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**KELUN-BIOTECH**  
**科伦博泰**

**Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.**

**四川科倫博泰生物醫藥股份有限公司**

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

**(Stock Code: 6990)**

## **INTERIM RESULTS ANNOUNCEMENT FOR THE SIX MONTHS ENDED JUNE 30, 2025**

The Board is pleased to announce the unaudited condensed consolidated interim results of the Group for the six months ended June 30, 2025, together with comparative figures for the six months ended June 30, 2024. The independent auditor of the Company has carried out a review of the interim financial information in accordance with the Hong Kong Standard on Review Engagements 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity", issued by the HKICPA. Unless otherwise defined herein, capitalized terms used in this announcement shall have the same meanings as those defined in the Prospectus.

### **FINANCIAL HIGHLIGHTS**

	<b>Six months ended June 30,</b>		
	<b>2025</b>	<b>2024</b>	<b>Period to</b>
	<b>RMB'000</b>	<b>RMB'000</b>	<b>period change</b>
	<b>(Unaudited)</b>	<b>(Unaudited)</b>	
<b>Revenue</b>	<b>950,445</b>	1,382,791	-31.3%
<b>Research and development expenses</b>	<b>(611,539)</b>	(652,337)	-6.3%
<b>(Loss)/profit for the period</b>	<b>(145,175)</b>	310,226	-146.8%
<b>Adjusted (loss)/profit for the period<sup>1</sup></b>	<b>(69,398)</b>	385,636	-118.0%
	<b>As at</b>	<b>As at</b>	
	<b>June 30,</b>	<b>December 31,</b>	
	<b>2025</b>	<b>2024</b>	
<b>Cash and financial assets<sup>2</sup></b>	<b>4,527,814</b>	3,075,651	47.2%
<b>Total Equity</b>	<b>5,014,290</b>	3,308,661	51.6%

<sup>1</sup> Calculated by deducting equity-settled share-based payment from profit/(loss) for the period. The equity-settled share-based payment was RMB75.8 million and RMB75.4 million for the six months ended June 30, 2025 and 2024, respectively.

<sup>2</sup> Comprises cash and cash equivalents, restricted deposits, financial assets measured at fair value through profit or loss, financial assets measured at amortized cost and financial assets measured at fair value through other comprehensive income.

## BUSINESS HIGHLIGHTS

Since the beginning of 2025, we have made encouraging progress in our business:

- **Key developments of our ADC and novel DC assets:**
  - o We have more than 10 ADC and novel DC assets at clinical stage or above, including sac-TMT (佳泰莱®) which has received marketing authorization for two indications, and trastuzumab botidotin (舒泰莱®)<sup>3</sup> which has reached NDA stage for HER2+ BC.
  - o Sac-TMT has received the following marketing authorizations in China from the NMPA, and we have commenced their commercialization:
    - Sac-TMT in adult patients with unresectable locally advanced or metastatic TNBC who have received at least two prior systemic therapies (at least one of them for advanced or metastatic setting); and
    - Sac-TMT in treatment of adult patients with EGFR mutant-positive locally advanced or metastatic non-squamous NSCLC following progression on EGFR-TKI therapy and platinum-based chemotherapy. This is the first TROP2 ADC drug approved for marketing in LC globally.
  - o ***Our Core Product sac-TMT (sacituzumab tirumotecan, TROP2 ADC) (also known as SKB264/MK-2870) (佳泰莱®):***
    - o **TNBC.** In November 2024, we received marketing authorization in China from the NMPA for sac-TMT in adult patients with unresectable locally advanced or metastatic TNBC who have received at least two prior systemic therapies (at least one of them for advanced or metastatic setting). Sac-TMT is the first domestically developed ADC with global intellectual property rights to receive complete marketing authorization in China.

<sup>3</sup> Trade name to be approved by NMPA.

Our results from the Phase 3 study of sac-TMT in patients with previously treated locally recurrent or metastatic TNBC were presented at the ASCO Annual Meeting in May 2024. Sac-TMT demonstrated a statistically significant and clinically meaningful improvement in PFS and OS. The median PFS, as assessed by BICR, was 6.7 months (95% CI: 5.5, 8.0) with sac-TMT and 2.5 months (95% CI: 1.7, 2.7) with chemotherapy, and HR was 0.32 (95% CI: 0.24, 0.44,  $p < 0.00001$ ), and the risk of disease progression or death was reduced by 68%. The median OS was not reached with sac-TMT (95% CI: 11.2, NE) and 9.4 months with chemotherapy (95% CI: 8.5, 11.7), HR was 0.53 (95% CI: 0.36, 0.78,  $p = 0.0005$ ), and the risk of death was reduced by 47%. ORR was 45.4% with sac-TMT compared to 12% with chemotherapy. The subset of patients with high TROP2 expression (H-score > 200) had a higher median PFS (8.3 months) and ORR (52.1%) with sac-TMT.

We have initiated a Phase 3 registrational study of sac-TMT monotherapy versus investigator-choice chemotherapy for 1L advanced TNBC.

- o **HR+/HER2- BC.** In May 2025, the NDA for sac-TMT for the treatment of adult patients with unresectable locally advanced or metastatic HR+/HER2- BC who have received prior endocrine therapy and other systemic treatments in the advanced or metastatic setting was accepted by the NMPA, and was included in the priority review and approval process. A Phase 3 registrational study of sac-TMT versus investigator's choice of chemotherapy for treatment of patients with unresectable locally advanced, recurrent or metastatic HR+/HER2- BC who received prior endocrine therapy is in progress.
- o **EGFR-mutant NSCLC.** In March 2025, we received marketing authorization in China from the NMPA for sac-TMT for the treatment of adult patients with EGFR mutant-positive locally advanced or metastatic non-squamous NSCLC following progression on EGFR-TKI therapy and platinum-based chemotherapy. Sac-TMT monotherapy demonstrated a statistically significant and clinically meaningful improvement in ORR, PFS and OS compared with docetaxel. This is the first TROP2 ADC drug approved for marketing in LC globally.

