million. Revenue for the year ended 31 December 2023 was nil. This change was primary due to license and stock purchase agreements with TRC 2004, Inc.

3. Cost of Revenue

Cost of revenue for the Reporting Period was RMB1.3 million, as compared to nil for the year ended 31 December 2023. This change was primary due to increase in our revenue.

4. Administrative Expenses

Administrative expenses decreased by 42.7% from RMB125.2 million in 2023 to RMB71.7 million in 2024, primarily due to the decrease in employee benefits expenses.

5. Research and Development Expenses

Research and development expenses decreased by 64.1% from RMB564.3 million in 2023 to RMB202.8 million in 2024, primarily due to (i) the decrease in employee benefits expenses for research and development personnel; (ii) the decrease in our new drugs development fee and clinical trial expenses; and (iii) the decrease in raw material and consumables used.

The following table summarises the components of the research and development expenses of the Group for the years ended 31 December 2024 and 2023:

	Year ended 31 December	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Development fee and clinical trial expenses	78,298	194,298
Employee benefits expenses	44,179	127,367
Impairment of property and equipment	31,472	39,924
Depreciation and amortisation	15,841	69,951
Traveling and transportation expenses	8,787	9,881
Professional and technical service fee	5,618	8,732
Write down of inventories	4,972	33,832
Impairment of intangible assets	2,118	39,362
Raw material and consumables used	4,310	34,399
Others	7,183	6,532
Total	202,778	564,278

6. Other Income – Net

Other income – net was approximately RMB37.1 million, mainly attributable to the government grants increased from RMB3.7 million in 2023 to RMB36.8 million in 2024.

7. Finance Income and Costs

Finance income increased from RMB34.7 million in 2023 to RMB37.7 million in 2024, primarily due to the fluctuation of the interest income from bank deposits.

Finance costs decreased from RMB1.0 million in 2023 to RMB0.3 million in 2024, primarily due to decreased interest expense on lease liabilities.

8. Loss for the Reporting Period

As a result of the foregoing, our losses decreased from RMB675.2 million in 2023 to RMB53.0 million in 2024.

9. Liquidity and Source of Funding and Borrowing

Our management monitors and maintains a level of cash and bank balances deemed adequate to finance our operations and to mitigate the effects of fluctuations in cash flow. We rely on equity financing as the major source of liquidity.

As at 31 December 2024, our cash and bank balances decreased to RMB1,058.8 million from RMB1,165.5 million as at 31 December 2023. The decrease was mainly due to the operating loss for the Reporting Period.

10. Non-HKFRS Measure

To supplement the Group's consolidated financial statements which are prepared in accordance with the Hong Kong Financial Reporting Standards (the "HKFRS"), the Company also uses adjusted loss as an additional financial measure, which is not required by, or presented in accordance with HKFRS. The Company believes that this non-HKFRS financial measure is useful for understanding and assessing underlying business performance and operating trends. The Company also believes that the Company's management and investors may benefit from referring to this non-HKFRS financial measure in assessing the Group's financial performance by eliminating the impact of certain items that the Group does not consider indicative of the performance of the Group's business. However, the presentation of this non-HKFRS financial measure is not intended to be considered in isolation or as a substitute for the financial information prepared and presented in accordance with HKFRS. The use of this non-HKFRS measure has limitations as an analytical tool, and investors should not view the non-HKFRS financial results on a stand-alone basis or as a substitute for results under HKFRS, or as being comparable to results reported or forecasted by other companies.

The following table reconciles our Adjusted Loss for the Reporting Period to the most directly comparable financial measure calculated and presented in accordance with HKFRS:

	Year ended 31 December	
	2024	2023
	RMB'000	RMB'000
HKFRS Loss for the year	(52,974)	(675,216)
Add:		
Share-based payment expenses	<u>11,645</u>	<u>60,910</u>
Adjusted Loss for the year	<u>(41,329)</u>	<u>(614,306)</u>

11. Key Financial Ratios

The following table sets forth the key financial ratios for the details indicated:

	As at 31 December 2024	As at 31 December 2023
Current ratio ¹	8.74	5.41
Quick ratio ²	8.72	5.25
Gearing ratio ³	<u>0.11</u>	<u>0.18</u>

Notes:

1. Current ratio is calculated using current assets divided by current liabilities as at the same date.
2. Quick ratio is calculated using current assets less inventories and prepayments and divided by current liabilities as at the same date.
3. Gearing ratio is calculated using total liabilities divided by total assets as at the same date.

