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**JW (Cayman) Therapeutics Co. Ltd**

**藥明巨諾（開曼）有限公司\***

*(Incorporated in the Cayman Islands with limited liability)*

**(Stock Code: 2126)**

## **ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED DECEMBER 31, 2022**

The board (the “**Board**”) of directors (the “**Directors**”) of JW (Cayman) Therapeutics Co. Ltd (the “**Company**”) is pleased to announce the audited condensed consolidated results of the Company and its subsidiaries (collectively, the “**Group**”, “**we**” or “**us**”) for the year ended December 31, 2022 (the “**Reporting Period**”) together with the comparative figures for the year ended December 31, 2021.

### **ANNUAL RESULTS HIGHLIGHTS**

#### **Financial Highlights**

##### ***IFRS Measure:***

- **Revenue** was RMB145.7 million for the year ended December 31, 2022, representing an increase of 373.1% from RMB30.8 million for the year ended December 31, 2021, as we successfully commercialized our anti-CD19 autologous chimeric antigen receptor T (“**CAR-T**”) cell immunotherapy product Carteyva<sup>®</sup> (relmacabtagene autoleucel (“**relma-cel**”), R&D code: JWCAR029) for the treatment of adult patients with relapsed or refractory (“**r/r**”) large B-cell lymphoma (“**LBCL**”) after two or more lines of systemic therapy after we obtained the marketing approval for the product from the National Medical Products Administration of China (“**NMPA**”) on September 1, 2021. We expect that the revenue will continue to increase from the sales of Carteyva<sup>®</sup> along with our commercialization progress as more patients are treated with Carteyva<sup>®</sup>.

- **Gross profit** was RMB58.8 million for the year ended December 31, 2022, representing an increase of 549.6% from RMB9.0 million for the year ended December 31, 2021. Gross profit margin of sales was 40.3% for the year ended December 31, 2022, representing an increase from 29.4% for the year ended December 31, 2021. The improvement was primarily due to the implementation of our near-term cost reduction plan and more patients are treated with Carteyva®.
- **Research and development (“R&D”) expenses** decreased by RMB6.6 million to RMB407.8 million for the year ended December 31, 2022, compared to RMB414.4 million for the year ended December 31, 2021, primarily due to a decrease in R&D materials which resulted from implementation of cost reduction plan, raw material localization and less batch numbers. The effects of these factors were partially offset by an increase in depreciation and amortization, which resulted principally from depreciation of the Suzhou manufacturing facility and Shanghai Waigaoqiao upgraded manufacturing facility which began from the fourth quarter of 2021.
- **Selling expenses** increased by RMB20.2 million to RMB190.9 million for the year ended December 31, 2022, compared to RMB170.7 million for the year ended December 31, 2021, primarily due to an increase in staff costs, as well as an increase in business promotion fees as we carried out commercial activities comprehensively in 2022 to fully support the commercialization of Carteyva®.
- **General and administrative expenses** decreased by RMB21.7 million to RMB179.8 million for the year ended December 31, 2022, compared to RMB201.5 million for the year ended December 31, 2021, primarily due to a decrease in staff costs and a decrease in professional service fees.
- **Other gains and losses** amounted to net other losses of RMB159.6 million for the year ended December 31, 2022, as compared with net other gains of RMB12.1 million for the year ended December 31, 2021. This change mainly arose from the unrealized foreign exchange loss as a result of the weakening of the Renminbi (“RMB”) against the U.S. dollar (“USD”) and the HK dollar (“HKD”) when exchanging from the transactional currency (RMB) to the functional currencies (USD and HKD) for our offshore companies within the Group. These unrealized foreign exchange gains and losses are non-cash items.

- **Loss for the year** was RMB846.1 million for the year ended December 31, 2022, compared to RMB702.3 million for the year ended December 31, 2021. The increase was primarily due to: (i) increased unrealized foreign exchange loss and (ii) one-time non-cash income recognized in 2021 from de-recognition of “warrants of upfront payment” under our B Cell maturation antigen (“**BCMA**”) License Agreement with Juno Therapeutics, Inc. (“**Juno**”) which did not recur in 2022. The effects of the foregoing factors were partially offset by (i) increased revenue and gross profit generated from sales of Carteyva<sup>®</sup> and (ii) increased other income from government subsidies and net finance income.

***Non-IFRS Measure:***

Adjusted loss<sup>1</sup> was RMB605.1 million for the year ended December 31, 2022, representing a decrease of RMB73.9 million from RMB679.0 million for the year ended December 31, 2021. The decrease was primarily due to: (i) increased revenue and gross profit generated from sales of Carteyva<sup>®</sup>; (ii) decreased general and administrative expenses and research and development expenses; and (iii) increased other income from government subsidies and net finance income. The effects of these factors were partially offset by an increase in selling expenses.

**BUSINESS HIGHLIGHTS**

For the year ended December 31, 2022, as an independent, innovative biotechnology company focused on developing, manufacturing and commercializing cell immunotherapy products, we have made significant further progress in our business and achieved important milestones. Our lead product, Carteyva<sup>®</sup> made remarkable progress in its commercialization as a treatment for LBCL. Additionally, our outstanding clinical development and operational capabilities led to NMPA approval of our supplemental New Drug Application (“**sNDA**”) relating to Carteyva<sup>®</sup> as a treatment for follicular lymphoma (“**FL**”), obtaining breakthrough therapy designation for Carteyva<sup>®</sup> as a treatment for mantle cell lymphoma (“**MCL**”), and initiation of clinical trials for second-line and frontline treatment studies. We also commenced clinical trials of JWATM204 and JWATM 214 for the treatment of solid tumors and expanded our pipeline to include autoimmune disease. Moreover, we maintained a high manufacturing success rate for Carteyva<sup>®</sup> and completed implementation of the first stage of our cost reduction plan. Furthermore, we strengthened our in-house R&D capability by appointing a new chief scientific officer and establishing an in-house discovery and pre-clinical research team to develop novel products.

<sup>1</sup> *Adjusted loss for the year is not a financial measure defined under IFRS. It represents the loss for the year excluding the effect of the following non-cash items: (a) fair value changes of warrants; (b) share-based compensation expenses; and (c) net foreign exchange losses. For the calculation and reconciliation of this non-IFRS measure, please refer to “Management Discussion and Analysis — Financial Review — 12. Non-IFRS Measure” in this announcement.*

Since the beginning of 2022, we have achieved the following significant milestones in our business:

### ***Commercialization***

- For the year ended December 31, 2022, we generated 165 prescriptions of Carteyva<sup>®</sup> and completed 141 infusions for r/r LBCL patients.
- We successfully executed our near-term cost reduction plans in 2022, which enabled us to reduce cost of goods sold per batch as compared to 2021 and to increase our gross profit margin from 29.4% in 2021 to 40.3% in 2022.
- Among 145 assessable patients from 171 infused patients who have been treated with Carteyva<sup>®</sup> since launch, Carteyva<sup>®</sup> remains at or above the level of the best complete response rate (“**CRR**”) achieved in the registrational clinical trial, demonstrating strong efficacy in the real world.
- As of December 31, 2022, Carteyva<sup>®</sup> has been listed in 56 commercial insurance products and 75 local governmental complementary medical insurance programs, and out of the total of 141 Carteyva<sup>®</sup>-infused patients, 34 patients received insurance reimbursements, representing 24% of the Carteyva<sup>®</sup> infusions, with an expense coverage ranging from 38% to 100%.
- We continued to support the establishment of industry standards for CAR-T therapies in China:
  - In January 2022, the “Guiding Principles for the Clinical Application of relmacabtagene autoleucel injection (2021)” were published jointly by several medical societies with our active input.
  - In November 2022, the “Guiding Principles” were upgraded to “Diagnosis and Treatment Guideline for the Whole Process Management of relmacabtagene autoleucel in Treating B-NHL (2022)”.
  - Also in November 2022, the “Technical Specification for the Clinical Application of Chimeric Antigen Receptor T-Cell Therapy Drug” was published at the 25<sup>th</sup> National Congress of Clinical Oncology”.

## ***Research & Development***

### *Hematologic malignancies*

- In March 2022, the NMPA approved our previously submitted investigational new drug (“**IND**”) application for a Phase III registrational clinical trial comparing Carteyva<sup>®</sup> to second-line LBCL standard of care therapy. In addition, in January 2023 we submitted a new IND application relating to Carteyva<sup>®</sup> as a second-line therapy for transplant-ineligible patients with r/r LBCL.
- In April 2022, the NMPA approved our IND application with respect to a clinical trial to evaluate Carteyva<sup>®</sup> as a third-line treatment for pediatric and young adult patients with r/r acute lymphoblastic leukemia (“**ALL**”), and we have commenced patient enrollment and administered the first several doses of Carteyva<sup>®</sup> to patients in this trial.
- In April 2022, the NMPA granted Breakthrough Therapy Designation for Carteyva<sup>®</sup> as a treatment for patients with MCL who have received certain prior lines of treatment.
- In June 2022, at the Annual Meeting of the American Society of Clinical Oncology, we published the two-year overall survival (“**OS**”) rate from our Phase II registrational clinical trial of Carteyva<sup>®</sup> as a third-line treatment for LBCL. The two-year OS was 69.3%, with no new safety signals.
- In October 2022, the NMPA approved our sNDA with respect to Carteyva<sup>®</sup> as a third-line treatment for adult patients with r/r FL, making Carteyva<sup>®</sup> the first CAR-T product approved for treatment of r/r FL in China.
  - o The NMPA approval of our sNDA relating to Carteyva<sup>®</sup> as a treatment for r/r FL was based on 6-month clinical results from cohort B of our RELIANCE study.
  - o In December 2022, we reported updated clinical results relating to our RELIANCE study at the Annual Meeting of the American Society of Hematology. As of the data cut-off date of December 17, 2021, based on 28 patients who had been treated with Carteyva<sup>®</sup> with 11.7 months of median follow-up, Carteyva<sup>®</sup> demonstrated remarkable clinical responses, achieving high rates of overall response rate (“**ORR**”) and CRR (best ORR and best CRR were 100.0% and 92.6%, respectively), and a manageable safety profile.

- In March 2023, we announced the commencement of an investigator-initiated trial (“**IIT**”) relating to Cartheyva<sup>®</sup> as a first-line treatment for patients with high-risk LBCL, and the first patient infusion was completed.

#### *Autoimmune diseases*

- In March 2023, to further evaluate Cartheyva<sup>®</sup>’s potential for treatment of a broader range of diseases, we initiated an IIT in China to evaluate the safety, tolerability and pharmacokinetic profile of Cartheyva<sup>®</sup> as a treatment for patients with moderately or severely active systemic lupus erythematosus (“**SLE**”), and the first patient infusion was achieved. We believe that we may be able to secure a first-mover advantage in a highly promising market through development of Cartheyva<sup>®</sup> as a treatment for SLE.

#### *Solid tumors*

- In July 2022, we announced the commencement of an IIT to evaluate JWATM204 as a treatment for patients with advanced hepatocellular carcinoma (“**HCC**”), and JWATM204 has already been administered to several patients in connection with this trial.
- In October 2022, we established a strategic alliance with 2seventy bio, Inc. to develop and commercialize a cell therapy product directed to MAGE-A4 in oncology indications.
- In December 2022, we strengthened our relationship with Juno by entering into an agreement with Juno for the research, development, manufacturing and commercialization of new cell therapy products directed to Delta-like canonical Notch ligand 3 (“**DLL3**”) in Greater China.
- In February 2023, we announced the commencement of an IIT to evaluate JWATM214 as a treatment for patients with advanced HCC, and JWATM214 has already been administered to the first patient. JWATM214 is our novel product that combines JWATM204 with Lyell’s T-cell anti-exhaustion technology.

### ***Discovery and Early Research***

In 2022, we strengthened our in-house R&D capabilities with the appointment of Dr. Shaun Paul Cordoba (“**Dr. Cordoba**”) as our chief scientific officer. Dr. Cordoba is a highly regarded scientist in driving new innovations in cell immunotherapy technology. Under Dr. Cordoba’s leadership, we have established an in-house early discovery and pre-clinical team with the goal of developing novel products reflecting three key attributes: (i) global commercial rights; (ii) incorporation of “Armored” elements to enhance product performance and increase the duration of clinical response; and (iii) taking advantage of our new next-generation product processing methods to reduce costs.