Our results from the pivotal study of sac-TMT in patients with previously treated advanced EGFR-mutant NSCLC were presented at the ASCO Annual Meeting in June 2025. Sac-TMT achieved statistically significant clinical outcomes compared to docetaxel: confirmed ORR (BIRC: 45.1% vs 15.6%, one-sided  $p=0.0004$ ); PFS (BIRC: median 6.9 vs 2.8 months, HR=0.30, one-sided  $p<0.0001$ ; INV: median 7.9 vs 2.8 months, HR=0.23); with 36.4% of patients in docetaxel group crossed over to receive sac-TMT, median OS was NR for both groups (HR=0.49, one-sided  $p=0.007$ ). The median OS analysed by pre-specified RPSFT model adjusted for crossover was 9.3 months for docetaxel and NR for sac-TMT (HR=0.36).

In addition, a Phase 3 registrational study of sac-TMT combined with osimertinib as first-line treatment of locally advanced or metastatic non-squamous EGFR-mutant NSCLC is in progress.

- o **EGFR-wild type NSCLC.** Two Phase 3 registrational studies of sac-TMT, namely (i) sac-TMT in combination with pembrolizumab (KEYTRUDA®)<sup>4</sup> versus pembrolizumab for first-line treatment of patients with PD-L1 positive locally advanced or metastatic NSCLC, and (ii) sac-TMT in combination with pembrolizumab versus chemotherapy combined with pembrolizumab as first-line treatment for patients with PD-L1 negative locally advanced or metastatic non-squamous NSCLC are in progress.

In June 2025, sac-TMT in combination with tagitanlimab was granted Breakthrough Therapy Designation by the NMPA for the first-line treatment of locally advanced or metastatic non-squamous NSCLC without actionable genomic alterations.

- o **Other indications.** We are actively exploring the potential of sac-TMT both as a monotherapy and in combination with other therapies for treating other solid tumors, including GC, EC, CC, OC, UC, CRPC and HNSCC.

<sup>4</sup> Pembrolizumab (KEYTRUDA®) is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

- o **Global clinical development.** In May 2022, we licensed to MSD the exclusive rights to develop, use, manufacture and commercialize sac-TMT in all territories outside of Greater China (which includes Mainland China, Hong Kong, Macao, and Taiwan). As of the date of this announcement, MSD is progressing 14 ongoing Phase 3 global, multi-center clinical studies for sac-TMT for several types of cancer including BC, LC, gynecological cancer and GI cancer. We are also collaborating with MSD on several global Phase 2 basket studies for sac-TMT as monotherapy or in combination with other agents for multiple solid tumors and those studies are ongoing.
- o **Clinical data readout.** We presented clinical data on studies of sac-TMT at various academic conferences and published in journals, such as:
  - *2025 ASCO GU Cancers Symposium.*
    - Efficacy and safety results from the Phase 1/2 KL 264-01/MK-2870-001 study (NCT04152499) of sac-TMT monotherapy in patients with unresectable, locally advanced or metastatic UC who progressed on or after prior anti-cancer therapies;
  - *2025 ASCO Annual Meeting.*
    - Sac-TMT in patients with previously treated advanced EGFR-mutated NSCLC: Results from the randomized OptiTROP-Lung03 study;
    - Sac-TMT as first-line treatment for unresectable locally advanced/metastatic TNBC: Initial results from the Phase 2 OptiTROP-Breast05 study;
    - Sac-TMT in combination with tagitanlimab (anti-PD-L1) in first-line advanced NSCLC: Non-squamous cohort from the Phase 2 OptiTROP-Lung01 study;
    - Sac-TMT in patients with previously treated locally advanced or metastatic NSCLC harboring uncommon EGFR mutations: Preliminary results from a Phase 2 Study;

- *The British Medical Journal.*
  - Sac-TMT versus docetaxel for previously treated EGFR-mutated advanced NSCLC: multicentre, open label, randomised controlled trial (OptiTROP-Lung03);
- *Nature Medicine.*
  - Sac-TMT in previously treated metastatic TNBC: a randomized Phase 3 trial (OptiTROP-Breast01);
  - Sac-TMT in advanced NSCLC with or without EGFR mutations: Phase 1/2 and Phase 2 trials; and
- *Journal of Hematology & Oncology.*
  - Results of a phase 1/2 study of sac-TMT in patients with unresectable locally advanced or metastatic solid tumors refractory to standard therapies.

In addition, we will present results from a few clinical studies of sac-TMT at 2025 ESMO Congress to be held in Berlin, Germany from October 17 to 21, 2025, local time.

*o Our Core Product trastuzumab botidotin (HER2 ADC, also known as A166) (舒泰莱®)<sup>5</sup>:*

- In January 2025, an NDA for the treatment of adult patients with HER2+ unresectable or metastatic BC who have received at least one prior anti-HER2 therapy was accepted by the CDE of the NMPA. At a pre-specified interim analysis, trastuzumab botidotin monotherapy demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of PFS as assessed by the BICR compared with T-DM1.
- Trastuzumab botidotin has met the primary endpoints of its pivotal Phase 2 trial for 3L+ advanced HER2+ BC based on results from the primary analysis, which we used to submit an NDA to the NMPA.
- We have also initiated an open, multicenter Phase 2 clinical study of trastuzumab botidotin in the treatment of HER2+ unresectable or metastatic BC that previously received a topoisomerase inhibitor ADC.

<sup>5</sup> Trade name to be approved by NMPA.