12. Significant Investments

As a consideration for the license sale, the Group was settled with an unlisted equity investment. The Group designated this equity investments as equity investment designated at fair value through other comprehensive income. As at 31 December 2024, the measurement of this equity investment designated at fair value through other comprehensive income was categorized within Level 3 hierarchy.

13. Material Acquisitions and Disposals

Save for the Proposed Merger, the Group did not have any material acquisitions or disposals of subsidiaries, consolidated affiliated entities or associated companies during the Reporting Period (for the year ended 31 December 2023: nil).

14. Pledge of Assets

As at 31 December 2024, none of the Group's assets were pledged (as at 31 December 2023: nil).

15. Contingent Liabilities

In April 2024, Genor Biopharma, an indirectly wholly-owned subsidiary of the Company, was notified that it has been named as a defendant in the lawsuit brought by an independent third party for an alleged breach of cooperation agreement once entered into among the two parties and its relevant supplemental agreements. The claim amounted to RMB15,000,000.

The directors, based on the advice from the Group's legal counsel, believed that it could not make reliable estimation of the outcome of the claim. Therefore, the Group did not provide for any claim arising from the litigation, other than the related legal and other costs.

In the opinion of the Company's directors, the Group had no significant contingent liabilities as at 31 December 2024 (as at 31 December 2023: nil).

16. Foreign Exchange Exposure

During the Reporting Period, we operated in the People's Republic of China (the "PRC") with most of the transactions settled in Renminbi. Our presentation and functional currency is Renminbi. We were not exposed to significant foreign exchange risk as there were no significant financial assets or liabilities of us denominated in the currencies other than Renminbi, except for the cash at bank in U.S. Dollar ("USD") which were primarily received from the investors as capital contributions and the proceeds obtained from the initial public offering.

The Group's monetary items mainly consisted of cash and bank balances. As at 31 December 2024, if RMB weakened or strengthened by 10% against USD, with all other variables held constant, loss before tax would have been RMB102,897,000 lower or higher (2023: RMB18,226,000).

We did not use any derivative contracts to hedge against our exposure to currency risk during the Reporting Period. However, our management monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

17. Employees and Remuneration

As at 31 December 2024, the Group had a total of 24 employees in Shanghai. The following table sets forth the total number of employees by function as at 31 December 2024:

	Number of employees	% of total
Function		
Research and Development	6	25
Clinical Development	11	46
General and Administration	7	29
	<hr/>	<hr/>
Total	<u>24</u>	<u>100</u>

The total remuneration cost incurred by the Group for the Reporting Period was RMB81.4 million, as compared to RMB225.4 million for the year ended 31 December 2023.

Our employees' remuneration comprises salaries, bonuses, social security contributions and other welfare payments. In accordance with applicable Chinese laws, we have made contributions to social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing funds for our employees. As at 31 December 2024, we had complied with all statutory social security insurance fund and housing fund obligations applicable to us under Chinese laws in all material aspects.

The Company has also adopted a pre-IPO share option plan (the “**Pre-IPO Share Option Plan**”), a post-IPO share option plan (the “**Post-IPO Share Option Plan**”), a 2021 restricted share unit plan (the “**2021 RSU Plan**”), a 2023 share option plan (the “**2023 Share Option Plan**”) and a 2023 restricted share unit plan (the “**2023 RSU Plan**”) to provide incentives or rewards to eligible participants for their contribution to the Group. The Post-IPO Share Option Plan and the 2021 RSU Plan were terminated on 27 October 2023. All outstanding share options (to the extent not already exercised) granted under the Post-IPO Share Option Plan shall continue to be valid and exercisable in accordance with the terms of the Post-IPO Share Option Plan and the relevant grant agreements. All unvested restricted share units granted under the 2021 RSU Plan shall continue to be valid and shall vest in accordance with the terms of the 2021 RSU Plan and the relevant grant agreements.

Please refer to the section headed “Statutory and General Information – D. Share Option Schemes” in Appendix IV to the prospectus of the Company dated 23 September 2020 (the “**Prospectus**”) for further details of the Pre-IPO Share Option Plan and the Post-IPO Share Option Plan and the announcements of the Company dated 3 June 2021, dated 27 August 2021, dated 5 October 2022 for further details of the 2021 RSU Plan, and the circular of the Company dated 12 October 2023 for further details of the 2023 Share Option Plan and 2023 RSU Plan.