### ***Manufacturing***

In 2022, we continued to maintain a manufacturing success rate of 98% for Carteyva<sup>®</sup>, which remains close to the very high level that we originally attained in our LBCL registrational clinical trial. We also achieved our near-term cost reduction goal and advanced into our mid-term plan for raw materials localization, which we believe will enable us to achieve further improvements in gross margin in the medium term. Moreover, we completed the technical transfer of the JWATM204 manufacturing process from the laboratory to our Waigaoqiao clinical manufacturing facility, and such factory was qualified for manufacturing in accordance with Good Manufacturing Practice (“**GMP**”).

## **MANAGEMENT DISCUSSION AND ANALYSIS**

### **BUSINESS REVIEW**

#### **Overview**

The Company is an independent, innovative biotechnology company focused on developing, manufacturing and commercializing cell immunotherapy products. Since our founding in 2016, we have built an integrated platform for product development in cell immunotherapy, as well as a product pipeline covering hematologic malignancies, solid tumors and autoimmune diseases. We are committed to bringing breakthrough and quality cell immunotherapy products and the hope of a cure to patients in China and beyond, and to leading the healthy and standardized development of China’s cell immunotherapy industry.



We are an early entrant into the field of cell-based immunotherapy in China. Cell-based immunotherapies, including CAR-T treatments, are an innovative treatment method that uses human immune cells to fight cancer, representing a paradigm shift and the latest innovation in cancer treatment. Our lead product, Cartheyva<sup>®</sup>, is an autologous anti-CD19 CAR-T cell immunotherapy product independently developed by us based on a CAR-T cell process platform of Juno Therapeutics (a Bristol Myers Squibb company). Cartheyva<sup>®</sup> has been approved by the NMPA for two indications, including the treatment of adult patients with r/r LBCL after two or more lines of systemic therapy, and the treatment of adult patients with r/r FL in which a relapse occurs within 24 months of second-line or higher systemic treatment. Cartheyva<sup>®</sup> is the first CAR-T product approved as a Category 1 biologics product in China, and currently it is the only CAR-T product in China that has been simultaneously included in the National Significant New Drug Development Program and granted priority review and breakthrough therapy designations.

2022 was the first full year of CAR-T product commercialization in China. Given the unmet medical needs that can be effectively addressed by CAR-T therapies, the market for CAR-T therapies in China is expected to experience strong growth through 2030, according to Frost & Sullivan. We believe that we are well-positioned to take advantage of this growing market, based on the best-in-class potential of our anti-CD19 CAR-T product profile; our robust and differentiated cell therapy pipeline covering both hematological cancers and solid tumors; our fully integrated cell therapy development platform; our leading commercial manufacturing infrastructure and supply chain; and our seasoned management and strong support from the shareholders of the Company (the “**Shareholders**”). In 2022 we made significant progress on the development of Cartheyva<sup>®</sup> for the treatment of hematological malignancies, expanded our portfolio of products for the treatment of solid tumors, and advanced Cartheyva<sup>®</sup> as a potential treatment for SLE, an autoimmune disease widely prevalent in China.

## **Commercialization**

2022 was the first full year of CAR-T product commercialization in China, and we have had the privilege of providing a breakthrough product to serve Chinese patients. In 2022, we generated 165 prescriptions of Cartheyva<sup>®</sup> and completed 141 infusions for r/r LBCL patients. Among 145 assessable patients from 171 infused patients who had been treated with Cartheyva<sup>®</sup> since launch, Cartheyva<sup>®</sup> remains at or above the level of the best CRR achieved in the registrational clinical trial, demonstrating strong efficacy in the real world.



We have built a focused and dedicated commercial team to commercialize Carteyva<sup>®</sup> across China. As of February 2023, we have a fully established commercial team of around 88 employees with strong marketing and promotion capabilities, including Sales, Marketing, CAR-T Consultant, Innovative Payment, Channel Management and Operation. To meet our upcoming sales and marketing needs, the structure of our commercial team has been optimized in respect of streamlined administration and improved operation efficacy. These teams are led by experienced commercial team leaders with a clear business model. To support hospitals ready to use our product, we conducted training for each hospital to help physicians and nurses to gain a comprehensive understanding about Carteyva<sup>®</sup> itself and the entire process from prescription to infusion. Furthermore, we conducted a systematic evaluation of delivery hospitals to ensure they meet our requirements to administer CAR-T products. As of December 31, 2022, we had completed evaluation and training for the top 96 hospitals in China, and we certified those hospitals as qualified to administer Carteyva<sup>®</sup>. In partnership with Shanghai Pharma KDL (上藥康德樂), serving as our national distributor, we have fully developed the distribution infrastructure to provide professional cell therapy product delivery services for each and every Carteyva<sup>®</sup>-prescribed patient.

To improve affordability, we have upgraded our multi-layer medical care system by listing Carteyva<sup>®</sup> in more local governmental complementary medical insurance programs and health insurance products. As of December 31, 2022, Carteyva<sup>®</sup> has been listed in 56 commercial insurance products in and 75 local governmental complementary medical insurance programs. In 2022, 34 Carteyva<sup>®</sup>-infused patients out of a total of 141 Carteyva<sup>®</sup>-infused patients received insurance reimbursements (representing 24% of the Carteyva<sup>®</sup> infusions in 2022) with an expense coverage ranging from 38% to 100%. To further alleviate financial pressure on patients, we continued to cooperate with industry-leading innovative payment platforms which are able to provide installment payment services or mortgage loans to potential recipients of Carteyva<sup>®</sup> as a treatment. We intend to continue to enhance our multi-layer medical care system with the goal of improving affordability for patients who are eligible to be treated with Carteyva<sup>®</sup>.

In addition, we established manufacturing cost reduction strategies in 2020 that consist of the following elements: (i) near-term (1–2 years) — realize significant cost reduction by implementing technologies and procedures that reduce raw material wastes and scraps; (ii) mid-term (2–3 years) — realize further cost reduction by replacing imported materials with domestic supplies; and (iii) long-term (3–5 years) — implement new technologies that would simplify and/or replace/combine unit operations and thereby reduce raw material and labor costs; and potentially shorten production cycle time and possibly improve product characteristics and clinical outcome. We have successfully executed our near-term cost reduction plans in 2022, which enabled us to reduce cost of goods sold per batch as compared to 2021 and to increase our gross profit margin from 29.4% to 40.3% in 2022. We continue optimizing our manufacturing operations to improve efficiency. We are steadily advancing the mid-term strategy and successfully obtained an approval for adding a domestic supply of an important material. We will continue to explore new technologies for process improvement or new process platforms.

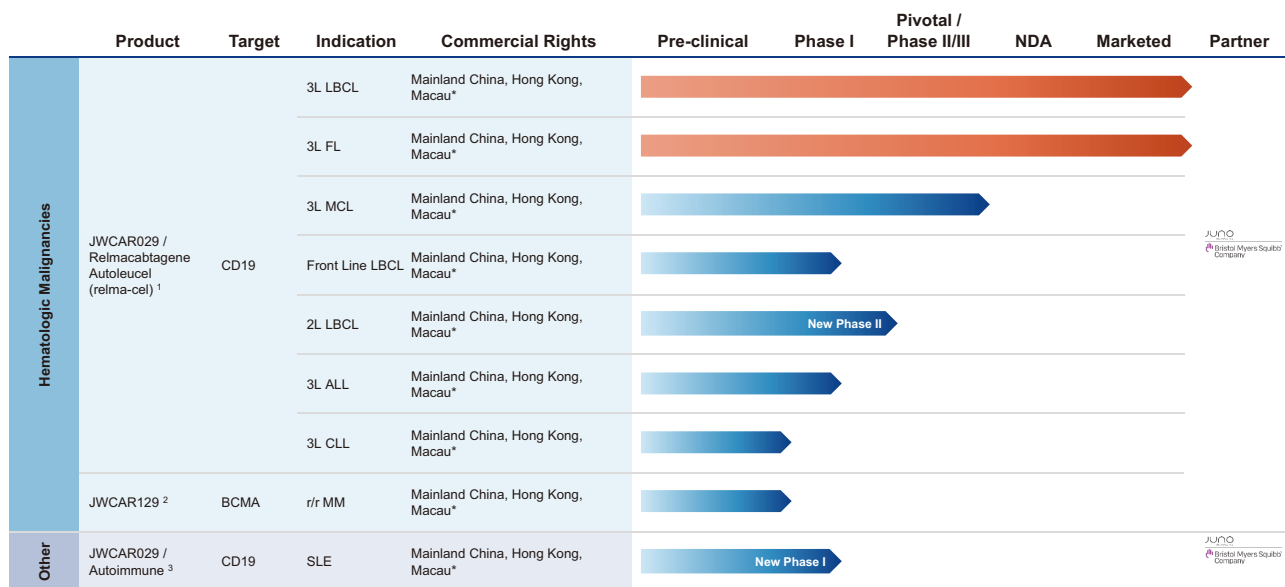
As CAR-T therapies are a new and comprehensive treatment process that is unlike any other treatment currently approved in the Chinese market, we have made significant efforts and closely collaborate with government agency and healthcare experts to establish best practices and industry standards for CAR-T therapies, and to demonstrate the proper process in administering and monitoring the treatment as well as managing adverse effects with Carteyva<sup>®</sup>. In January 2022, the “Guiding Principles for the Clinical Application of relmacabtagene autoleucel injection (2021 version)” was published by the Lymphoma Expert Committee of the Chinese Society of Clinical Oncology, the Hematology Branch of the Chinese Medical Association and the Hematology Branch of the Chinese Medical Doctor Association, and in November 2022, these Guiding Principles were upgraded to “Diagnosis and Treatment Guideline for the Whole Process Management of relmacabtagene autoleucel in Treating B-NHL (2022 version)”. This Guiding Principle was formulated by combining the current status of CAR-T practice and published data from Carteyva<sup>®</sup>-related studies, and it is the first clinical guiding principle for a commercialized CAR-T product in China in order to further standardize the clinical application of Carteyva<sup>®</sup> and provide a reference for physicians. In order to further explore the application of CAR-T therapy, the “Technical Specification for the Clinical Application of Chimeric Antigen Receptor T Cell Therapy Drug (2022 version)” was jointly written and formulated by multidisciplinary experts organized by the Lymphoma Expert Committee of the Chinese Society of Clinical Oncology (“CSCO”) and supported by China National Health Development Research Center. In November 2022, this Technical Specification was also officially published at the 25th National Congress of Clinical Oncology (the 2022 CSCO Academic Annual Meeting), and the first batch of 28 national CAR-T clinical applications technical specification demonstration units were concomitantly awarded licenses. Being the first domestic technical specification for the clinical application of CAR-T drugs that clarifies the responsibilities of multidisciplinary teams in the whole process, this Technical Specification is intended to cover all aspects of CAR-T cell therapy (including in-hospital and out-of-hospital) and is applicable to the management of CAR-T cell therapy products that have been marketed in China.

With the proven efficacy of Carteyva<sup>®</sup>, together with our clear strategy and strong commercialization ability, we are confident that Carteyva<sup>®</sup> is well positioned to benefit more patients in the medium and longer term.

## **Our Product Pipeline**

We have developed a robust and differentiated cell-based immunotherapy pipeline, with a risk-balanced approach that has shown clear benefit in the field of cell therapies for hematological cancers and provides an opportunity to expand into the nascent field of cell therapies for solid tumors and autoimmune diseases. Our product pipeline features a mix of product candidates targeting both proven and novel tumor antigens. In 2022 we made significant progress on the development of Carteyva<sup>®</sup> for the treatment of hematological malignancies, expanded our portfolio of products for the treatment of solid tumors, and advanced Carteyva<sup>®</sup> as a potential treatment for SLE, a widely prevalent autoimmune disease. With respect to hematological malignancies, we obtained NMPA approval of our sNDA relating to Carteyva<sup>®</sup> as a treatment for r/r FL, among other clinical development milestones. With respect to solid tumors, we not only commenced clinical development of JWATM204 and JWATM214, completing first patient infusions for both products as a treatment for HCC, but also (i) entered into an agreement with 2seventy bio, Inc. (a NASDAQ listed company) to develop and commercialize a cell therapy product directed to MAGE-A4 in Greater China and (ii) strengthened our strategic alliance with Juno by entering into a new agreement relating to the research, development, manufacturing and commercialization of new cellular therapy products specifically directed to DLL3 in Greater China. Moreover, in March 2023, we initiated the clinical study of Carteyva<sup>®</sup> as a treatment for patients with moderately or severely active SLE, and the first patient infusion was achieved in this trial. We also currently expect to receive NMPA approval of an IND application relating to Carteyva<sup>®</sup> as a treatment for SLE in the first half of 2023, expanding our potential range into the treatment of autoimmune diseases.