*o Others:*

- **SKB315 (CLDN18.2 ADC).** The early-stage clinical data of SKB315 demonstrates promising efficacy and acceptable safety profile in GC with mid and high CLDN18.2 expression. We are conducting a Phase 1b clinical trial of SKB315 and have initiated the exploration in combination with immunotherapy for the treatment of GC/GEJC. Results of a Phase 1 study of SKB315 will be presented at 2025 ESMO Congress in October 2025.
- **SKB410/MK-3120 (Nectin-4 ADC).** SKB410 has shown promising Phase 1 clinical data. MSD, as the sponsor, has launched the global Phase 1/2 clinical trial of SKB410/MK-3120.
- **SKB571/MK-2750.** SKB571 is a novel bsADC that primarily targets various solid tumors such as LC and CRC etc. being developed in collaboration with MSD. The Phase 2 clinical trial in China is to be initiated.
- **SKB518, SKB535/MK-6204 and SKB445.** SKB518, SKB535 and SKB445 are novel ADC drugs with potential FIC targets. The Phase 2 clinical trial for SKB518 and the Phase 1 clinical trials for SKB535 and SKB445 are ongoing in China. The Company has entered into a license and collaboration agreement with MSD to develop SKB535.
- **SKB500 and SKB501.** SKB500 and SKB501 are novel ADC drugs with verified targets but differentiated payload-linker strategies. In November and December 2024, we received a clinical trial notice approving the IND application of SKB501 and SKB500, respectively, for advanced solid tumors from the NMPA.
- **SKB107.** SKB107 is a RDC drug jointly developed by us and the Affiliated Hospital of Southwest Medical University (西南醫科大學附屬醫院) targeting bone metastases in solid tumors. In March 2025, an IND application for SKB107 was approved by the NMPA and the Phase 1 study is ongoing.

• **Key developments of our non-DC assets:**

- o We have received the following marketing authorizations in China from the NMPA for tagitanlimab and Cetuximab N01:



- *Tagitanlimab* (科泰莱®). (1) Tagitanlimab for the treatment of patients with recurrent or metastatic NPC who have failed after prior 2L+ chemotherapy, and (2) tagitanlimab used in combination with cisplatin and gemcitabine for the first-line treatment of patients with recurrent or metastatic NPC; and
  - *Cetuximab N01* (达泰莱®). Cetuximab N01 Injection used in combination with FOLFOX or FOLFIRI regimens for first-line treatment of RAS wild-type mCRC.
- o **Tagitanlimab (PD-L1 mAb, also known as A167) (科泰莱®).** In December 2024, we received marketing authorization of tagitanlimab in China from NMPA for the treatment of patients with recurrent or metastatic NPC who have failed after prior 2L+ chemotherapy. In January 2025, we received marketing authorization of tagitanlimab used in combination with cisplatin and gemcitabine for the first-line treatment of patients with recurrent or metastatic NPC in China from NMPA. Tagitanlimab is the first PD-L1 mAb globally to receive authorization for the first-line treatment of NPC.

Based on a randomized, double-blinded, placebo controlled, multi-center, Phase 3 clinical study which evaluates the efficacy and safety results of tagitanlimab in combination with cisplatin and gemcitabine versus placebo in combination with cisplatin and gemcitabine for the treatment of recurrent or metastatic NPC, as presented at the ASCO Annual Meeting in May 2025, tagitanlimab used in combination with cisplatin and gemcitabine for the first-line treatment of recurrent or metastatic NPC has better PFS, higher ORR and extended DoR compared with chemotherapy, and has benefitted all patients regardless of PD-L1 expression. The median PFS for tagitanlimab in combination with chemotherapy is not reached compared to 7.9 months for placebo in combination with chemotherapy (HR=0.47, 95% CI: 0.33-0.66,  $p<0.0001$ ), and the risk of disease progression and death is reduced by 53%; ORR is 81.7% vs 74.5%; median DoR is 11.7 vs 5.8 months (HR=0.48, 95% CI: 0.32-0.70), which is nearly double compared to the placebo arm; the beneficial trend for OS of tagitanlimab in combination with chemotherapy has already been observed (HR=0.62, 95% CI: 0.32-1.22), and its risk of death is reduced by 38%.



- o **Cetuximab N01 (EGFR mAb, also known as A140) (达泰莱®).** In February 2025, we received marketing authorization in China from the NMPA for Cetuximab N01 Injection used in combination with FOLFOX or FOLFIRI regimens for first-line treatment of RAS wild-type mCRC. As demonstrated by a large-scale domestic Phase 3 clinical study conducting a head-to-head comparison of Cetuximab N01 Injection with Cetuximab Solution for Injection (Erbix®), the Cetuximab N01 combination chemotherapy was clinical equivalent in ORR (Cetuximab N01 vs Cetuximab Solution for Injection (Erbix®): 71.0% vs 77.5%; ORR ratio is 0.93 [95% CI: 0.87, 0.99]), and Cetuximab N01 did not demonstrate any clinically meaningful or statistically significant differences in DoR and PFS compared with Cetuximab Solution for Injection (Erbix®) (median PFS: 10.9 months vs 10.8 months, HR: 1.03 [95% CI: 0.83, 1.28]; median DoR: 10.2 months vs 9.5 months). As for safety, this study has sufficiently proven that the Cetuximab N01 combination chemotherapy is comparable in terms of safety, tolerance and immunogenicity to the Cetuximab Solution for Injection (Erbix®) combination chemotherapy.
- o **A400/EP0031 (RET inhibitor).** We are currently conducting pivotal clinical studies for 1L & 2L+ advanced RET+ NSCLC as well as a Phase 1b/2 clinical study for RET+ MTC and solid tumor in China. Through our collaboration and license agreement, Ellipses Pharma is progressing their phase 2 clinical study globally outside of China.