During the Reporting Period, the Group did not experience significant labour disputes or difficulties in recruiting employees.

FINAL DIVIDEND

The Board does not recommend the distribution of a final dividend for the Reporting Period.

SUPPLEMENTAL INFORMATION

Reference is made to the circular of the Company dated 4 February 2025. During the course of preparation of financial statements for the purposes of the New Listing Application, the Company discovered a suspected misappropriation of funds from 2022 to 2024 by a former employee of the Group. An investigation was led by the Audit Committee to investigate the incident with the assistance of an external forensic consultant. The Company reported the incident to the public security bureau in the PRC in January 2025 based on the findings of the Audit Committee and the external forensic consultant, and the case is currently under investigation. To the best of the knowledge, information and belief of the Directors after having made all reasonable enquiries, the net amount involved in the incident was approximately RMB9.8 million.

The Company had assessed the impact of the incident and was of the view that the incident would not have any material adverse impact on the financial results of the Group for the year ended 31 December 2024 and did not expect such incident would cause any material adverse impact to the cashflow and financial condition of the Group.

ANNUAL GENERAL MEETING

The annual general meeting of the Company is scheduled to be held on Thursday, 26 June 2025 (the “AGM”). A notice convening the AGM will be published and dispatched to the Shareholders as soon as practicable in accordance with the Company’s articles of association and the Listing Rules in due course.

CLOSURE OF THE REGISTER OF MEMBERS

The register of members of the Company will be closed from Monday, 23 June 2025 to Thursday, 26 June 2025, both days inclusive, in order to determine the identity of the Shareholders who are entitled to attend and vote at the AGM, during which period no share transfers will be registered. To be eligible to attend and vote at the AGM, unregistered holders of shares must lodge all properly completed transfer forms accompanied by the relevant share certificates with the Company’s branch share registrar in Hong Kong, Computershare Hong Kong Investor Services Limited, at Shops 1712-1716, 17th Floor, Hopewell Centre, 183 Queen’s Road East, Wanchai, Hong Kong for registration not later than 4:30 p.m. on Friday, 20 June 2025.

CORPORATE GOVERNANCE AND OTHER INFORMATION

The Company was incorporated under the laws of the Cayman Islands on 10 April 2017 as an exempted company with limited liability, and the shares of the Company were listed on the Stock Exchange on 7 October 2020 (the “Listing”).

1. Compliance with the Corporate Governance Code

The Board is committed to establishing and maintaining high standards of corporate governance so as to enhance corporate transparency and protect the interests of the Shareholders. The Company devotes to best practice on corporate governance, and to comply with the extent practicable, with the Corporate Governance Code (the “CG Code”) as set out in Appendix C1 of the Listing Rules.

During the year ended 31 December 2024, to the best knowledge of the Board, the Company has complied with all the code provisions in the CG Code, save for deviation from code provision C.2.1 as explained below:

Pursuant to code provision C.2.1 of the CG Code, the roles of chairman and chief executive officer should be separated and should not be performed by the same individual. The division of responsibilities between the chairman and chief executive should be clearly established and set out in writing.

Dr. GUO Feng (“**Dr. Guo**”) performed both of the roles as the chairman and the chief executive officer of the Company with effect from 2 November 2021, and tendered his resignation as the chairman and an executive Director with effect from 12 September 2024, but remained as the chief executive officer of the Company. During Dr. Guo’s tenure of office as the chairman and the chief executive of the Company (the “**Relevant Period**”), code provision C.2.1 of the CG Code was deviated, which requires that the roles of chairman and chief executive should be separated and should not be performed by the same individual.

During the Relevant Period, after evaluation of the situation of the Company and taking into account of the experience and past performance of Dr. Guo, the Board was of the opinion that it was appropriate and in the best interests of the Company for Dr. Guo to hold both positions as the chairman and the chief executive officer of the Company as it helped facilitate the execution of the Group's business strategies and boost effectiveness of its operation. Therefore, the Board considered that the deviation from code provision C.2.1 of the CG Code during the Relevant Period was appropriate in such circumstance. In addition, during the Relevant Period, under the supervision of the Board which comprised one executive Director, three non-executive Directors and three independent non-executive Directors, the Board was appropriately structured with balance of power to provide sufficient checks to protect the interests of the Company and the Shareholders.

Following Dr. Guo's resignation as the chairman and the chief executive of the Company with effect from 12 September 2024, the Company has re-complied with code provision C.2.1 of the CG Code. The Company will continue to regularly review and monitor its corporate governance practices to ensure compliance with the CG Code, and maintain a high standard of corporate governance practices of the Company.