The following chart summarizes the current development status of our hematology pipeline which includes hematologic malignancies and autoimmune diseases:



**Abbreviations:** LBCL = large B-cell lymphoma; FL = follicular lymphoma; MCL = mantle cell lymphoma; ALL = acute lymphoblastic leukemia; CLL = chronic lymphocytic leukemia; MM = multiple myeloma; NHL = non-Hodgkin lymphoma; SLE = systemic lupus erythematosus.

\* Mainland China, Hong Kong and Macau refer to Mainland China, Hong Kong (China) and Macau (China), respectively.

1. Relma-cel is based on the same chimeric antigen receptor (“CAR”) construct as the product lisocabtagene maraleucel (Breyanzi or lisocabtagene or liso-cel) of Juno, which was approved by the U.S. Food and Drug Administration (“FDA”) in February 2021.
2. JWCAR129 is based on the same CAR construct as Juno’s product orvacabtagene autoleucel (orva-cel).
3. SLE is a chronic autoimmune disease characterized by the production of autoantibodies and abnormal B-lymphocyte function. To further extend relma-cel’s potential in broader disease area, we are planning a study to evaluate the safety, tolerability, and pharmacokinetic profile of relma-cel in Chinese patients with moderately or severely active SLE.

## Hematologic Malignancies

### *Our Core Product Candidate — Carteyva® (relma-cel, R&D code: JWCAR029)*

Carteyva®, our lead product, has the potential to be a superior CAR-T therapy. It targets an antigen called CD19, which is expressed in a broad range of hematological cancers, including LBCL. Lymphomas are hematological cancers involving lymphocytes of the immune system, and LBCL is one of several types of non-Hodgkin's lymphoma (“**NHL**”) that affect B-cells within the immune system. In addition to marketing Carteyva® as a third-line treatment for LBCL, we are also exploring the further clinical potential for Carteyva® by developing relma-cel as a third-line treatment for other types of NHL, including FL, MCL, ALL and chronic lymphocytic leukemia (“**CLL**”), and moreover as a frontline and second-line treatment for LBCL.

Carteyva® is based on a CAR construct that we have in-licensed from Juno for Mainland China, Hong Kong and Macau<sup>2</sup>. Juno's biologics license application for its product based on that same CAR construct (“**Breyanzi**” or “**lisocabtagene**” or “**liso-cel**”) was approved by the U.S. FDA for third-line LBCL in February 2021 and for second-line LBCL that is r/r within 12 months of frontline therapy in June 2022.

#### *Third-line LBCL*

On September 1, 2021, the NMPA approved our NDA for Carteyva® as a treatment for adult patients with r/r LBCL after two or more lines of systemic therapy. Carteyva® is the first CAR-T product approved as a Category 1 biologics product in China, and the sixth approved CAR-T product globally.

Carteyva®'s potential to be a superior CAR-T therapy is based on its potential best-in-class safety profile and competitive efficacy. Our Phase II registrational clinical trial of Carteyva® as a third-line treatment for LBCL demonstrated efficacy results of best ORR of 77.6% and best CRR of 53.5%. In the same trial, severe cytokine release syndrome (“**sCRS**”) was observed in 5.1% of treated patients, severe neurotoxicity (“**sNT**”) was observed in 3.4% of treated patients, and no treatment-related deaths were reported. In addition, the two-year overall survival (“**OS**”) rate was 69.3%, and there were no new safety signals. We reported these two years of follow-up results at the Annual Meeting of the American Society of Clinical Oncology held in Chicago, Illinois in June 2022. Although head-to-head studies with comparable products have not been conducted, we believe that these data demonstrate a potential best-in-class safety profile and competitive efficacy of Carteyva® and its ability to provide unique benefit to patients.

<sup>2</sup> *Mainland China, Hong Kong and Macau refer to Mainland China, Hong Kong (China) and Macau (China), respectively.*

## *Second-line LBCL*

We have completed a single-arm Phase I trial in China to evaluate Carteyva<sup>®</sup> as a treatment for high risk LBCL patients due who are refractory to primary treatment. This was an open-label, single-arm, multi-centre, Phase I study, aiming to evaluate the safety and efficacy of relma-cel in patients with primary refractory disease after first-line standard of care. A total of 12 patients received relma-cel infusion and completed 9 months follow-up. Data showed relma-cel was tolerable, no grade 3 or higher CRS or NT was observed. The most common treatment-emergent adverse event at grade 3 or higher was cytopenia. The best ORR and best CRR were 75.0% and 33.3%, respectively, and 3-month ORR and CRR were 41.7% and 33.3%, respectively. Median duration of response and OS were not yet reached. We reported these findings at the Annual Meeting of the American Society of Clinical Oncology held in Chicago, Illinois in June 2022.

In December 2021, on the basis of data generated from this trial, we submitted to the NMPA an IND application for a multi-center, randomized Phase III registrational clinical trial comparing Carteyva<sup>®</sup> to second-line LBCL standard of care therapy, including salvage chemotherapy +/- high dose chemotherapy followed by autologous stem cell transplant. The design is similar to the TRANSFORM study evaluating Breyanzi, a CAR-T using the same CAR construct as Carteyva<sup>®</sup> in this indication, which demonstrated highly statistically significant improvement in Event Free Survival for Breyanzi and led to the U.S. FDA approval of Breyanzi as a second-line treatment for LBCL. In March 2022, the NMPA approved our IND application relating to this trial. Further, we submitted a new IND application for Carteyva<sup>®</sup> as second-line therapy for transplant-ineligible patients with r/ r LBCL in January 2023. The design is similar to the PILOT study evaluating Breyanzi, on the basis of which the U.S. FDA has approved Breyanzi for second-line treatment of transplant-ineligible patients.

## *Frontline LBCL*

In March 2023, we announced the commencement of an IIT relating to Carteyva<sup>®</sup> as a first-line treatment for patients with high risk LBCL, and the first patient infusion was completed. Recent reports have suggested that anti-CD19 CAR-T therapy may be beneficial to individuals who have not fully responded to early frontline therapy. As a result and given Carteyva<sup>®</sup>'s low frequency of severe toxicity to date, we expect to continue enrolling frontline or treatment-naive patients with LBCL for our Phase I IIT. In the planned study, these patients will receive two cycles of conventional frontline therapy with R-CHOP<sup>3</sup> and if not achieving a complete response will then receive a single infusion of Carteyva<sup>®</sup> at

<sup>3</sup> *R-CHOP is a cancer drug combination to treat NHL. It includes rituximab, cyclophosphamide, anthracycline, vincristine and corticosteroid.*



a dose of 100 million cells. These trial data, if favorable, may then be used to design and conduct an expanded Phase I trial of LBCL patients without prior chemotherapy or a larger registrational trial in frontline LBCL similar to the approach described for the initial IIT in the frontline setting.

### *Third-line FL*

With respect to Carteyva<sup>®</sup> as a third-line treatment for adult patients with r/r FL, the NMPA granted Breakthrough Therapy Designation in September 2020, accepted our sNDA in February 2022 and approved our sNDA in October 2022. Carteyva<sup>®</sup> has thus become the first CAR-T product approved for treatment of r/r FL in China.

The NMPA's approval of our sNDA relating to Carteyva<sup>®</sup> as a third-line treatment for adult patients with r/r FL was based on the 6-months clinical results from cohort B of a single-arm, multi-center pivotal study (the “**RELIANCE**” study) on Carteyva<sup>®</sup> in adult patients with r/r B cell non-Hodgkin lymphoma in China. The 3-months data had been presented at the 63rd Annual Meeting of the American Society of Hematology in December 2021. The cohort B results of the RELIANCE study showed that Carteyva<sup>®</sup> demonstrated high rates of durable disease response (ORR=100.0%, CRR=85.2% at month 3; ORR=92.6%, CRR=77.8% at month 6) and controllable CAR-T associated toxicities in patients with r/r FL.

In December 2022, we reported cohort B clinical response of this pivotal Phase II RELIANCE study on efficacy and safety of Carteyva<sup>®</sup> in adults with r/r FL in China at the 64th Annual Meeting of the American Society of Hematology. As of the data cut-off date of December 17, 2021, based on 28 patients who had been treated with Carteyva<sup>®</sup> with 11.7 months of median follow-up, Carteyva<sup>®</sup> demonstrated remarkable clinical responses, achieving high rates of CRR and ORR (best ORR and best CRR were 100.0% and 92.6% respectively) and a manageable safety profile — only one patient experienced grade 3 or above neurotoxicity (“**NT**”), and no patient experienced grade 3 or above cytokine release syndrome (“**CRS**”). We are continuing the RELIANCE study.

### *Third-line MCL*

We are conducting a registrational trial in China to evaluate Carteyva<sup>®</sup> as a treatment for MCL patients who previously received chemotherapy, anti-CD20 agent and Bruton tyrosine kinase inhibitors (“**BTKi**”). This is a Phase II, open-label, single-arm, multicenter study which aims to assess the efficacy and safety of Carteyva<sup>®</sup> in adults with r/r MCL in China. The study enrolled a total of 59 r/r MCL patients who were r/r to second-line or above treatments. Prior therapies must include an anti-CD20 monoclonal antibody, anthracycline-or bendamustine-containing chemotherapy, and BTKi therapy. We plan to follow up on long-term survival (two years or above) for these patients. Patient enrollment began in January 2021 and is currently on schedule to be completed in 2023. In April 2022, the NMPA granted Breakthrough Therapy Designation for Carteyva<sup>®</sup> as a treatment for patients with MCL.



At the 64th Annual Meeting of the American Society of Hematology in December 2022, we reported preliminary safety and efficacy data for our study of Carteyva® as a treatment for MCL. As of November 30, 2021, the preliminary data based on 11 patients showed a promising clinical efficacy outcome (best ORR = 81.8% and best CRR = 54.5%) in high risk patients with r/r MCL. In those 11 patients, the incidence of safety-related effects was low — only one patient experienced grade 3 or above CRS, and only one patient experienced immune effector cell-associated neurotoxicity syndrome. Based on this progress, we currently expect to complete the pivotal clinical study, and to submit an sNDA to the NMPA by the end of 2023.

#### *Third-line ALL*

We have commenced a single-arm Phase I/II registrational trial in China to evaluate Carteyva® in pediatric and young adult patients with r/r ALL after at least two prior lines of therapy. The NMPA approved our IND application with respect to this clinical trial in April 2022, and we have commenced patient enrollment and administered the first several doses of Carteyva® to patients in this trial.

#### *Third-line CLL*

We continue to assess the appropriate time for commencement of a study to evaluate Carteyva® as a treatment for high-risk r/r CLL patients.

#### ***JWCAR129***

JWCAR129 is an autologous CAR-T therapy for the treatment of multiple myeloma (“MM”), based on a CAR construct that we have in-licensed from Juno (the H125 vector). MM is a cancer of plasma cells, which are an important part of the immune system formed from matured B-cells to produce antibodies that help the body to attack and kill germs. MM is a condition in which plasma cells become cancerous and grow out of control. JWCAR129 targets BCMA, a protein which is highly expressed in a number of hematological malignancies, including MM. In December 2021, the NMPA approved our IND application relating to JWCAR129 as a treatment for fourth-line or greater r/r MM.

We will continue to evaluate opportunities for the development of JWCAR129 and other product candidates intended for the treatment of MM, taking into account the development status and potential of our other product candidates and availability of funding.

## Autoimmune Diseases

### *Systemic Lupus Erythematosus (“SLE”)*

SLE is a chronic autoimmune disease characterized by the production of autoantibodies and abnormal B-lymphocyte function. Prevalence of SLE in China mainland is about 30/100,000 or around 270,000 cases patient-year<sup>4</sup>, 40% of SLE patients develop organ damage in the first year, and 50% of patients develop irreversible organ damage within five years of onset. Current standards of care are neither effective nor safe, which addresses the big unmet medical needs.

B Cell Depletion Therapy (“BCDT”) has now become one of the main novel therapy candidates targeted at SLE.

CD19 is widely expressed at all differentiation stages from pre-B cells to plasma cells. Hence, CD19-targeted CAR-T cells may target and deplete B cells or plasma cells that are directly responsible for autoantibody production. Compared with antibodies, CAR-T cell therapy could retain potency over time and rapidly lead to lasting remission. We estimate that at least 15,000 patients are CAR-T eligible in the targeted setting with high treatment willingness.