Our results from the Phase 1 study of A400 in patients with advanced RET-mutant MTC were presented at the ASCO Annual Meeting in May 2025. The confirmed ORR was 63.0% and the DCR was 100% for overall population. The confirmed ORR was 56.3% (9/16) and 62.5% (5/8) in patients with prior MKI or treatment naïve, respectively. Median DoR was not reached, with the longest duration still ongoing at 25.8 months. Similarly, median PFS was not reached, with the 24-month PFS rate of 77.8%.

- o **SKB378/WIN378 (TSLP mAb).** We completed Phase 1 clinical trial in healthy subjects in China. In January 2025, an IND application for SKB378 for the treatment of COPD was approved by the NMPA. Our collaboration partner, Windward Bio, has launched the Phase 2 POLARIS trial in patients with asthma.
- o **SKB336 (FXI/FXIa mAb).** We completed Phase 1 clinical trial in China.
- o **A296 (STING agonist).** We are carrying out a Phase 1 trial in China.

- **Commercialization.** We have received marketing authorization for sac-TMT (佳泰莱®), tagitanlimab (科泰莱®) and Cetuximab N01 (达泰莱®) and have commenced their commercialization. Based on the expected approval timeline of each late-stage project in our pipeline, subject to regulatory communications and marketing approval, we expect to launch trastuzumab botidotin (舒泰莱®)<sup>6</sup> in the China market and file an NDA for A400 in the second half of 2025.

The total commercial sales reached RMB309.8 million for the first half of 2025. Among them, the sales of sac-TMT (佳泰莱®) accounted for 97.6%. At the same time, all accounts receivables from sales of pharmaceutical products were collected within the payment period, ensuring efficient and stable cash flow.

Currently, our businesses have covered 30 provinces, over 300 prefectures and over 2,000 hospitals, where over 1,000 hospitals generated sales, and reached tens of thousands of healthcare professionals through various types of marketing campaigns to convey product and medical professional information. In addition, we have obtained authoritative endorsement for our products from experts in clinical guidelines, such as “CSCO Diagnosis and Treatment Guidelines for Breast Cancer (2025 edition) (CSCO 乳腺癌診療指南(2025年版))”, “CSCO Diagnosis and Treatment Guidelines for Non-Small Cell Lung Cancer (2025 edition) (CSCO非小細胞肺癌診療指南(2025年版))”, “CBCS&CSOBO Guidelines for Breast Cancer Diagnosis and Treatment (2025 Concise Edition) (CBCS&CSOBO乳腺癌診治指南與規範(2025年精要本))”, “Guidelines for Diagnosis and Treatment of Advanced Breast Cancer in China (2024 edition) (中國晚期乳腺癌規範診療指南(2024版))” and “Chinese Medical Association Clinical Practice Guidelines for Lung Cancer (中華醫學會肺癌臨床診療指南(2025版))”, providing further support for the commercialization process.

We have established a fully-fledged marketing team of over 350 people, dedicated to preparing and implementing the marketing and commercialization of our strategic products. Within the marketing team, we have established a departmental structure that includes marketing, sales, medical affairs, strategic planning and commercial excellence as well as marketing compliance functions. The commercialization team will continue to expand to capture more market opportunities in the future as more products and indications are launched and are included in the medical insurance. Currently, among the commercialized products and therapeutic areas, the business team is divided into breast cancer, lung cancer, and other tumors based on indications, and the synergy of the indications of commercialized products are conducive to the implementation of marketing and promotional activities.

<sup>6</sup> Trade name to be approved by NMPA.

In the first half of 2025, our products were promoted through our self-built marketing teams and sold primarily through DTP pharmacies. We have established stable relationships with multiple leading commercial and distribution groups, including 60+ Tier 1 distributors and 400+ DTP pharmacies. A hierarchical management system for pharmacy retail has been adopted and trainings have been provided to around 4,500 pharmacists in the first half of 2025. By organizing nationwide pharmacy trainings, the company has significantly enhanced the professionalism of terminal services and improved the ability to provide patients with medication guidance.

The Company has actively optimized its network strategy. In the first half of 2025, sac-TMT (佳泰莱®), tagitanlimab (科泰莱®) and Cetuximab N01 (达泰莱®) have been included in 29, 25 and 15 provincial networks, respectively, ensuring rapid market access through provincial procurement channels. We have been actively advancing the preparation work for the National Reimbursement Drug List (國家醫保藥品目錄) access of the relevant strategic products, including preparing for the value dossier and application materials of the relevant products. All of our commercialized products, including sac-TMT (佳泰莱®), tagitanlimab (科泰莱®) and Cetuximab N01 (达泰莱®), have passed the preliminary formal examination of National Reimbursement Drug List.

Meanwhile, to further reduce the burden of patients and implement the concept of inclusive healthcare, we have been proactively facilitating the enrollment of sac-TMT (佳泰莱®) in provincial and prefecture city level Inclusive Insurance (惠民保). As at the end of the Reporting Period, sac-TMT (佳泰莱®) has been enrolled in more than 7 provinces and 20 cities.

Globally, we will continue to pursue a flexible strategy to capture the commercial value in major international markets, through forging synergistic license and collaboration opportunities worldwide.

- **Highlights of our License and Collaboration Arrangements.**

- ***Collaboration with MSD.*** We have entered into license and collaboration agreements with MSD to develop multiple ADC assets for cancer treatment.

- ***Sac-TMT:*** We have granted MSD an exclusive, royalty-bearing and sub-licensable license to develop, use, manufacture and commercialize sac-TMT outside Greater China. We retain the right to develop and commercialize sac-TMT within Greater China. As of the date of this announcement, MSD has initiated 14 ongoing Phase 3 global clinical studies of sac-TMT as a monotherapy or with pembrolizumab or other agents for several types of cancer. The following studies are sponsored and led by MSD:

➤ BC.