Further information concerning the corporate governance practices of the Company will be set out in the corporate governance report in the annual report of the Company for the Reporting Period.

2. Compliance with the Model Code for Securities Transactions by Directors

The Company has adopted the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix C3 to the Listing Rules (the "**Model Code**") to regulate all dealings by Directors and relevant employees in securities of the Company and other matters covered by the Model Code.

Specific enquiry has been made to all the Directors and they have confirmed that they have complied with the required standards as set out in the Model Code throughout the Reporting Period. No incident of non-compliance of the Model Code by the relevant employees was noted by the Company throughout the Reporting Period.

3. Scope of Work of Ernst & Young

The figures in respect of the Group's consolidated statement of profit or loss and other comprehensive income, consolidated statement of financial position and the related notes thereto for the year ended 31 December, 2024 as set out in the preliminary announcement have been agreed by the Company's auditor to the amounts set out in the Group's draft consolidated financial statements for the year. The work performed by the Company's auditor in this respect did not constitute an assurance engagement and consequently no opinion or assurance conclusion has been expressed by the Company's auditors on the preliminary announcement.

4. Review of Consolidated Annual Results by the Audit Committee

The Company has established the Audit Committee with written terms of reference in accordance with the Listing Rules. The Audit Committee comprises three members, namely Mr. Fung Edwin, Mr. Liu Yi and Ms. Cui Bai, with Mr. Fung Edwin (being the Company's independent non-executive Director with appropriate professional qualifications) as the chairman of the Audit Committee.

The Audit Committee has reviewed the consolidated financial statements of the Group for the Reporting Period and has met with the independent auditor, Ernst & Young. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company and internal control, risk management and financial reporting matters with senior management members of the Company. The Audit Committee is satisfied that the consolidated financial statements of the Group for the Reporting Period were prepared in accordance with the applicable accounting standards and fairly present the Group's financial position and results for the Reporting Period.

5. Other Board Committees

In addition to the Audit Committee, the Company has also established a nomination committee and a compensation committee.

6. Purchase, Sale or Redemption of the Company's Listed Securities

Neither the Company nor any of its subsidiaries purchased, sold or redeemed any of the Company's listed securities (including sale of treasury shares (as defined under the Listing Rules)) during the Reporting Period. As at 31 December 2024, the Company did not hold any treasury shares (as defined under the Listing Rules).

7. Material Litigation

During the Reporting Period and as at the date this announcement, the Company was not involved in any material litigations or arbitrations and the Directors are not aware of any material litigations or claims that are pending or threatened against the Group.

8. Use of Net Proceeds from Global Offering

The Company's shares were listed on the Stock Exchange on 7 October 2020 with a total of 129,683,500 offer shares (including shares issued as a result of the partial exercise of the overallotment option) issued and the net proceeds raised during the global offering were approximately HKD2,923 million (equivalent to approximately RMB2,536 million) (the "**Net Proceeds**"). As set out in the Company's announcement dated 28 October 2020, the Company shall utilise the additional Net Proceeds raised from the partial exercise of the over-allotment option on a prorata basis for the purposes set out in the Prospectus. There has been no issue for cash of equity securities by the Company during the Reporting Period.

As at 31 December 2024, the Company had utilised RMB1,866.1 million of Net Proceeds in accordance with the plan disclosed in the Prospectus, the change in use of net proceeds from the global offering allocated to the different stages of each of our Core Products, other key products and other pipeline products as disclosed in the interim results announcement of the Company for the six months ended 30 June 2022, and the further change in use of Net Proceeds as disclosed in the interim result announcement of the Company for the six months ended 30 June 2023 ("**2023 Interim Results Announcement**").

As at 31 December 2024, approximately RMB669.9 million of the Net Proceeds remained unutilised and will be allocated and used in accordance with the purposes and proportions as set out in the 2023 Interim Results Announcement. The Company will gradually utilize the residual amount of the Net Proceeds in accordance with such intended purposes depending on actual business needs.

Details of the use of the Net Proceeds are set out as below.