To further extend Carteyva<sup>®</sup>’s potential in broader disease area, we initiated a clinical study to evaluate the safety, tolerability, and pharmacokinetic profile of Carteyva<sup>®</sup> in Chinese patients with moderately or severely active SLE. The efficacy of Carteyva<sup>®</sup> and the recommended Phase II dose (“**RP2D**”) in SLE will also be explored in the study. We currently expect to receive NMPA approval of our IND application relating to Carteyva<sup>®</sup> as a treatment for SLE in the first half of 2023. We believe that the Company may be able to secure a first-mover or early-mover advantage in a highly promising market through development of such therapy.

<sup>4</sup> Rees F, Doherty M, Grainge MJ, et al. *The Worldwide Incidence and Prevalence of Systemic Lupus Erythematosus: A Systematic Review of Epidemiological Studies*. *Rheumatology*. 2017; 56(11): 1945-1961. Applied 30 cases/100,000 and assuming 900 million as China adult population in 2017.

## Solid Tumors

The following chart summarizes the current development status of each of solid tumor candidates:

	Product	Target	Indication	Commercial Rights	Pre-clinical	Phase I	Pivotal / Phase II/III	NDA	Marketed	Partner
Solid Tumors	JWATM204 <sup>1</sup>	GPC3	HCC	Mainland China, Hong Kong, Macau, Taiwan, and member countries of ASEAN*	▶					EUREKA
	JWATM204	GPC3	NSCLC/HAS	Mainland China, Hong Kong, Macau, Taiwan, and member countries of ASEAN*	▶					EUREKA
	JWATM214 <sup>2</sup>	GPC3	HCC	Mainland China, Hong Kong, Macau, Taiwan, and member countries of ASEAN*	▶					Lyell EUREKA
	JWATM203 <sup>1</sup>	AFP	HCC	Mainland China, Hong Kong, Macau, Taiwan, and member countries of ASEAN*	▶▶					EUREKA
	JWATM213	AFP	HCC	Mainland China, Hong Kong, Macau, Taiwan, and member countries of ASEAN*	▶					Lyell EUREKA
	JWTCR001	MAGE-A4	various solid tumors	Mainland China, Hong Kong, Macau*	▶ New Product					seventybio
	JWCAR031	DLL3	SCLC	Mainland China, Hong Kong, Macau*	▶ New Product					Bristol Myers Squibb

*Abbreviations:* HCC = hepatocellular carcinoma; NSCLC = non-small cell lung cancer; AFP = alpha-fetoprotein; GPC3 = glypican-3; r/r = relapsed or refractory; HAS = hepatoid adenocarcinoma of the stomach; MAGE-A4 = melanoma associated antigen A4; DLL3 = Delta-like ligand 3.

\* Mainland China, Hong Kong, Macau and Taiwan refer to Mainland China, Hong Kong (China), Macau (China) and Taiwan (China), respectively.

- JWATM204 is in a Phase I investigator-initiated trial in China. Eureka's products based on the CAR constructs underlying JWATM203 and JWATM204 are currently in Phase I/II trials in the US conducted by Eureka under an IND application. In November 2021, the U.S. FDA granted Fast Track Designation to Eureka's counterpart to JWATM203 for the treatment of hepatoblastoma ("HB") and HCC in pediatric patients, as well as "rare pediatric disease designation" for the treatment of HB. In February 2022, the U.S. FDA granted Orphan Drug Designation to Eureka's counterparts to JWATM203 and JWATM204.
- Developing using Lyell technology.

## ***JWATM204/214***

JWATM204 is a potentially superior autologous, non-HLA-restricted, TCR T-cell therapy candidate built on Eureka's ARTEMIS® and E-ALPHA® platforms and targeting glypican-3 (“GPC3”) for the treatment of HCC. Treatment of HCC represents a huge unmet medical need in China, and we believe that JWATM204 has the potential to be a promising treatment for patients with GPC3-positive HCC. In June 2020, we in-licensed from Eureka the rights to develop, manufacture and commercialize JWATM204 in Mainland China, Hong Kong, Macau, Taiwan<sup>5</sup> and the member countries of the Association of Southeast Asian Nations (the “**JW Territory**”). We completed manufacturing process development for the JWATM204 in the third quarter of 2021 by leveraging our relma-cel manufacturing process platform. In the fourth quarter of 2021, we completed an upgrade of our clinical manufacturing facility in Shanghai Waigaoqiao to enhance our capabilities to manufacture multiple products concurrently. In the first quarter of 2022, we completed the technical transfer of JWATM204 manufacturing process from process development laboratory to our Waigaoqiao clinical manufacturing facility, and qualified the facility for GMP manufacturing. In July 2022, we announced the commencement of an IIT of JWATM204 as a treatment for patients with advanced HCC, and we have already administered JWATM204 to several patients in connection with this trial. We plan to continue this clinical trial to further evaluate the initial efficacy and safety profile of JWATM204.

Through our partnerships with Eureka and Lyell, we also plan to combine Lyell's technology in T-cell anti-exhaustion functionality with JWATM204 to create a novel product, JWATM214, for HCC treatment. In 2022, we focused on vector manufacturing process development for the JWATM214 program, and we anticipate that our future vector manufacturing process development will be based entirely in China. In February 2023, we announced the commencement of an IIT relating to JWATM214 as a treatment for patients with advanced HCC, and the first patient infusion was completed.

## ***JWATM203/213***

JWATM203 is a potentially superior autologous T-cell receptor mimic (“**TCRm**”) T-cell therapy targeting alpha-fetoprotein (“**AFP**”) for the treatment of HCC. In June 2020, we in-licensed from Eureka the rights to develop, manufacture and commercialize JWATM203 in the JW Territory. As with JWATM204, we also plan to combine Lyell's technology in T-cell anti-exhaustion functionality with JWATM203 and Eureka's ARTEMIS® technology platform to create JWATM213, an additional autologous cell therapy for HCC treatment.

<sup>5</sup> *Mainland China, Hong Kong, Macau and Taiwan refer to Mainland China, Hong Kong (China), Macau (China) and Taiwan (China), respectively.*

## ***MAGE-A4***

Melanoma associated antigen A4 (“**MAGE-A4**”) is a well-known cancer-testis antigen (“**CTA**”) on the X chromosome, involving in the regulation of cell progression, transcriptional control, cell survival and apoptosis. MAGE-A4 is a highly prevalent antigen in a wide variety of malignant tumors, including non-small cell lung cancer, melanoma, bladder, head and neck, gastroesophageal and ovarian cancers, and thus an ideal target indication for T-cell receptor T-cell (“**TCR-T**”) therapy. Early phase clinical trials<sup>6</sup> have previously demonstrated that TCR-T cell therapies targeting MAGE-A4 can have meaningful clinical efficacy for treatment of MAGE-A4-expressing solid tumors.

In October 2022, we established a strategic alliance with 2seventy bio, Inc. to develop and commercialize a cell therapy product directed to MAGE-A4 (including any mutations, fragments, modifications or derivatives of the engineered binding element for MAGE-A4) in oncology indications. The agreement is focused on the technologies and know-how possessed by 2seventy bio, Inc., and also includes future prospects for the development and commercialization of the product in Greater China based on addressable patient population and unmet medical needs. We believe that the Company may be able to secure a first-mover or early-mover advantage in a highly promising market through development of such a therapy.

## ***DLL3***

DLL3, belonging to the Notch ligand family, is a single transmembrane protein attached to the cell surface. While activation and up-regulation of Notch would generally induce tumor formation and promote tumor development, its activation and up-regulation in neuroendocrine tumors could suppress tumor growth, specifically in small cell lung carcinoma (“**SCLC**”). Thus DLL3 plays a key role in the signaling pathway that regulates tumorigenesis, disease progression and chemoresistance. Taking SCLC as an illustration, DLL3 is highly expressed in about 80% of the patients, and clinical studies have demonstrated that DLL3 in SCLC is negatively correlated with patients’ survival.

In December 2022, we strengthened our relationship with Juno and by entering into an agreement with Juno for the research, development, manufacturing and commercialization of a new cellular therapy products specifically directed to DLL3 in Greater China, taking into consideration Juno’s leading position in the field of cell therapy and the significant market potential of such products as evidenced by the addressable markets. We believe that we have the potential to be one of the early movers in such highly promising market through this development.

<sup>6</sup> *Adaptimmune’s Surpass and Spearhead trials, as reported at the European Society for Medical Oncology (2022).*

**Cautionary Statement required by Rule 18A.05 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “Listing Rules”):** We cannot guarantee that we will be able to successfully develop or ultimately market Cartheyva® in indications beyond the current NMPA-approved label, or to successfully develop or ultimately market our other pipeline products. Shareholders and potential investors of the Company are advised to exercise due care when dealing in the shares of the Company.

## **Discovery and Pre-clinical Research**

Early research and discovery is focused on building on proven manufacturing approaches and leveraging the Company’s footprint in China. This involves developing autologous products designed to strengthen the Company’s stance in existing indications and engineering new pipeline products that will focus on unmet need in Asia for both liquid and solid cancers. These new products will be differentiated through the adoption of three attributes designed to increase value, improve efficiency and speed. The first attribute maximizes the value of the new pipeline by designing these new products with global commercial rights, giving the Company the potential to expand outside the Asia market. The second attribute is designed to improve efficiency of these new products; all new CAR products will incorporate additional protein components called “Armored” elements. These Armored elements are designed to enhance the product’s performance and increase the duration of the clinical response. As the third attribute, all new products will take advantage of the Company’s new next-generation product processing methods. These are new in-house manufacturing methods that are faster and maintain the product in a fitter state compared to conventional methods of manufacture. To achieve these attributes we have developed an in-house early discovery and pre-clinical team. This team is tasked with the development of these products and processes and will also build the Company’s IP portfolio that is required for global commercialization.

One of the first products to be developed in-house will be directed to B-cell malignancies. This product will be a dual targeting autologous CAR T-cell. The dual targeting will greatly reduce the chances of relapses from tumor antigen downregulation or loss. In addition, this product will be fitted with enhancing Armored elements engineered to improve performance and protect/shield the product from suppressive factors known to be presented by the tumor’s defense systems. This product will be manufactured using our next-generation processing designed to deliver a less differentiated, fitter, more potent product.

Lastly, the Company is exploring innovative areas design to simplify the manufacturing process. We are looking into the feasibility of non-viral approaches with the use of genomic editing and off-the-shelf CAR products for various indications. These approaches will ultimately increase the speed to deliver a product to the patient and reduce overall cost of goods sold.



## **Manufacturing**

In June 2020, we received a production license from Jiangsu Province authorities for our new commercial manufacturing facility in Suzhou. This facility provides approximately 10,000 square meters for commercial and clinical manufacturing in compliance with GMP and Quality Management System (“**QMS**”) standards. It is designed to house four independent modules. The design of these modules can be adapted to support all cell platforms, including those using gene-modified autologous T-cells and natural killer (“**NK**”) cells, gene-modified or non-gene-modified tumor-infiltrating lymphocyte and gene-modified allogeneic immune cells, as well as facilities to produce GMP grade viral vectors that are used to genetically modify these cells.

Our Suzhou operations have been executing according to our commercialization plans and have made significant achievements during the last year. In March 2021, we received and passed relma-cel Pre-approval Inspection (“**PAI**”) conducted jointly by the NMPA and Jiangsu Medical Products Administration with no critical or major observations. In June 2021, our production license for Suzhou site was renewed with the license type changed from As to As+Cs (A as Marketing Authorization Holder (“**MAH**”) owner and manufacturer, C as contract manufacturing organization (“**CMO**”), s as bio products). Currently, two of these modules have been approved and are in full GMP operations. The third module is in the process of regulatory review and approval. With current regulatory approval, we can meet manufacturing needs for both commercial and clinical supplies and have maintained a high manufacturing success rate of 98% since our LBCL registrational clinical trial. After initial product launch, we have gained multiple approvals for manufacturing capacity expansion in the fourth quarter of 2022 and the first quarter of 2023. We continue working with relevant regulatory agencies to further increase our manufacturing capacity in order to meet the increased demands.

As a critical material, sustainable lentiviral vector supply is necessary to ensure our final product manufacturing and supply. We continuously invest resources in establishing our own capability in vector development and manufacturing. We have developed a platform process and successfully manufactured vectors to support clinical programs. Furthermore, we are establishing vector capability for commercial product.



## **Impact of the COVID-19 pandemic**

We have taken a number of measures to address the challenge posed by the COVID-19 pandemic in 2022. We have continued to implement rigorous testing, reporting, ventilation and disinfection measures to manage risks for employees and contractors who are on-site. During the period in 2022 when restrictions on travel were put in place by the government to contain the outbreak of COVID-19, we experienced some delay in patient recruitment for some of our clinical trials and commercialization, yet overall we believe we have successfully addressed the challenge posed by the COVID-19 pandemic in 2022, and our revenue for 2022 remains in line with previous expectations.