- o Adjuvant sac-TMT plus pembrolizumab versus TPC in TNBC who received neoadjuvant pembrolizumab plus chemotherapy and did not achieve a pCR at surgery;
- o Sac-TMT as a monotherapy and in combination with pembrolizumab versus TPC in participants with previously untreated locally recurrent unresectable or metastatic TNBC expressing PD-L1 at CPS<10;
- o Sac-TMT as a single agent and in combination with pembrolizumab versus TPC in participants with unresectable locally advanced or metastatic HR+/HER2- BC (after one or more lines of ET);
- o Sac-TMT followed by carboplatin/paclitaxel versus chemotherapy, both in combination with pembrolizumab as neoadjuvant therapy for high-risk, early-stage TNBC or HR-low positive/HER2-negative BC;

➤ LC.

- o Adjuvant sac-TMT plus pembrolizumab versus pembrolizumab in adult participants with resectable NSCLC not achieving a pCR after receiving neoadjuvant pembrolizumab with platinum-based doublet chemotherapy followed by surgery;
- o Sac-TMT in combination with pembrolizumab versus pembrolizumab monotherapy in the first-line treatment of participants with metastatic NSCLC expressing PD-L1 greater than or equal to 50 percent;
- o Sac-TMT monotherapy versus standard chemotherapy for the treatment of previously treated advanced or metastatic NSCLC with EGFR mutations or other genomic alterations (after 1 or 2 prior lines of EGFR-TKI and 1 platinum-based therapy after progression on or after EGFR-TKI);
- o Sac-TMT versus pemetrexed and carboplatin combination therapy in participants with EGFR-mutated, advanced non-squamous NSCLC who have progressed on prior EGFR-TKI;

- o Sac-TMT in combination with pembrolizumab versus pembrolizumab as maintenance treatment in the first-line treatment of metastatic squamous NSCLC after induction treatment with pembrolizumab plus carboplatin and paclitaxel or nab-paclitaxel;
- Gynecological cancer.
  - o Sac-TMT monotherapy versus chemotherapy for the treatment of EC who have received prior platinum-based chemotherapy and immunotherapy;
  - o Sac-TMT in combination with pembrolizumab versus pembrolizumab alone as treatment in participants with mismatch repair proficient EC;
  - o Sac-TMT monotherapy versus TPC as second-line treatment for participants with recurrent or metastatic CC;
  - o Sac-TMT in patients with platinum-sensitive recurrent OC who have received 2L chemotherapy; and
- GI cancer. Sac-TMT in 3L+ advanced/metastatic GEA.

We are also collaborating with MSD on several global Phase 2 basket studies for sac-TMT as monotherapy or in combination with other agents for multiple solid tumors and those studies are ongoing.

- ***Other ADC assets:*** In addition to sac-TMT, we are also collaborating with MSD on certain ADC assets including SKB410/MK-3120, SKB571/MK-2750, SKB535/MK-6204, etc. to continuously explore favorable ADC pipeline portfolios. Through our ADC pipelines, we aim to cover a wide range of tumor indications via different targets, to apply differentiated payload-linker strategies for ADC assets with different targets to achieve better efficacy and/or differentiated safety profiles, and, through various strategies, to explore ADCs in combination. We have granted MSD exclusive global licenses to research, develop, manufacture and commercialize multiple ADC assets and exclusive options to obtain additional licenses to certain other ADC assets. We retain the right to research, develop, manufacture and commercialize certain licenses and option ADCs for mainland China, Hong Kong and Macau.

- o ***Collaboration with Ellipses Pharma.*** In March 2021, we have entered into a collaboration and license agreement with Ellipses Pharma, under which we granted Ellipses Pharma an exclusive, revenue sharing, royalty-bearing, sublicensable license to develop, manufacture and commercialize A400 (known as EP0031 by Ellipses Pharma). In March 2024, it was announced that A400/EP0031 was granted Fast Track designation by the FDA for the treatment of RET-fusion positive NSCLC. In April 2024, A400/EP0031 was cleared by the FDA to progress into Phase 2 clinical development. As of June 30, 2025, a total of 36 clinical sites in the United States, Europe and UAE were set up for EP0031.
- o ***Collaboration with Windward Bio.*** In January 2025, it was announced that we and Harbour BioMed had entered into an exclusive license agreement with Windward Bio, under which we and Harbour BioMed granted Windward Bio an exclusive license for the research, development, manufacturing and commercialization of SKB378/WIN378 globally (excluding Greater China and several Southeast and West Asian countries).

In return, we and Harbour BioMed are eligible to receive a total of up to US\$970 million upfront and milestone payments as well as single to double-digit tiered royalties on net sales of SKB378/WIN378. Subject to the terms and conditions of the license agreement, we and Harbour BioMed are also eligible to receive additional payment from Windward Bio if Windward Bio undergoes a near-term change of control or enters into a sublicense agreement with a third party. The payments to be made by Windward Bio under the license agreement shall be paid in equal amounts to us and Harbour BioMed.

In May 2025, it was announced that the Company had received an upfront payment from Windward Bio in line with the terms of the license agreement including: (i) a cash payment, which was received in February 2025, and (ii) an equity interest in the parent company of Windward Bio, which was settled in May 2025 upon satisfaction of relevant regulatory approvals in mainland China and other closing conditions.

- **ESG.** We have established a comprehensive three-tier ESG governance structure consisting of the Board of Directors, ESG Working Group and ESG Executive Body. Among them, the Board of Directors serves as the highest responsible and decision-making body for ESG management and information disclosure, guiding and supervising the Company's ESG development. Through the establishment and continuous improvement of the ESG governance structure, the Company comprehensively enhances ESG performance ability and ensures the Company's sustainable development. In May, 2025, the company was awarded "Best ESG" by Extel (formerly Institutional Investor Research) (前稱“機構投資者”).
- **Placing of New H Shares.** On June 12, 2025, the placing of 5,918,000 H Shares to not less than six placees at the placing price of HK\$331.80 per Share was completed. The net proceeds from the Placing amounted to approximately HK\$1,943.0 million.