		Unutilised Net Proceeds as at 1 January 2024	Net Proceeds utilised during the year ended 31 December 2024	Utilised Net Proceeds as at 31 December 2024	Unutilised Net Proceeds as at 31 December 2024	Expected timeline to fully utilise the remaining unutilised Net Proceeds ^(Note 2)
	Revised Allocation of Net Proceeds ^(Note 1)					
	<i>RMB million</i>	<i>RMB million</i>	<i>RMB million</i>	<i>RMB million</i>	<i>RMB million</i>	
Fund research and development activities of GB491, GB261 and GB263, including ongoing and planned clinical trials, indication expansion and preparation for registration filings, and commercialisation	1,329.2	591.5	152.4	890.1	439.1	On or before 31 December 2026
Fund the expansion of our drug pipeline	253.6	147.8	12.4	118.2	135.4	On or before 31 December 2026

		Unutilised Net Proceeds as at 1 January 2024 <i>RMB million</i>	Net Proceeds utilised during the year ended 31 December 2024 <i>RMB million</i>	Utilised Net Proceeds as at 31 December 2024 <i>RMB million</i>	Unutilised Net Proceeds as at 31 December 2024 <i>RMB million</i>	Expected timeline to fully utilise the remaining unutilised Net Proceeds <i>(Note 2)</i>
	Revised Allocation of Net Proceeds <i>(Note 1)</i> <i>RMB million</i>					
Fund ongoing and planned clinical trials, preparation for registration filings, and commercialization of GB226 (including combination trials with GB492), GB242 and the other drug candidates in our pipeline	699.6	73.7	25.1	651.0	48.6	On or before 31 December 2026
General corporate purposes	253.6	51.8	5.0	206.8	46.8	On or before 31 December 2025
Total	2,536.0	864.8	194.9	1,866.1	669.9	

Notes:

1. The Net Proceeds figure has been translated to Renminbi for the allocation and the utilisation calculation, and has been adjusted slightly due to the fluctuation of the foreign exchange rates since the Listing.
2. The expected timeline for fully utilising the remaining unutilised Net Proceeds is based on the best estimation of the future market conditions made by the Group. It may be subject to change based on the current and future development of market conditions.

The table below specifies further breakdown for the Net Proceeds to be allocated to different stages of our products and their utilisation during the Reporting Period.

Revised Allocation of Net Proceeds to Each Stage ^(Note 1)				Net Proceeds				Expected timeline to fully utilise the remaining unutilised Net Proceeds ^(Note 2)
Pre- clinical <i>RMB million</i>	Clinical <i>RMB million</i>	Commercialization (including registration) <i>RMB million</i>	Unutilised Net Proceeds as at 1 January 2023 <i>RMB million</i>	Unutilised Net Proceeds as at 31 December 2024 <i>RMB million</i>	Utilised Net Proceeds as at 31 December 2024 <i>RMB million</i>	Utilised Net Proceeds as at 31 December 2024 <i>RMB million</i>	Unutilised Net Proceeds as at 31 December 2024 <i>RMB million</i>	
GB491	–	736.4	100	273.8	106.7	669.3	167.1	On or before 31 December 2026
GB261	55.8	277.1	–	223.0	40.8	150.7	182.2	On or before 31 December 2026
GB263	45.8	114.1	–	94.7	4.9	70.1	89.8	On or before 31 December 2026
GB242, GB226, GB492 and other products ^(Note 3)	23.9	549.7	126	73.7	25.1	651.0	48.6	On or before 31 December 2026
Total				665.2	177.5	1,541.1	487.7	

Notes:

1. The Net Proceeds figure has been translated to Renminbi for the allocation and the utilisation calculation, and has been adjusted slightly due to the fluctuation of the foreign exchange rates since the Listing.
2. The expected timeline for fully utilising the remaining unutilised Net Proceeds is based on the best estimation of the future market conditions made by the Group. It may be subject to change based on the current and future development of market conditions.
3. Other products include GB221, GB223, GB241, GB251, GB262, and GB264. The Company will make investment on those products according to the current and future development conditions and market competition environment.