Future developments in the COVID-19 pandemic may have a potential impact on our operations, including but not limited to the enrollment of patients in clinical trials, regulatory reviews and approvals, recruitment of commercial patients, procurement of raw materials and delivery of finished products, etc. Based on the information available to us through the date of this announcement, future developments in the COVID-19 pandemic will not have material impact on our operation and we will continue to monitor the situation and adopt various measures to mitigate the impact.

## **Future and Development**

In addition to driving full-scale commercialization of Carteyva<sup>®</sup>, we intend to focus on pursuing the following strategies as we pursue our vision of becoming an innovation leader in cell immunotherapy:

***Solidify our leadership in hematology by continuing to develop Carteyva<sup>®</sup> for earlier lines of treatment and additional indications, as well as further expanding clinical development for autoimmune diseases***

Our approach to expand Carteyva<sup>®</sup>'s indications involves two key pillars for hematological cancers: advancing Carteyva<sup>®</sup> into earlier lines of LBCL treatment and developing Carteyva<sup>®</sup> as a potential therapy for other hematological cancers that express the CD19 antigen. With the infrastructure we have built, and if our development plan is realized, Carteyva<sup>®</sup> has great potential to be the leading cell therapy product for treatment of hematological cancers.

Furthermore, to further expand Carteyva<sup>®</sup>'s potential in broader disease area, we initiated a clinical study for Chinese patients with moderately or severely active SLE. We expect to receive NMPA approval of our IND application relating to Carteyva<sup>®</sup> as a treatment for SLE in the first half of 2023 with the goal of securing a first-mover or early-mover advantage in a highly promising market through development of such therapy.

***Leverage our integrated cell therapy platform to expand into the solid tumor market***

Our solid tumor portfolio includes indications such as HCC, lung cancer and others. With multiple cell therapy platforms we already integrated, we aim to achieve breakthroughs in the field of solid tumors through deep collaborations with world-class cell therapy partners, ultimately serving more patients. We have announced the commencement of IIT relating to JWATM204, which was acquired from Eureka, and JWATM214, which combines Eureka's ARTEMIS® platform with Lyell's T-cell anti-exhaustion technology. In 2022, we further expanded our solid tumor pipeline through strategic alliance with 2seventy bio, Inc. and deepened our collaboration with Juno to develop novel TCR-T and CAR-T products. We believe there is an opportunity to use these technologies as a platform for multiple new cell therapies that can be applied across a broad range of rare and prevalent solid tumors, including HCC, lung cancers as well as others.

***Continuously enhance our manufacturing capability and implement cost reduction plan through innovation and scale***

We have had a 98% success rate for the manufacturing of Carteyva® since commencement of our LBCL registrational clinical trial. In addition, we intend to invest in further optimizing our manufacturing processes through technological enhancements and achieving economies of scale, with the ultimate goal of making the production of our cell therapies better, faster, and more cost effective.

***Grow our business through in-licensing opportunities, partnerships and selective acquisitions, as well as in-house R&D***

Since the establishment of the Company, we have used a mix of in-licensing opportunities, selective acquisitions and in-house R&D to fuel our growth into a leading cell therapy player in China. We leveraged our exclusive licenses of certain rights from Juno to introduce relma-cel, JWCAR129 and DLL3 candidates into our pipeline, we acquired rights from Eureka and Lyell that enabled us to introduce JWATM203/213 and JWATM204/214 into our pipeline, and we established strategic alliance with 2seventy bio, Inc. to develop MAGE-A4 candidate for solid tumor in JW Territory.

In addition, in January 2022, we strengthened our in-house R&D capabilities with the appointment of Dr. Cordoba as our chief scientific officer. Dr. Cordoba is a highly regarded scientist in driving new innovations in cell immunotherapy technology. He is ranked third in the world as patent holder in relation to CAR technology, with over 270 patent filings in relation to enhancing CAR activity, shielding CAR-T cells from immunosuppression, and improving CAR safety. His scientist team will oversee the early-stage R&D and develop a robust cell immunotherapy pipeline for the Company.

We believe we have established a reputation in China as a preferred partner in cell therapy due to our proprietary platform and clinical track record, and we plan to leverage our platform and network to focus on potential opportunities in the cell therapy space that we deem to possess high growth or breakthrough technology potential. These potential opportunities include but are not limited to growth opportunities in alternative allogeneic approaches and new cellular targets which we believe represent novel and groundbreaking approaches to the treatment of cancer.

Moreover, we significantly enhanced our discovery platform through acquisition in June 2020 of certain rights to use Eureka's ARTEMIS® and E-ALPHA® platforms, and we intend to leverage our enhanced discovery platform to potentially identify and develop the next groundbreaking solution in cell therapy.

Finally, we plan to continue to leverage our network of strategic partners, leaders in the cell therapy field and the contract research organization field, respectively, as we continue to advance into new, undiscovered cellular targets and treatment.

## FINANCIAL REVIEW

### Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

#### *IFRS Measure:*

	<b>Year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Audited)</b>	<b>(Audited)</b>
Revenue	<b>145,702</b>	30,797
Cost of sales	<b>(86,946)</b>	(21,752)
Gross profit	<b>58,756</b>	9,045
Research and development expenses	<b>(407,818)</b>	(414,397)
General and administrative expenses	<b>(179,763)</b>	(201,518)
Selling expense	<b>(190,877)</b>	(170,732)
Other income	<b>23,380</b>	6,444
Other (losses)/gains, net	<b>(159,561)</b>	12,075
<b>Operating loss</b>	<b>(855,883)</b>	(759,083)
Finance income	<b>16,535</b>	8,296
Finance costs	<b>(6,787)</b>	(2,692)
Finance income — net	<b>9,748</b>	5,604
Fair value changes of warrants	<b>—</b>	51,151
<b>Loss before income tax</b>	<b>(846,135)</b>	(702,328)
Income tax expense	<b>—</b>	—
<b>Loss for the year</b>	<b><u>(846,135)</u></b>	<b><u>(702,328)</u></b>
<b><i>Other comprehensive income/(loss):</i></b>		
<i>Items that will not be reclassified to profit or loss</i>		
— Exchange differences on translation	<b>326,966</b>	(83,539)
Other comprehensive income/(loss) for the year, net of tax	<b>326,966</b>	(83,539)
<b>Total comprehensive loss for the year</b>	<b><u>(519,169)</u></b>	<b><u>(785,867)</u></b>
<b><i>Non-IFRS measure:</i></b>		
<b>Adjusted loss for the year</b>	<b><u>(605,093)</u></b>	<b><u>(678,951)</u></b>

## 1. Revenue

We successfully launched our anti-CD19 autologous CAR-T cell immunotherapy product Carteyva<sup>®</sup> (relma-cel, R&D code: JWCAR029) for the treatment of adult patients with r/r LBCL after two or more lines of systemic therapy after obtaining the marketing approval for the product from the NMPA on September 1, 2021.

Revenue was RMB145.7 million for the year ended December 31, 2022, as compared to RMB30.8 million for the year ended December 31, 2021. Revenue was recognized at the point of infusion. We expect that revenue will continue to increase from the sales of Carteyva<sup>®</sup> along with our commercialization progress as more patients are treated with Carteyva<sup>®</sup>.

The following table sets forth a breakdown of revenue from our product for the years indicated:

	Year ended December 31,			
	2022		2021	
	<i>RMB'000</i>	<i>%</i>	<i>RMB'000</i>	<i>%</i>
	(Audited)		(Audited)	
Carteyva <sup>®</sup>	<u>145,702</u>	<u>100.0</u>	<u>30,797</u>	<u>100.0</u>
<b>Total revenue</b>	<b><u>145,702</u></b>	<b><u>100.0</u></b>	<b><u>30,797</u></b>	<b><u>100.0</u></b>

## 2. Cost of Sales

Cost of sales was RMB86.9 million for the year ended December 31, 2022, as compared to RMB21.8 million for the year ended December 31, 2021. Cost of sales primarily consists of raw material costs, staff costs, depreciation and amortization, manufacturing overhead and others.

The following table sets forth a breakdown of cost of sales by product for the years indicated:

	Year ended December 31,			
	2022		2021	
	<i>RMB'000</i>	%	<i>RMB'000</i>	%
	(Audited)		(Audited)	
Carteyva®	<u>86,946</u>	<u>100.0</u>	<u>21,752</u>	<u>100.0</u>
<b>Total cost of sales</b>	<b><u>86,946</u></b>	<b><u>100.0</u></b>	<b><u>21,752</u></b>	<b><u>100.0</u></b>

### 3. Gross Profit and Gross Profit Margin

Gross profit represents revenue minus cost of sales. Gross profit margin represents gross profit as a percentage of revenue.

Gross profit was RMB58.8 million and gross profit margin was 40.3% for the year ended December 31, 2022, compared to RMB9.0 million and 29.4%, respectively, for the year ended December 31, 2021.

### 4. Research and Development Expenses

The following table provides a breakdown of research and development expenses for the years ended December 31, 2021 and 2022.

	Year ended December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
	(Audited)	(Audited)
Employee benefit expenses	<b>196,090</b>	192,404
— <i>Share-based compensation expenses</i>	<b>19,445</b>	25,100
R&D materials	<b>72,281</b>	97,488
Testing and clinical fees	<b>63,468</b>	64,230
Depreciation and amortization	<b>50,088</b>	31,931
Office expenses	<b>15,549</b>	17,586
Others	<b>10,342</b>	10,758
<b>Research and development expenses</b>	<b><u>407,818</u></b>	<u>414,397</u>

Research and development expenses decreased from RMB414.4 million for the year ended December 31, 2021 to RMB407.8 million for the year ended December 31, 2022. This decrease was primarily due to a decrease of approximately RMB25.2 million in R&D materials which resulted from implementation of cost reduction plan, raw material localization and less batch numbers. The effects of the foregoing factors were partially offset by an increase of approximately RMB18.2 million in depreciation and amortization, which resulted principally from depreciation of the Suzhou manufacturing facility and Shanghai Waigaoqiao upgraded manufacturing facility which began from the fourth quarter of 2021.

## 5. General and Administrative Expenses

The following table provides a breakdown of general and administrative expenses for the years ended December 31, 2021 and 2022.

	<b>Year ended December 31,</b>	
	<b>2022</b>	2021
	<b><i>RMB'000</i></b>	<i>RMB'000</i>
	<b>(Audited)</b>	(Audited)
Employee benefit expenses	<b>97,489</b>	114,145
— <i>Share-based compensation expenses</i>	<b>50,282</b>	55,909
Professional service fees	<b>40,415</b>	50,587
Depreciation and amortization	<b>11,963</b>	8,126
Office expenses	<b>16,355</b>	15,815
Auditor's remuneration	<b>2,661</b>	2,490
Non-audit remuneration	<b>934</b>	1,161
Others	<b>9,946</b>	9,194
	<hr/>	<hr/>
<b>General and Administrative Expenses</b>	<b><u>179,763</u></b>	<u>201,518</u>

General and administrative expenses decreased from RMB201.5 million for the year ended December 31, 2021 to RMB179.8 million for the year ended December 31, 2022. This decrease resulted primarily from a decrease of approximately RMB16.7 million in staff costs. To a lesser extent, the decrease resulted from a decrease of approximately RMB10.2 million in professional service fees. The effects of the foregoing factors were partially offset by an increase in other general and administrative expenses.



## 6. Selling Expenses

The following table provides a breakdown of selling expenses for the years ended December 31, 2021 and 2022.

	Year ended December 31,	
	2022	2021
	RMB'000	RMB'000
	(Audited)	(Audited)
Employee benefit expenses	100,838	78,376
— <i>Share-based compensation expenses</i>	12,775	8,361
Business promotion fees	75,943	68,424
Professional service fees	9,811	13,448
Office expenses	2,878	8,995
Others	1,407	1,489
	<u>190,877</u>	<u>170,732</u>
<b>Selling expenses</b>	<b><u>190,877</u></b>	<b><u>170,732</u></b>

Selling expenses increased from RMB170.7 million for the year ended December 31, 2021 to RMB190.9 million for the year ended December 31, 2022. This increase was primarily due to an increase of approximately RMB22.5 million in staff costs and an increase of approximately RMB7.5 million in business promotion fees, as we carried out commercial activities comprehensively in 2022 to fully support the commercialization of Carteyva<sup>®</sup>.