## INTERIM RESULTS

**Consolidated statement of profit or loss  
for the six months ended June 30, 2025 – unaudited**  
(Expressed in Renminbi (“RMB”))

		<b>Six months ended June 30,</b>	
	<i>Note</i>	<b>2025</b>	<b>2024</b>
		<b>RMB’000</b>	<b>RMB’000</b>
<b>Revenue</b>	3	<b>950,445</b>	1,382,791
Cost of sales		<u>(290,457)</u>	<u>(306,101)</u>
<b>Gross profit</b>		<b>659,988</b>	1,076,690
Other net income		<b>31,787</b>	94,395
Administrative expenses		<b>(73,844)</b>	(65,839)
Selling and distribution expenses		<b>(178,925)</b>	(41,151)
Research and development expenses		<u><b>(611,539)</b></u>	<u>(652,337)</u>
<b>(Loss)/profit from operations</b>		<b>(172,533)</b>	411,758
Finance costs		<u><b>(3,022)</b></u>	<u>(2,507)</u>
<b>(Loss)/profit before taxation</b>		<b>(175,555)</b>	409,251
Income tax	4	<u><b>30,380</b></u>	<u>(99,025)</u>
<b>(Loss)/profit for the period attributable to equity shareholders of the Company</b>		<u><b>(145,175)</b></u>	<u>310,226</u>
<b>(Loss)/earnings per share</b>	5		
Basic and diluted (RMB)		<u><b>(0.64)</b></u>	<u>1.41</u>



**Consolidated statement of profit or loss and other comprehensive income  
for the six months ended June 30, 2025 – unaudited**

*(Expressed in RMB)*

	<b>Six months ended June 30,</b>	
<i>Note</i>	<b>2025</b>	2024
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
<b>(Loss)/profit for the period</b>	<u><b>(145,175)</b></u>	<u>310,226</u>
<b>Other comprehensive income for the period (after tax)</b>		
<i>Item that may be reclassified subsequently to profit or loss:</i>		
<i>Exchange differences on translation of financial statements of an overseas subsidiary</i>	<u><b>(2,407)</b></u>	<u>1,337</u>
<b>Other comprehensive income for the period</b>	<u><b>(2,407)</b></u>	<u>1,337</u>
<b>Total comprehensive income for the period attributable to equity shareholders of the Company</b>	<u><b>(147,582)</b></u>	<u>311,563</u>

**Consolidated statement of financial position**  
**at June 30, 2025 – unaudited**  
*(Expressed in RMB)*

	<i>Note</i>	<b>As at June 30, 2025 RMB'000</b>	<b>As at December 31, 2024 RMB'000</b>
<b>Non-current assets</b>			
Property, plant and equipment		<b>596,456</b>	594,822
Right-of-use assets		<b>144,898</b>	163,283
Intangible assets		<b>1,703</b>	2,579
Other non-current assets		<b>17,169</b>	14,512
		<b>760,226</b>	775,196
<b>Current assets</b>			
Inventories		<b>200,196</b>	110,506
Trade and other receivables	6	<b>459,592</b>	303,728
Amounts due from related parties		<b>5,058</b>	2,921
Financial assets measured at fair value through profit or loss (“FVPL”)		<b>852,337</b>	1,448,319
Financial assets measured at fair value through other comprehensive income (“FVOCI”)		<b>70,757</b>	–
Financial assets measured at amortized cost		<b>488,294</b>	283,979
Restricted deposits		<b>13,634</b>	6,850
Cash and cash equivalents		<b>3,102,792</b>	1,336,503
		<b>5,192,660</b>	3,492,806
<b>Current liabilities</b>			
Trade and other payables	7	<b>457,148</b>	446,832
Amounts due to related parties		<b>27,436</b>	8,792
Contract liabilities		<b>261,808</b>	312,375
Lease liabilities		<b>43,960</b>	41,842
		<b>790,352</b>	809,841
<b>Net current assets</b>		<b>4,402,308</b>	2,682,965
<b>Total assets less current liabilities</b>		<b>5,162,534</b>	3,458,161

**Consolidated statement of financial position**  
**at June 30, 2025 – unaudited (continued)**  
*(Expressed in RMB)*

	<i>Note</i>	<b>As at June 30, 2025 RMB'000</b>	<b>As at December 31, 2024 RMB'000</b>
<b>Non-current liabilities</b>			
Lease liabilities		<b>87,122</b>	84,905
Deferred income		<b>61,122</b>	64,595
		<b>148,244</b>	149,500
<b>NET ASSETS</b>		<b>5,014,290</b>	3,308,661
<b>CAPITAL AND RESERVES</b>			
Share capital	8	<b>233,186</b>	227,268
Reserves		<b>4,781,104</b>	3,081,393
<b>TOTAL EQUITY</b>		<b>5,014,290</b>	3,308,661

**Consolidated statement of changes in equity  
for the six months ended June 30, 2025 – unaudited**  
(Expressed in RMB)

	Share capital <i>RMB'000</i>	Capital reserves <i>RMB'000</i>	Exchange reserves <i>RMB'000</i>	Accumulated losses <i>RMB'000</i>	Total <i>RMB'000</i>
Balance at January 1, 2024	219,196	6,161,075	5,542	(4,056,316)	2,329,497
<b>Changes in equity for the six months ended June 30, 2024</b>					
Profit for the period	–	–	–	310,226	310,226
Exchange differences on translation of financial statements of overseas subsidiaries	–	–	1,337	–	1,337
Total comprehensive income	–	–	1,337	310,226	311,563
Issuance of new shares	3,649	489,066	–	–	492,715
Equity-settled share-based payment	–	75,410	–	–	75,410
<b>Balance at June 30, 2024 and July 1, 2024</b>	<b>222,845</b>	<b>6,725,551</b>	<b>6,879</b>	<b>(3,746,090)</b>	<b>3,209,185</b>