CONSOLIDATED FINANCIAL STATEMENTS

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

		Year ended 31 December	
	Notes	2024 RMB'000	2023 RMB'000
Revenue	3	206,229	—
Cost of revenue		(1,341)	—
Gross profit		204,888	—
Administrative expenses		(71,707)	(125,237)
Research and development expenses		(202,778)	(564,278)
Impairment losses on financial assets		(31,588)	(8,922)
Other income – net		37,107	5,649
Other loss – net		(8,475)	(18,408)
Operating loss		(72,553)	(711,196)
Finance income		37,703	34,739
Finance costs		(282)	(1,039)
Finance income – net		37,421	33,700
Loss before tax		(35,132)	(677,496)
Income tax (expense)/credit	4	(17,842)	2,280
Loss for the year		(52,974)	(675,216)
Loss for the year is attributable to:			
Owners of the Company		(51,283)	(674,362)
Non-controlling interests		(1,691)	(854)
		(52,974)	(675,216)

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME (CONTINUED)

		Year ended 31 December	
	<i>Notes</i>	2024	2023
		RMB'000	RMB'000
Other comprehensive income/(loss) for the year, net of tax			
<i>Items that may be reclassified to profit or loss</i>			
– Exchange differences on translation of foreign operations		(11,691)	(745)
<i>Items that may be not reclassified to profit or loss</i>			
– Equity investments at fair value through other comprehensive income			
<i>Changed in fair value</i>		13,178	–
Total other comprehensive income/(loss) for the year, net of tax		1,487	(745)
Total comprehensive loss for the year		(51,487)	(675,961)
Total comprehensive loss for the year is attributable to:			
Owners of the Company		(49,801)	(675,107)
Non-controlling interests		(1,686)	(854)
		(51,487)	(675,961)
Loss per share attributable to the ordinary equity holders of the Company			
Basic and diluted loss per share (in RMB)	5	(0.10)	(1.33)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	As at 31 December	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
ASSETS		
Non-current assets		
Property and equipment	4,915	53,417
Right-of-use assets	904	6,720
Intangible assets	100,466	110,099
Equity investment designated at fair value through other comprehensive income	83,732	—
Other receivables, deposits and prepayments	23,503	27,168
Deferred tax assets	8,915	8,350
Total non-current assets	222,435	205,754
Current assets		
Inventories	—	5,667
Contract cost	—	1,341
Other receivables, deposits and prepayments	8,503	68,634
Cash and bank balances	1,058,790	1,165,481
Total current assets	1,067,293	1,241,123
Total assets	1,289,728	1,446,877

CONSOLIDATED STATEMENT OF FINANCIAL POSITION (CONTINUED)

		As at 31 December	
	Notes	2024	2023
		RMB'000	RMB'000
LIABILITIES			
Non-current liabilities			
Lease liabilities		555	3,924
Amounts due to a related party		350	559
Deferred income		4,262	10,574
Deferred tax liabilities		10,796	11,595
Total non-current liabilities		15,963	26,652
Current liabilities			
Trade payables	7	82,825	141,661
Contract liabilities		–	4,893
Other payables and accruals		26,711	75,883
Lease liabilities		356	3,231
Amounts due to a related party		–	165
Deferred income		5,853	3,692
Tax payable		6,341	–
Total current liabilities		122,086	229,525
Total liabilities		138,049	256,177
EQUITY			
Equity attributable to the ordinary equity holders of the Company			
Share capital		70	69
Share premium		9,477,833	9,397,851
Treasury shares		(747)	(5,198)
Other reserves		(1,484,058)	(1,413,572)
Accumulated losses		(6,841,619)	(6,790,336)
		1,151,479	1,188,814
Non-controlling interests		200	1,886
Total equity		1,151,679	1,190,700
Total equity and liabilities		1,289,728	1,446,877

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

1 GENERAL INFORMATION

Genor Biopharma Holdings Limited (the “**Company**”), previously known as JHBP (CY) Holdings Limited, and its subsidiaries (together the “**Group**”), are principally engaged in developing and commercializing oncology and autoimmune drugs in the People’s Republic of China (the “**PRC**”).

The Company was incorporated in the Cayman Islands as an exempted company with limited liability under the Companies Law (Cap.22, Law 3 of 1961 as consolidated and revised) of the Cayman Islands. The address of the Company’s registered office is Maples Corporate Services Limited, PO Box 309, Ugland House, Grand Cayman, KY1-1104, Cayman Islands.

These financial statements are presented in Renminbi (“**RMB**”), unless otherwise stated.

2 BASIS OF PREPARATION AND CHANGES IN ACCOUNTING POLICIES

This note provides a list of the material accounting policies adopted in the preparation of these consolidated financial statements. These policies have been consistently applied to all the years presented, unless otherwise stated. The financial statements are for the Group consisting of Genor Biopharma Holdings Limited and its subsidiaries.

(a) Compliance with HKFRS and the disclosure requirements of HKCO

The consolidated financial statements of the Group have been prepared in accordance with Hong Kong Financial Reporting Standards (“**HKFRS**”) and the disclosure requirements of the Hong Kong Companies Ordinance Cap. 622.