## 7. Other Income

Other income amounted to RMB23.4 million for the year ended December 31, 2022, as compared to RMB6.4 million for the year ended December 31, 2021. Other income in both years was related to government grants.

## **8. Other Gains and Losses**

Other gains and losses amounted to net other losses of RMB159.6 million for the year ended December 31, 2022, as compared to net other gains of RMB12.1 million for the year ended December 31, 2021. This change resulted primarily from a net foreign exchange loss of RMB158.5 million for the year ended December 31, 2022, as compared to a net foreign exchange gain of RMB14.8 million for the year ended December 31, 2021. This change mainly arose from the unrealized foreign exchange loss as a result of the weakening of RMB against USD and HKD when exchanging from the transactional currency (RMB) to the functional currencies (USD and HKD) for our offshore companies within the Group. These unrealized foreign exchange gains and losses are non-cash items.

## **9. Fair Value Changes of Warrants**

Fair value changes of warrants changed from a gain of RMB51.2 million for the year ended December 31, 2021 to nil for the year ended December 31, 2022. In 2021, when Juno discontinued clinical development of orva-cel, we derecognized the “warrants of upfront payment” as defined in our BCMA License Agreement with Juno, leading to recognition of a gain of RMB51.2 million from fair value changes of warrants. No income or loss from fair value changes of warrants occurred in 2022.

## **10. Income Tax Expense**

For the years ended December 31, 2021 and 2022, we did not incur any income tax expense, as we did not generate taxable income in either year.

## **11. Loss for the Year**

As a result of the above items, loss for the year was RMB846.1 million for the year ended December 31, 2022, compared to RMB702.3 million for the year ended December 31, 2021. The increase was primarily due to: (i) increased unrealized foreign exchange loss and (ii) one-time non-cash income recognized in 2021 from de-recognition of “warrants of upfront payment” under our BCMA License Agreement with Juno which did not recur in 2022. The effects of the foregoing factors were partially offset by (i) increased revenue and gross profit generated from sales of Carteyva<sup>®</sup> and (ii) increased other income from government subsidies and net finance income.

## 12. Non-IFRS Measure

To supplement the Group's consolidated financial statements, which are presented in accordance with IFRS, we also use adjusted loss for the year as an additional financial measure, which is not required by, or presented in accordance with IFRS. We believe that these adjusted measures provide useful information to Shareholders and potential investors in understanding and evaluating our consolidated results of operations in the same manner as they help our management.

Adjusted loss was RMB605.1 million for the year ended December 31, 2022, representing a decrease of RMB73.9 million from RMB679.0 million for the year ended December 31, 2021. The decrease was primarily due to: (i) increased revenue and gross profit generated from sales of Carteyva®; (ii) decreased general and administrative expenses and research and development expenses; and (iii) increased other income from government subsidies and net finance income. The effects of these factors were partially offset by an increase in selling expenses.

Adjusted loss for the year represents the loss for the year excluding the effect of certain non-cash items and one-time events, namely the loss on fair value changes of warrants, share-based compensation expenses and net foreign exchange losses. The term adjusted loss for the year is not defined under IFRS. The use of this non-IFRS measure has limitations as an analytical tool, and you should not consider it in isolation from, or as substitute for analysis of, our results of operations or financial condition as reported under IFRS. Our presentation of this adjusted figure may not be comparable to similarly titled measures presented by other companies. However, we believe that this non-IFRS measure reflects our core operating results by eliminating potential impacts of items that our management do not consider to be indicative of our core operating performance, and thus, facilitate comparisons of core operating performance from period to period and company to company to the extent applicable. The table below sets forth a reconciliation of loss to adjusted loss for the years indicated:

	<b>Year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Audited)</b>	<b>(Audited)</b>
<b>Loss for the year</b>	<b>(846,135)</b>	<b>(702,328)</b>
Added:		
Fair value changes of warrants	—	(51,151)
Share-based compensation expenses	<b>82,502</b>	89,370
Net foreign exchange losses/(gains)	<b>158,540</b>	(14,842)
	<hr/>	<hr/>
<b>Adjusted loss for the year (Non-IFRS)</b>	<b>(605,093)</b>	<b>(678,951)</b>
	<hr/> <hr/>	<hr/> <hr/>

*Selected Data from Statement of Financial Position*

	<b>As at December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
	<b>(Audited)</b>	<b>(Audited)</b>
Total current assets	<b>1,485,168</b>	1,895,040
Total non-current assets	<b>1,306,179</b>	1,221,566
	<hr/>	<hr/>
<b>Total assets</b>	<b>2,791,347</b>	<b>3,116,606</b>
	<hr/> <hr/>	<hr/> <hr/>
Total current liabilities	<b>310,835</b>	198,900
Total non-current liabilities	<b>126,228</b>	126,849
	<hr/>	<hr/>
<b>Total liabilities</b>	<b>437,063</b>	<b>325,749</b>
	<hr/> <hr/>	<hr/> <hr/>
<b>Net current assets</b>	<b>1,174,333</b>	<b>1,696,140</b>
	<hr/> <hr/>	<hr/> <hr/>

### 13. Liquidity and Sources of Funding and Borrowing

As at December 31, 2022, current assets amounted to RMB1,485.2 million, including cash and cash equivalents of RMB1,383.3 million and other current assets of RMB101.9 million. As at the same date, current liabilities amounted to RMB310.8 million, primarily including trade and other payables of RMB157.9 million, borrowings of RMB142.3 million and lease liabilities of RMB10.6 million.

In 2022, we strictly controlled our cash expenditures and actively diversified and expanded our financing channels to provide financial assurance for our future development. As at December 31, 2022 we have unsecured bank borrowings in the amount of RMB234.8 million, which includes: (i) an unsecured long term bank borrowing in the amount of RMB97.5 million in Suzhou and (ii) unsecured bank liquidity borrowings drawdown in the amount of RMB137.3 million from the bank facilities which multiple banks have granted. As of the date of this announcement, the Group has available unutilized bank loan facilities of RMB367.7 million.

As at December 31, 2022, cash and cash equivalents were RMB1,383.3 million, representing a net cash outflow of RMB451.1 million compared to RMB1,834.4 million as at December 31, 2021. The cash outflow was primarily due to payments of research and development expenses, general and administrative expenses, selling expenses and capital expenditure for long term assets. Those payments were partially offset by increased revenue and above short term bank borrowings.

### 14. Key Financial Ratios

The following table sets forth the key financial ratios of the Group as of the dates indicated:

	<b>As at December 31, 2022</b>	<b>As at December 31, 2021</b>
Current ratio <sup>(1)</sup>	<b>4.8</b>	9.5
Ratio of total liabilities to total assets <sup>(2)</sup>	<b>0.2</b>	0.1
Gearing ratio <sup>(3)</sup>	N/A <sup>(4)</sup>	N/A <sup>(4)</sup>

(1) Current ratio equals current assets divided by current liabilities as of the date indicated.

(2) Ratio of total liabilities to total assets equals total liabilities divided by total assets as of the date indicated.

(3) Gearing ratio is calculated using interest-bearing borrowings less cash and cash equivalents divided by total equity and multiplied by 100%.

(4) Gearing ratio is not applicable as our interest-bearing borrowings less cash and cash equivalents was negative.

## **15. Material Investments**

We did not make any material investments during the year ended December 31, 2022.

## **16. Material Acquisitions and Disposals**

We did not engage in any material acquisitions or disposals during the year ended December 31, 2022.

## **17. Pledge of Assets**

As at December 31, 2022, the Group had no pledge of assets.

## **18. Contingent Liabilities**

As at December 31, 2022, we did not have any material contingent liabilities.

## **19. Foreign Exchange Exposure**

The Group mainly operated in Mainland China and a majority of its transactions were settled in RMB. We have financed our business principally through equity financings and the Global Offering with related proceeds denominated in USD ultimately. We converted a portion of those USD proceeds to RMB, with the remaining amounts reserved for additional conversions to RMB as needed. With the continuous appreciation of USD against the RMB, holding USD assets will enhance the purchasing power of the Group.

Monetary assets and liabilities denominated in foreign currencies are translated at the functional currency rates of exchange ruling at the end of the Reporting Period. Differences arising on settlement or translation of monetary items are recognized in profit or loss. During the year ended December 31, 2022, foreign exchange risk arose from the assets and liabilities denominated in RMB which is different from the functional currencies of the Company due to the weakening of RMB against USD and HKD in 2022. The management seeks to limit our exposure to foreign currency risk by closely monitoring and minimizing its net foreign currency position. During the Reporting Period, the Group did not enter into any currency hedging transactions.

## 20. Employees and Remuneration

As at December 31, 2022, we had 528 employees. The following table sets forth the total number of employees by function as at December 31, 2022:

	<b>Number of Employees</b>	<b>% of total</b>
Technical operations	198	37.5
Quality	101	19.1
Medical	81	15.4
Commercial	95	18.0
Business development and general administrative	10	1.9
Support functions	43	8.1
	<hr/>	<hr/>
<b>Total</b>	<b>528</b>	<b>100.0</b>

The total remuneration cost (including Directors' emoluments) incurred by the Group for the year ended December 31, 2022 was RMB405.9 million, as compared to RMB392.0 million for the year ended December 31, 2021.

The remuneration of the employees of the Group comprises salaries, bonuses, employees provident fund and social security contributions, other welfare payments and share-based compensation expenses. In accordance with applicable Chinese laws, the Group has 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 the Group's employees.

The Company has also adopted the Pre-IPO Incentivization Scheme, the Restricted Share Unit Schemes, the Post-IPO Incentivization Scheme and the Post-IPO Restricted Share Unit Scheme. Please refer to the section headed "Statutory and General Information — D. Share Incentivization Schemes" in Appendix V to the prospectus dated October 22, 2020 (the "**Prospectus**") for further details.

### EVENTS AFTER THE REPORTING PERIOD

There have been no significant events since the end of the Reporting Period.



## CONSOLIDATED STATEMENT OF PROFIT OR LOSS

*FOR THE YEAR ENDED DECEMBER 31, 2022*

		<b>Year ended December 31,</b>	
		<b>2022</b>	<b>2021</b>
	<i>Note</i>	<i>RMB'000</i>	<i>RMB'000</i>
Revenue	3	<b>145,702</b>	30,797
Cost of sales	6	<b>(86,946)</b>	(21,752)
<b>Gross Profit</b>		<b>58,756</b>	9,045
Other income	4	<b>23,380</b>	6,444
Other (losses)/gains — net	5	<b>(159,561)</b>	12,075
Selling expenses	6	<b>(190,877)</b>	(170,732)
General and administrative expenses	6	<b>(179,763)</b>	(201,518)
Research and development expenses	6	<b>(407,818)</b>	(414,397)
<b>Operating loss</b>		<b>(855,883)</b>	(759,083)
Finance income		<b>16,535</b>	8,296
Finance costs		<b>(6,787)</b>	(2,692)
Finance income — net		<b>9,748</b>	5,604
Fair values gain of warrants		<b>—</b>	51,151
<b>Loss before income tax</b>		<b>(846,135)</b>	(702,328)
Income tax expense	7	<b>—</b>	—
<b>Loss for the year and attribute to the equity holders of the Company</b>		<b><u>(846,135)</u></b>	<b><u>(702,328)</u></b>
<b>Loss per share for the loss attributable to owners of the Company</b>			
— Basic and diluted ( <i>in RMB</i> )	8	<b><u>(2.06)</u></b>	<b><u>(1.76)</u></b>

## CONSOLIDATED STATEMENT OF COMPREHENSIVE LOSS

FOR THE YEAR ENDED DECEMBER 31, 2022

	Year ended December 31,	
	2022	2021
	RMB'000	RMB'000
<b>Loss for the year</b>	<b>(846,135)</b>	<b>(702,328)</b>
<b>Other comprehensive income/(loss):</b>		
<i>Items that will not be reclassified to profit or loss</i>		
— Exchange differences on translation	<u>326,966</u>	<u>(83,539)</u>
Other comprehensive income/(loss) for the year, net of tax	<u>326,966</u>	<u>(83,539)</u>
<b>Total comprehensive loss for the year and attribute to the equity holders of the Company</b>	<b><u>(519,169)</u></b>	<b><u>(785,867)</u></b>