**Consolidated statement of changes in equity**  
**for the six months ended June 30, 2025 – unaudited (continued)**  
*(Expressed in RMB)*

	Share capital <i>RMB'000</i>	Capital reserves <i>RMB'000</i>	Exchange reserves <i>RMB'000</i>	Accumulated losses <i>RMB'000</i>	Total <i>RMB'000</i>
<b>Balance at July 1, 2024</b>	222,845	6,725,551	6,879	(3,746,090)	3,209,185
<b>Changes in equity for the six months ended December 31, 2024</b>					
Loss for the period	–	–	–	(576,992)	(576,992)
Exchange differences on translation of financial statements of overseas subsidiaries	–	–	2,200	–	2,200
Total comprehensive income	–	–	2,200	(576,992)	(574,792)
Issuance of new shares	4,423	596,970	–	–	601,393
Equity-settled share-based payment	–	72,875	–	–	72,875
<b>Balance at December 31, 2024 and January 1, 2025</b>	<u>227,268</u>	<u>7,395,396</u>	<u>9,079</u>	<u>(4,323,082)</u>	<u>3,308,661</u>
	<i>Note</i>				
	Share capital <i>RMB'000</i>	Capital reserves <i>RMB'000</i>	Exchange reserves <i>RMB'000</i>	Accumulated losses <i>RMB'000</i>	Total <i>RMB'000</i>
<b>Balance at January 1, 2025</b>	<u>227,268</u>	<u>7,395,396</u>	<u>9,079</u>	<u>(4,323,082)</u>	<u>3,308,661</u>
<b>Changes in equity for the six months ended June 30, 2025</b>					
Loss for the period	–	–	–	(145,175)	(145,175)
Exchange differences on translation of financial statements of overseas subsidiaries	–	–	(2,407)	–	(2,407)
Total comprehensive income	–	–	(2,407)	(145,175)	(147,582)
Issuance of new shares	5,918	1,771,516	–	–	1,777,434
Equity-settled share-based payment	–	75,777	–	–	75,777
<b>Balance at June 30, 2025</b>	<u>233,186</u>	<u>9,242,689</u>	<u>6,672</u>	<u>(4,468,257)</u>	<u>5,014,290</u>

**Condensed consolidated statement of cash flows**  
**for the six months ended June 30, 2025 – unaudited**  
*(Expressed in RMB)*

	<b>Six months ended June 30,</b>	
	<b>2025</b>	<b>2024</b>
	<b>RMB'000</b>	<b>RMB'000</b>
<b>Operating activities</b>		
<b>Net cash used in operating activities</b>	<b>(373,194)</b>	<b>(68,912)</b>
<b>Investing activities</b>		
Payment for the purchase of property, plant and equipment	(41,302)	(35,218)
Proceeds from disposal of property, plant and equipment	–	16
Payment for intangible assets	(54)	(2,194)
Payment for investment in financial assets measured at FVPL	(2,240,000)	(950,000)
Proceeds from redemption of financial assets measured at FVPL	2,849,010	1,219,427
Payment for investment in financial assets measured at amortized cost	(1,873,856)	(103,102)
Proceeds from maturity of financial assets measured at amortized cost	1,674,005	50,801
<b>Net cash generated from investing activities</b>	<b>367,803</b>	<b>179,730</b>
<b>Financing activities</b>		
Net proceeds from issuance of new shares	1,777,434	492,847
Capital element of lease rentals paid	(2,811)	(20,368)
Interest element of lease rentals paid	(243)	(2,454)
<b>Net cash generated from financing activities</b>	<b>1,774,380</b>	<b>470,025</b>
<b>Net increase in cash and cash equivalents</b>	<b>1,768,989</b>	<b>580,843</b>
<b>Cash and cash equivalents at January 1</b>	<b>1,336,503</b>	<b>1,528,774</b>
<b>Effect of foreign exchange rate changes</b>	<b>(2,700)</b>	<b>20,679</b>
<b>Cash and cash equivalents at June 30</b>	<b>3,102,792</b>	<b>2,130,296</b>

## **NOTES TO THE UNAUDITED INTERIM FINANCIAL REPORT**

*(Expressed in thousands of RMB, unless otherwise indicated)*

### **1. BASIS OF PREPARATION**

This interim financial report has been prepared in accordance with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, including compliance with International Accounting Standard (“IAS”) 34, Interim financial reporting, issued by the International Accounting Standards Board (“IASB”). It was authorised for issue on August 18, 2025.

The interim financial report has been prepared in accordance with the same accounting policies adopted in the 2024 annual financial statements except for the accounting policy changes that are expected to be reflected in the 2025 annual financial statements. Details of any changes in accounting policies are set out in note 2.

The preparation of an interim financial report in conformity with IAS 34 requires management to make judgements, estimates and assumptions that affect the application of policies and reported amounts of assets and liabilities, income and expenses on a year-to-date basis. Actual results may differ from these estimates.

This interim financial report contains condensed consolidated financial statements and selected explanatory notes. The notes include an explanation of events and transactions that are significant to an understanding of the changes in financial position and performance of the Group since the 2024 annual financial statements. The condensed consolidated interim financial statements and notes thereon do not include all of the information required for a full set of financial statements prepared in accordance with IFRS Accounting Standards.

The interim financial report is unaudited, but has been reviewed by KPMG in accordance with Hong Kong Standard on Review Engagements 2410, Review of interim financial information performed by the independent auditor of the entity, issued by the HKICPA.