(b) Historical cost convention

The financial statements have been prepared on a historical cost basis, except for certain financial assets and liabilities measured at fair value.

(c) Changes in Accounting Policies and Disclosures

The Group has adopted the following revised HKFRSs for the first time for the current year’s financial statements.

Amendments to HKFRS 16	<i>Lease Liability in a Sale and Leaseback</i>
Amendments to HKAS 1	<i>Classification of Liabilities as Current or Non-current</i>
	(the “ 2020 Amendments ”)
Amendments to HKAS 1	<i>Non-current Liabilities with Covenants</i>
	(the “ 2022 Amendments ”)
Amendments to HKAS 7 and HKFRS 7	<i>Supplier Finance Arrangements</i>

The Group has adopted the following revised HKFRSs for the first time for the current year’s financial statements.

(d) Issued but not yet effective Hong Kong Financial Reporting Standards

The Group has not applied the following new and revised HKFRSs, that have been issued but are not yet effective, in these financial statements. The Group intends to apply these new and revised HKFRSs, if applicable, when they become effective.

HKFRS 18	<i>Presentation and Disclosure in Financial Statements</i> ³
HKFRS 19	<i>Subsidiaries without Public Accountability: Disclosures</i> ³
Amendments to HKFRS 9 and HKFRS 7	<i>Amendments to the Classification and Measurement of Financial Instruments</i> ²
Amendments to HKFRS 10 and HKAS 28	<i>Sale or Contribution of Assets between an Investor and its Associate or Joint Venture</i> ⁴
Amendments to HKAS 21	<i>Lack of Exchangeability</i> ¹
Annual Improvements to HKFRS Accounting Standards – Volume 11	Amendments to HKFRS 1, HKFRS 7, HKFRS 9, HKFRS 10 and HKAS 7 ²

- 1 Effective for annual periods beginning on or after 1 January 2025
- 2 Effective for annual periods beginning on or after 1 January 2026
- 3 Effective for annual/reporting periods beginning on or after 1 January 2027
- 4 No mandatory effective date yet determined but available for adoption

Certain amendments to accounting standards and interpretation have been published that are not mandatory for 31 December 2024 reporting periods and have not been early adopted by the group. These amendments are not expected to have a material impact on the entity in the current or future reporting periods and on foreseeable future transactions.

3 REVENUE

	2024 RMB'000	2023 RMB'000
Types of goods or services		
Licensing revenue	<u>206,229</u>	<u>–</u>

4 INCOME TAX

(a) Income tax

	Year ended 31 December 2024 RMB'000	Year ended 31 December 2023 RMB'000
Current	19,206	–
Deferred	<u>(1,364)</u>	<u>(2,280)</u>
Total	<u>17,842</u>	<u>(2,280)</u>

- (b) A reconciliation of the tax expense/credit applicable to loss before tax at the statutory tax rates for the jurisdictions in which the Company and the majority of its subsidiaries are domiciled and/or operate to the tax expense at the effective tax rates, and a reconciliation of the applicable rates (i.e., the statutory tax rates) to the effective tax rates, are as follows:

	Year ended 31 December 2024 <i>RMB'000</i>	Year ended 31 December 2023 <i>RMB'000</i>
Loss before tax	(35,132)	(677,496)
Calculated at the statutory tax rate of 25%	(8,783)	(169,374)
Effect of different tax rates of operating entities in other jurisdictions	(125,391)	11,700
Effect of preferential tax rates	–	44,780
Expenses not deductible for taxation purposes:		
– Share-based payment expenses	2,872	11,976
– Others	133	918
Additional deduction of research and development expenses	(23,514)	(34,189)
Unused tax loss not recognised as deferred tax assets	153,319	131,909
USA withholding tax	19,206	–
	<hr/>	<hr/>
Income tax	<u>17,842</u>	<u>(2,280)</u>

(i) Accounting for research and development tax credit

Companies within the Group may be entitled to claim special tax deductions for investments in qualifying assets or in relation to qualifying expenditure. The Group accounts for such allowances as tax credits, which means that the allowance reduces income tax payable and current tax expense.

(ii) Cayman Islands income tax

The Company is incorporated in the Cayman Islands as an exempted company with limited liability under the Companies Law of Cayman Islands and accordingly is exempted from Cayman Islands income tax.

(iii) Hong Kong profits tax

No Hong Kong profit tax was provided for as there was no estimated assessable profit that was subject to Hong Kong profits tax for the years ended 31 December 2024 and 2023.