## CONSOLIDATED BALANCE SHEETS

AS AT DECEMBER 31, 2022

		As at December 31,	
		2022	2021
	Note	RMB'000	RMB'000
<b>ASSETS</b>			
<b>Non-current assets</b>			
Property, plant and equipment		348,107	319,894
Right-of-use assets		45,112	45,784
Intangible assets	10	893,684	816,289
Prepayment for license		6,965	6,376
Other non-current assets		12,311	33,223
		<u>1,306,179</u>	<u>1,221,566</u>
<b>Total Non-current Assets</b>			
<b>Current assets</b>			
Inventories	11	40,159	31,402
Other current assets		9,700	17,405
Other receivables and prepayments		22,553	11,834
Trade receivable	12	5,305	—
Amount Due from Related Party	13	24,115	—
Cash and cash equivalents		1,383,336	1,834,399
		<u>1,485,168</u>	<u>1,895,040</u>
<b>Total current assets</b>			
		<u>2,791,347</u>	<u>3,116,606</u>
<b>Total assets</b>			

## CONSOLIDATED BALANCE SHEETS (CONT'D)

AS AT DECEMBER 31, 2022

		As at December 31,	
		2022	2021
	Note	RMB'000	RMB'000
<b>EQUITY</b>			
<b>Equity attributable to owners of the Company</b>			
Share capital		27	27
Reserves		6,551,595	6,142,033
Accumulated losses		(4,197,338)	(3,351,203)
<b>Total equity</b>		<b>2,354,284</b>	<b>2,790,857</b>
<b>LIABILITIES</b>			
<b>Non-current liabilities</b>			
Borrowings	15	92,500	95,000
Lease liabilities		33,728	31,849
<b>Total non-current liabilities</b>		<b>126,228</b>	<b>126,849</b>
<b>Current liabilities</b>			
Borrowings	15	142,300	5,000
Lease liabilities		10,600	15,186
Trade and other payables	14	157,935	178,714
<b>Total current liabilities</b>		<b>310,835</b>	<b>198,900</b>
<b>Total liabilities</b>		<b>437,063</b>	<b>325,749</b>
<b>Total equity and liabilities</b>		<b>2,791,347</b>	<b>3,116,606</b>

## NOTES:

### 1 General information

JW (Cayman) Therapeutics Co. Ltd (the “**Company**”) was incorporated in the Cayman Islands, with its registered office situate at the offices of Maples Corporate Services Limited, PO Box 309, Umland House, Grand Cayman, KY1-1104, Cayman Islands, on September 6, 2017 as an exempted company with limited liability.

The Company and its subsidiaries, hereinafter collectively referred to as the “**Group**” are primarily engaged in research and development (“**R&D**”), manufacturing, and marketing of anti-tumor drugs in the People’s Republic of China (the “**PRC**”).

The Company’s shares listed on the Main Board of The Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”) on November 3, 2020 (the “**Listing**”).

The consolidated financial statements are presented in thousands of Renminbi (“**RMB’000**”), unless otherwise stated.

### 2 Summary of significant accounting policies

#### 2.1 *Basis of preparation*

The annual results set out in this announcement do not constitute the consolidated financial statements of the Group for the year ended December 31, 2022 but are extracted from these financial statements, which are prepared in accordance with International Financial Reporting Standards (“**IFRS**”) issued by International Accounting Standards Board and disclosure requirements of the Hong Kong Companies Ordinance Cap. 622.

The consolidated financial statements has been prepared under the historical cost convention, as modified by the revaluation of financial liabilities at fair value through profit or loss, which are carried at fair value.

#### 2.2 *New standard, amendments and interpretation adopted by the Group*

A number of new standard, amendments and interpretation became applicable for the current reporting period and the Group changed its accounting policies and make adjustments as a result of adopting these new standard, amendments and interpretation set out below:

- Property, Plant and Equipment: Proceeds before Intended Use — Amendments to IAS 16
- Onerous Contracts — Cost of Fulfilling a Contract — Amendments to IAS 37
- Annual Improvements to IFRS Standards 2018–2020
- Reference to the Conceptual Framework — Amendments to IFRS 3
- Covid-19 Related Rent Concessions beyond June 30, 2021 — Amendment to IFRS 16
- Amendments to AG 5 Merger Accounting for Common Control Combinations

The adoption of the above new standard, amendments, improvement and interpretation to existing standards do not have a material impact on the Group.

### 2.3 *New standards and interpretations not yet adopted*

Certain new accounting standards, amendments to accounting standards and interpretations have been published that are not mandatory for December 31, 2022 reporting periods and have not been early adopted by the Group. These standards, amendments or interpretations 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

	<b>Year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Revenue from sales of goods		
— at point in time	<u><b>145,702</b></u>	<u><b>30,797</b></u>

## 4 Other income

	<b>Year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Government grants — cost related ( <i>Note</i> )	<u><b>23,380</b></u>	<u><b>6,444</b></u>

*Note:* The government grants and subsidies related to funding received to compensate for the Group's research and development expenses. Some of the grants received are related to future costs expected to be incurred and require the Group to comply with conditions attached to the grants and the government to acknowledge the compliance of these conditions. When the required conditions set by the government for such grants are met, the proportion of the qualified funds is recognized as "other income" and the remaining balance is recorded as "Trade and other payables-deferred income".

## 5 Other (losses)/gains — net

	<b>Year ended December 31,</b>	
	<b>2022</b>	<b>2021</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Net foreign exchange (loss)/gain	<b>(158,540)</b>	14,842
Net loss on disposal of property, plant and equipment	<b>(168)</b>	(120)
Fair value loss of contingent consideration for business combination	—	(2,089)
Others	<u><b>(853)</b></u>	<u>(558)</u>
<b>Total</b>	<u><b>(159,561)</b></u>	<u><b>12,075</b></u>

## 6 Expenses by nature

	Year ended December 31,	
	2022	2021
	RMB'000	RMB'000
Employee benefit expenses (including directors' emoluments)	404,328	386,915
Materials and consumables	113,972	109,051
Business promotion fee	77,385	70,124
Testing and clinical expenses	63,729	64,285
Depreciation of property, plant and equipment	54,474	27,084
Professional service expenses	51,281	64,190
Office expenses	31,320	33,852
Depreciation-right of use assets	13,718	13,314
Amortization of license	11,055	3,563
Royalty fee	8,742	1,857
Short term lease and low value lease expenses	6,749	9,168
Amortization of other intangible assets	5,563	1,687
Auditors' remuneration-audit service	3,595	3,651
— Audit service	2,661	2,490
— Non-Audit service	934	1,161
Other expenses	19,493	19,658
<b>Total cost of sales, selling, general and administrative expenses and research and development expenses</b>	<b>865,404</b>	<b>808,399</b>

## 7 Income tax expense

	Year ended December 31,	
	2022	2021
	RMB'000	RMB'000
Current income tax	—	—
Deferred income tax	—	—
<b>Total</b>	<b>—</b>	<b>—</b>

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operated.

### (a) Cayman Islands income tax

The Company is incorporated in the Cayman Islands as an exempted company with limited liability under the Companies Law of the Cayman Islands. There is no income tax in the Cayman Islands and accordingly, the operating results reported by the Company, is not subject to any income tax in the Cayman Islands.



**(b) Hong Kong income tax**

No provision for Hong Kong profits tax has been provided for at the rate of 16.5% as the Company has no estimated assessable profit.

**(c) The PRC corporate income tax**

Subsidiaries in Mainland China are subject to income tax at a rate of 25% pursuant to the Corporate Income Tax Law of the PRC and the respective regulations (the “CIT Law”), with the exception of JW Therapeutics (Shanghai) Co., Ltd. (“JW Shanghai”) obtained its High-Tech Enterprise status in year 2022 and hence is entitled to a preferential tax rate of 15% for a three-year period commencing 2022.

No provision for Mainland China corporate income tax was provided for, as there’s no assessable profit.

**8 Loss per share**

**(a) Basic loss per share**

Basic loss per share is calculated by dividing the loss of the Group attribute to owners of the Company by weighted average number of ordinary shares issued during the year.

	Year ended December 31,	
	2022	2021
Loss attributable to the ordinary equity holders of the Company (RMB'000)	(846,135)	(702,328)
Weighted average number of ordinary shares in issue (in thousand)	<u>410,093</u>	<u>399,749</u>
Basic loss per share (RMB)	<u><u>(2.06)</u></u>	<u><u>(1.76)</u></u>

**(b) Diluted loss per share**

Diluted loss per share is calculated by adjusting the weighted average number of ordinary shares outstanding to assume conversion of all dilutive potential ordinary shares.

For the year ended December 31, 2022, the Company had one category of potential ordinary shares: the stock options granted to employees. As the Group incurred losses for the years ended December 31, 2022 and 2021, the potential ordinary shares were not included in the calculation of diluted loss per share as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the years ended December 31, 2022 and 2021 are the same as basic loss per share.

**9 Dividend**

No dividend was paid nor declared by the Company for the year ended December 31, 2022 (2021: nil).

## 10 Intangible assets

	<b>Computer software</b> <i>RMB'000</i>	<b>Licenses</b> <i>RMB'000</i> <i>(Note)</i>	<b>Construction in progress</b> <i>RMB'000</i>	<b>Total</b> <i>RMB'000</i>
<b>As at January 1, 2021</b>				
Cost	5,226	756,953	13,505	775,684
Accumulated amortization	(710)	—	—	(710)
<b>Net book amount</b>	<b><u>4,516</u></b>	<b><u>756,953</u></b>	<b><u>13,505</u></b>	<b><u>774,974</u></b>
<b>Year ended December 31, 2021</b>				
Opening net book amount	4,516	756,953	13,505	774,974
Additions	—	31,879	32,164	64,043
Transfer	44,092	—	(44,092)	—
Amortization charges	(1,898)	(3,563)	—	(5,461)
Currency translation differences	—	(17,267)	—	(17,267)
<b>Closing net book amount</b>	<b><u>46,710</u></b>	<b><u>768,002</u></b>	<b><u>1,577</u></b>	<b><u>816,289</u></b>
<b>As at December 31, 2021</b>				
Cost	49,318	771,565	1,577	822,460
Accumulated amortization	(2,608)	(3,563)	—	(6,171)
<b>Net book amount</b>	<b><u>46,710</u></b>	<b><u>768,002</u></b>	<b><u>1,577</u></b>	<b><u>816,289</u></b>
<b>Year ended December 31, 2022</b>				
Opening net book amount	46,710	768,002	1,577	816,289
Additions	—	21,938	1,771	23,709
Transfer	3,220	—	(3,220)	—
Amortization charges	(5,708)	(11,055)	—	(16,763)
Currency translation differences	—	70,449	—	70,449
<b>Closing net book amount</b>	<b><u>44,222</u></b>	<b><u>849,334</u></b>	<b><u>128</u></b>	<b><u>893,684</u></b>
<b>As at December 31, 2022</b>				
Cost	52,538	863,952	128	916,618
Accumulated amortization	(8,316)	(14,618)	—	(22,934)
<b>Net book amount</b>	<b><u>44,222</u></b>	<b><u>849,334</u></b>	<b><u>128</u></b>	<b><u>893,684</u></b>

Notes:

**(i) License and Strategic Alliance Agreement**

In December 2017, the Group entered into the License and Strategic Alliance Agreement with Juno Therapeutics, Inc. (“**Juno**”) to develop and commercialize relma-cel in Mainland China, Hong Kong and Macau. The Group recognized a total amount of USD11,570,000 (equivalent to RMB75,601,000) as intangible assets in year 2017.

In January 2021, the Group completed the treatment of 100 patients with relma-cel in clinical trials. As such, the Group provided Juno milestone payment in cash in an amount of USD5,000,000 (equivalent to RMB32,462,000) in connection with the License and Strategic Alliance Agreement and further recognized it as intangible assets.

In December 2022, the Group provided Juno reimbursement in cash in an amount of USD150,000 (equivalent to RMB1,045,000) and further recognized it as intangible assets.

**(ii) BCMA license**

In April 2019, the Group entered into the License Agreement — BCMA (“**BCMA License Agreement**”) with Juno to develop and commercialize JWCAR129 in Mainland China, Hong Kong and Macau. The Group recognized a total amount of USD9,140,000 (equivalent to RMB61,318,000) as intangible assets in year 2019.

**(iii) Eureka licenses**

Licenses acquired in a business combination are recognized at fair value at the acquisition date (“**Eureka Licenses**”), which includes certain licenses under development and commercialization in Mainland China, Hong Kong, Macau, Taiwan and the member countries of Association of South East Asia Nation. The Group recognized a total amount of USD95,300,000 (equivalent to RMB674,676,000) as intangible assets in year 2020.

**(iv) 2seventy license**

In October 2022, the Group entered into the Collaboration Agreement with 2seventy bio, Inc. (“**2seventy**”) for the development and commercialization a cell therapy product directed to MAGE-A4 in Greater China. The Group provided 2seventy upfront payment in cash in an amount of USD3,000,000 (equivalent to RMB20,894,000) and recognized it as intangible assets.