(iv) USA corporate income tax

Except for certain revenue arising from license-out transaction this year, which was subject to USA withholding tax, no USA profit tax was provided for as there was no estimated assessable profit that was subject to USA profits tax for the years ended 31 December 2024 and 2023.

(v) PRC corporate income tax

In 2022, a “Certificate of New Hi-tech Enterprise” was granted to Genor Biopharma with a valid period of 3 years, and then Genor Biopharma becomes eligible for a preferential corporate income tax rate of 15% for the year ended 31 December 2023. In 2024, Genor Biopharma had its qualification as a High and New Technology Enterprise revoked, and the 2024 income tax rate was changed from 15% to 25%. Other subsidiaries established and operated in Mainland China are subject to the PRC corporate income tax at the rate of 25% for the year ended 31 December 2024 (2023: 25%).

(vi) Australia corporate income tax

No Australian corporate tax was provided for as there was no estimated assessable profit that was subject to Australian corporate tax for the year ended 31 December 2024 and 2023.

(vii) Investment allowances and similar tax incentives

Companies within the Group may be entitled to claim special tax deductions for investments in qualifying assets or in relation to qualifying expenditure. The Group accounts for such allowances as tax credits, which means that the allowance reduces income tax payable and current tax expense.

(c) Tax losses

As at 31 December 2024, ABT had net operating losses amounting to RMB29,876,000 (2023: RMB27,982,000). Under federal tax regulations, the net operating losses can be carried forward and deductible for income tax purposes indefinitely. Under California state tax regulations, the net operating losses can generally be carried forward 20 years following the year of the loss incurred. Accordingly, the Company recognised deferred tax assets amounting to RMB8,915,000.

The Group also has tax losses arising in Mainland China of RMB3,857,000 (2023: RMB4,837,000) that will expire in one to five years for offsetting against future taxable profits. Deferred tax assets have not been recognised in respect of these losses as they have arisen in subsidiaries that have been loss-making for some time and it is not considered probable that taxable profits will be available against which the tax losses can be utilised.

5 LOSS PER SHARE

(a) Basic loss per share

Basic loss per share is calculated by dividing the loss attributable to owners of the Company by the weighted average number of ordinary shares outstanding during the financial year.

	Year ended 31 December 2024	Year ended 31 December 2023
Loss attributable to owners of the Company (in RMB'000)	(51,283)	(674,362)
Weighted average number of ordinary shares in issue (in thousand)	513,547	506,245
Basic loss per share (in RMB)	<u>(0.10)</u>	<u>(1.33)</u>

(b) Diluted loss per share

The Group has potential dilutive shares throughout for the year ended 31 December 2024 in relation to the shares held for employee option plan and shares to be issued to Ab Studio Inc. (“ABS”), which was a non-controlling shareholder of ABT. Due to the Group’s losses during the year ended 31 December 2024, the potential dilutive shares have anti-dilutive effect on the Group’s loss per share. Thus, the diluted loss per share is the same as basic loss per share

6 DIVIDEND

No dividend has been paid or declared by the Company during the years ended 31 December 2024 and 2023.

7 TRADE PAYABLES

The aging analysis, based on invoice date, of trade payables as at the consolidated balance sheet date were as follows:

	As at 31 December 2024 RMB'000	As at 31 December 2023 RMB'000
Within 1 year	79,826	139,012
More than 1 year	2,999	2,649
	<u>82,825</u>	<u>141,661</u>

The carrying amounts of trade payables are denominated in RMB. The carrying amounts approximate their fair values due to short-term maturities.

PUBLICATION OF THE ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL REPORT

This announcement is published on the website of the Stock Exchange at www.hkexnews.hk and the website of the Company at www.genorbio.com. The annual report of the Company for the Reporting Period will be published on the aforesaid websites and dispatched to the Shareholders upon request in due course.

By order of the Board
Genor Biopharma Holdings Limited
Mr. Weng Chengyi
Executive Director and Chief Financial Officer

Hong Kong, 28 March 2025

As at the date of this announcement, the Board comprises seven (7) Directors, namely Mr. Weng Chengyi (Chief Financial Officer) as an executive Director; Dr. Lyu Dong, Mr. Yu Tieming and Mr. Liu Yi as non-executive Directors; and Ms. Cui Bai, Mr. Fung Edwin and Mr. Chen Wen as independent non-executive Directors.