As at December 31, 2022, BCMA license, Eureka licenses and 2seventy license with total net book value of RMB748,277,000 were not ready for use.

## 11 Inventories

	As at December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Raw materials	29,821	22,643
Work in progress	10,338	8,759
<b>Total</b>	<b>40,159</b>	<b>31,402</b>

## 12 Trade receivable

	As at December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Trade receivables from contracts with customer	5,305	—

As of December 31, 2022 and 2021, the aging analysis of the trade receivables based on invoice date is as follows:

	As at December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Within 30 days	5,305	—

The maximum exposure to credit risk at December 31, 2022 and 2021 is the carrying value of each class of receivables mentioned above.

The carrying amounts of the Group's trade receivables approximate their fair values.

The carrying amounts of trade receivables are primarily denominated in RMB.

### 13 Amount due from related party

	As at December 31,	
	2022	2021
	RMB'000	RMB'000
Yiping James Li ( <i>Note</i> )	<u>24,115</u>	<u>—</u>

*Note:* On March 6, 2022, the Company, JW Shanghai and Dr. Yiping James Li, the Chairman of the Company entered into a tri-party agreement (the “**Agreement**”). Pursuant to the Agreement, JW Shanghai provides Dr. Li one year loan facility of up to HKD43 million for the purpose to withhold the individual income tax in relation to the restricted share units and share options granted to Dr. Li by the Company. RMB23.6 million was drew in April and May of 2022. This loan is secured by certain shares legally and beneficially owned by Dr. Li himself or through companies wholly-owned by him and bearing an interest rate of 3.6% per annum.

### 14 Trade and other payables

	As at December 31,	
	2022	2021
	RMB'000	RMB'000
Trade payables	7,604	2,565
Payables for purchase of services and R&D materials	63,551	69,514
Staff salaries and welfare payables	38,941	40,479
Accrued expenses	32,523	42,313
Payables for purchase of property, plant and equipment	10,288	16,934
Payroll tax	4,028	5,468
Deferred income	1,000	1,441
Total	<u>157,935</u>	<u>178,714</u>

The aging of trade payables based on the demand note as at December 31, 2022 are as follows:

	As at December 31,	
	2022	2021
	RMB'000	RMB'000
Less than 1 year	<u>7,604</u>	<u>2,565</u>

The carrying amounts of trade and other payables(excluding accrued expenses) of the Group are denominated in the following currencies:

	<b>As at December 31,</b>	
	<b>2022</b>	2021
	<b><i>RMB'000</i></b>	<i>RMB'000</i>
RMB	<b>109,356</b>	119,306
USD	<b>15,573</b>	17,095
SGD	<b>483</b>	—
	<u><b>125,412</b></u>	<u>136,401</u>

## **15 Borrowings**

	<b>As at December 31,</b>	
	<b>2022</b>	2021
	<b><i>RMB'000</i></b>	<i>RMB'000</i>
Non-current unsecured bank borrowings	<b>97,500</b>	100,000
Less: Current portion of long-term borrowings	<b>(5,000)</b>	(5,000)
	<u><b>92,500</b></u>	<u>95,000</u>
Total non-current unsecured bank borrowings	<u><b>92,500</b></u>	<u>95,000</u>
Current unsecured bank borrowings	<b>137,300</b>	—
Current portion of long-term borrowings	<b>5,000</b>	5,000
	<u><b>142,300</b></u>	<u>5,000</u>
Total current unsecured bank borrowings	<u><b>142,300</b></u>	<u>5,000</u>

## USE OF NET PROCEEDS FROM LISTING

Our shares were listed on the main board of the Stock Exchange of Hong Kong Limited (the “**Stock Exchange**”) on November 3, 2020 (the “**Listing**”). The Group received net proceeds (after deducting the underwriting fees and related costs and expenses) from the issue of new shares by the Company in its Listing and the subsequent over-allotment option partially exercised by the Joint Global Coordinators (as defined in the Prospectus) of approximately HKD2,495.8 million. There was no change in the intended use of net proceeds as previously disclosed in the Prospectus and the Company will gradually utilize the residual amount of the net proceeds in accordance with such intended purposes depending on actual business needs.

The net proceeds (adjusted on a pro rata basis based on the actual net proceeds) have been and will be utilized in accordance with the purposes set out in the Prospectus. The table below sets out the planned applications of the net proceeds and actual usage up to December 31, 2022:

<b>Intended Applications</b>	<b>Amount of net proceeds (HKD million)</b>	<b>Percentage of total net proceed</b>	<b>Net proceeds brought forward for the Reporting Period (HKD million)</b>	<b>Actual usage up to December 31, 2022 (HKD million)</b>	<b>Unutilized net proceeds as at December 31, 2022 (HKD million)</b>
Research and development activities relating to relma-cel	748.74	30%	338.64	203.18	135.46
Building a focused in-house sales and marketing team to market relma-cel across Mainland China	249.58	10%	58.01	58.01	—
Research and development activities relating to JWCAR129	149.75	6%	83.13	4.79	78.34
Research and development activities relating to our other pre-clinical product candidates including our JWATM203 Program, our JWATM204 Program and Nex-G	698.82	28%	617.02	162.33	454.69
Acquisition of the Acepodia license through exercising the Acepodia Option	99.83	4%	99.83	—	99.83
New potential acquisitions and in-licensing opportunities	299.50	12%	299.50	23.71	275.79
Working capital and general corporate purposes	249.58	10%	123.83	58.82	65.01
<b>Total</b>	<b>2,495.80</b>	<b>100.0%</b>	<b>1,619.96</b>	<b>510.84</b>	<b>1,109.12</b>



As at December 31, 2022, the net proceeds applied for building a focused in-house sales and marketing team to market relma-cel across Mainland China has been fully utilized and the rest of the planned applications of the net proceeds are expected to be fully utilized by December 31, 2024. The expected timeline for utilizing the remaining proceeds is based on the best estimation of the future market conditions made by the Group. It will be subject to change based on the current and future development of market conditions.

## **FINAL DIVIDEND**

The Board did not recommend the payment of a final dividend for the year ended December 31, 2022 (2021: nil).

## **OTHER INFORMATION**

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

The annual general meeting of the Company (“AGM”) will be held on June 28, 2023. A notice convening the AGM is expected to be published and dispatched to the Shareholders in due course in accordance with the requirements of the Listing Rules.

The register of members of the Company will be closed from June 23, 2023 to June 28, 2023, both days inclusive, in order to determine the identity of the Shareholders who are entitled to attend the AGM, during which period no share transfers will be registered. To be eligible to attend the AGM, all properly completed transfer forms accompanied by the relevant share certificates must be lodged for registration 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 not later than 4:30 p.m. on June 21, 2023.

### **COMPLIANCE WITH THE CORPORATE GOVERNANCE CODE**

The Group is committed to maintaining high standards of corporate governance to safeguard the interests of the Shareholders and to enhance corporate value and accountability. The Company has adopted the Corporate Governance Code (the “CG Code”) as set out in Appendix 14 to the Listing Rules as its own code of corporate governance throughout the year ended December 31, 2022.

Except as expressly described below, the Company has complied with all applicable code provisions set out in Part 2 of the CG Code during the year ended December 31, 2022.

## **Separation of the Roles of the Chairman of the Board and Chief Executive Officer**

Dr. Yiping James Li (“**Dr Li**”) is currently the chairman of the Board (the “**Chairman**”) and chief executive officer of the Company (the “**CEO**”). We consider that having Dr. Li acting as both the Chairman and CEO will provide a strong and consistent leadership to us and allow for more effective planning and management of the Group. Pursuant to code provision C.2.1 in Part 2 of the CG Code, the roles of the chairman of the Board and CEO should be separate and should not be performed by the same individual. However, in view of Dr. Li’s extensive experience in the industry, personal profile and critical role in the Group and our historical development, we consider that it is beneficial to the business prospects of the Group that Dr. Li continues to act as both the Chairman and CEO upon Listing.

The Company will continue to review and monitor its corporate governance practices to ensure compliance with the CG Code.

## **Non-Compliance with the Requirements Under the Listing Rules**

Following the resignation of Mr. Chi Shing Li (“**Mr. Li**”) as Director on January 1, 2023, the composition of the Board comprised one executive Director, five non-executive Directors and two independent non-executive Directors, and each of the remuneration Committee (the “**Remuneration Committee**”) and nomination committee (the “**Nomination Committee**”) of the Company comprised two members only. Accordingly, the Company failed to meet the following requirements:

- (a) at least three independent non-executive directors on the Board under Rule 3.10(1) of the Listing Rules;
- (b) the Remuneration Committee chaired by an independent non-executive director and comprising a majority of independent non-executive directors under Rule 3.25 of the Listing Rules and the relevant terms of reference of the Company; and
- (c) the Nomination Committee chaired by the chairman of the board or an independent non-executive director and comprising a majority of independent non-executive directors under Rule 3.27A of the Listing Rules and the relevant terms of reference of the Company.

Following the appointment of Dr. Debra Yu as a Director which took effect from March 1, 2023, the Company has fully complied with the requirements as set out in Rules 3.10(1), 3.25 and 3.27A of the Listing Rules. For details, please refer to the Company’s announcement dated March 1, 2023.

## **COMPLIANCE WITH THE MODEL CODE FOR SECURITIES TRANSACTIONS**

The Company has adopted its own code of conduct regarding securities transactions, namely the Code for Securities Transactions by Directors (the “**Securities Transactions Code**”), which applies to all directors of the Company on terms no less than the required standard indicated by the Model Code for Securities Transactions by Directors of Listed Issuers as set out in the Appendix 10 to the Listing Rules (the “**Model Code**”).

Having made specific enquiries of all Directors, each of the Directors has confirmed that he or she has complied with the required standards as set out in the Securities Transactions Code for the year ended December 31, 2022.

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

During the Reporting Period, neither the Company nor any of its subsidiaries has purchased, sold or redeemed any of the Company’s listed securities.

## **AUDIT COMMITTEE**

The Board has established the audit committee (the “**Audit Committee**”) which is chaired by an independent non-executive Director, Mr. Yiu Leung Andy Cheung, and consists of another independent non-executive Director, Mr. Kin Cheong Kelvin Ho, and one non-executive Director, Ms. Xing Gao. The primary duties of the Audit Committee are to assist the Board by monitoring the Company’s ongoing compliance with the applicable laws and regulations that governs its business operations, providing an independent view on the effectiveness of the Company’s internal control policies, financial management processes and risk management systems.

The Audit Committee had, together with the management and external auditor of the Company, reviewed the accounting principles and policies adopted by the Group and the consolidated financial statements for the year ended December 31, 2022.

## **SCOPE OF WORK OF PRICEWATERHOUSECOOPERS**

The figures in respect of the Group’s consolidated balance sheet, consolidated statement of profit or loss, consolidated statement of comprehensive loss and the related notes thereto for the year ended December 31, 2022 as set out above in this preliminary announcement have been agreed by the Group’s auditor, PricewaterhouseCoopers, to the amounts set out in the Group’s consolidated financial statements for the year. The work performed by PricewaterhouseCoopers in this respect did not constitute an audit, review or other assurance engagement and consequently no assurance has been expressed by PricewaterhouseCoopers on this announcement.

## **PUBLICATION OF THE ANNUAL RESULTS AND 2022 ANNUAL REPORT ON THE WEBSITES OF THE STOCK EXCHANGE AND THE COMPANY**

This annual results announcement is published on the websites of the Stock Exchange ([www.hkexnews.hk](http://www.hkexnews.hk)) and the Company ([www.jwtherapeutics.com](http://www.jwtherapeutics.com)), and the 2022 annual report containing all the information required by the Listing Rules will be dispatched to the Shareholders and published on the respective websites of the Stock Exchange and the Company in due course.

By order of the Board  
**JW (Cayman) Therapeutics Co. Ltd**  
藥明巨諾（開曼）有限公司\*  
**Yiping James Li**  
*Chairman and Executive Director*

Shanghai, PRC, March 29, 2023

*As at the date of this announcement, the Board of Directors of the Company comprises Dr. Yiping James Li as Chairman and executive Director, Dr. Krishnan Viswanadhan, Ms. Xing Gao, Dr. Ann Li Lee, Mr. Jinyin Wang, Dr. Cheng Liu as non-executive Directors, and Mr. Yiu Leung Andy Cheung, Mr. Kin Cheong Kelvin Ho and Dr. Debra Yu as independent non-executive Directors.*

\* *For identification purpose only*