### **2. CHANGES IN ACCOUNTING POLICIES**

The Group has applied the amendments to IAS 21, The effects of changes in foreign exchange rates – Lack of exchangeability issued by the IASB to this interim financial report for the current accounting period. The amendments do not have a material impact on this interim report as the Group has not entered into any foreign currency transactions in which the foreign currency is not exchangeable into another currency.

The Group has not applied any new standard or interpretation that is not yet effective for the current accounting period.

### **3. REVENUE AND SEGMENT REPORTING**

#### **(a) Revenue**

The principal activities of the Group are the researching and developing service of innovative drugs, manufacturing and commercialization of novel drugs.



### ***Disaggregation of revenue***

Disaggregation of revenue from contracts with customers by major service lines and by geographic markets is as follows:

	<b>Six months ended June 30,</b>	
	<b>2025</b>	<b>2024</b>
	<b>RMB'000</b>	<b>RMB'000</b>
<b>Revenue from contracts with customers within the scope of IFRS 15</b>		
Revenue from license and collaboration agreements	<b>628,015</b>	1,377,978
Revenue from provision of research and development service	<b>12,674</b>	4,813
Revenue from sales of pharmaceutical products	<b>309,756</b>	–
	<b>950,445</b>	<b>1,382,791</b>

Disaggregation of revenue from contracts with customers by the timing of revenue recognition is as follows:

	<b>Six months ended June 30,</b>	
	<b>2025</b>	<b>2024</b>
	<b>RMB'000</b>	<b>RMB'000</b>
<b>Disaggregated by timing of revenue recognition</b>		
Point in time	<b>603,791</b>	929,313
Over time	<b>346,654</b>	453,478
	<b>950,445</b>	<b>1,382,791</b>

## **4. INCOME TAX**

	<b>Six months ended June 30,</b>	
	<b>2025</b>	<b>2024</b>
	<b>RMB'000</b>	<b>RMB'000</b>
<b>Current tax</b>		
Provision for the period		
– The PRC Corporate Income Tax	–	–
– Withholding Tax	<b>16,335</b>	99,025
– Withholding Tax refunded	<b>(46,715)</b>	–
	<b>(30,380)</b>	<b>99,025</b>

**(i) PRC Corporate Income Tax**

Effective from January 1, 2008, the PRC statutory income tax rate is 25% under the PRC Corporate Income Tax Law. The Group's subsidiaries in the PRC are subject to PRC income tax at 25% unless otherwise specified.

According to the PRC Corporate Income Tax Law and its relevant regulations, entities that qualified as high-technology enterprise are entitled to a preferential income tax rate of 15%. The Company obtained its certificate of high-technology enterprise on December 3, 2020 and October 16, 2023 respectively and is entitled to preferential income tax of 15% from 2020 to 2026.

**(ii) Hong Kong Profit Tax**

The provision for Hong Kong Profits Tax for 2025 is calculated at 16.5% (2024: 16.5%) of the estimated assessable profits for the period. There were no assessable profits generating from the subsidiary incorporated in Hong Kong of the Group during the six months ended June 30, 2025.

**(iii) United States Withholding Tax**

Pursuant to US Income Tax laws and regulations and the agreement between the government of the People's Republic of China and the USA for avoidance of double taxation and the prevention of fiscal evasion with respect to taxes on income (中華人民共和國政府和美利堅合眾國政府關於對所得避免雙重徵稅和防止偷漏稅的協定), a 10% US federal withholding tax is charged on royalties paid pursuant to license and collaboration agreements entered between the Company and a US company.

In 2025, Internal Revenue Service refunded USD6,500 thousand (equivalent to RMB46,715 thousand) of withholding tax to the Company pursuant to relevant US federal income tax laws and regulations.

**5. LOSS/EARNINGS PER SHARE**

**(a) Basic loss/earnings per share**

The calculation of basic loss/earnings per share is based on the loss/profit for the period attributable to ordinary equity shareholders of the Company and the weighted average number of ordinary shares in issue during the period, calculated as follows.

- (i) Loss/profit attributable to ordinary equity shareholders of the Company used in basic loss/earnings per share calculation:

	<b>Six months ended June 30,</b>	
	<b>2025</b>	<b>2024</b>
	<b>RMB'000</b>	<b>RMB'000</b>
(Loss)/profit for the period attributable to ordinary equity shareholders of the Company for the purpose of basic (loss)/profit per share	<b>(145,175)</b>	<b>310,226</b>

(ii) Weighted average number of shares

	<b>Six months ended June 30,</b>	
	<b>2025</b>	<b>2024</b>
	<b>RMB'000</b>	<b>RMB'000</b>
Issued ordinary shares at January 1	<b>227,267,969</b>	219,195,499
Effect of issuance of new shares	<b>588,530</b>	902,126
	<hr/>	<hr/>
Weighted average number of ordinary shares at June 30	<b>227,856,499</b>	220,097,625
	<hr/> <hr/>	<hr/> <hr/>

**(b) Diluted loss/earnings per share**

No adjustment has been made to the basic loss/earnings per share presented for six months ended 30 June 2025 and 2024 as the Group had no potentially dilutive ordinary shares in issue during those periods.

**6. TRADE AND OTHER RECEIVABLES**

	<b>As at June 30, 2025 RMB'000</b>	<b>As at December 31, 2024 RMB'000</b>
Trade receivables	<b>202,042</b>	57,842
Other receivables	<b>9,525</b>	12,083
Value Added Tax ("VAT") recoverable	<b>188,766</b>	171,243
Prepayments	<b>59,147</b>	60,475
Prepaid tax	<b>112</b>	2,085
	<hr/>	<hr/>
	<b>459,592</b>	303,728
	<hr/> <hr/>	<hr/> <hr/>

**(a) Ageing analysis**

As at the end of each reporting period, the ageing analysis of trade receivables (which are included in trade and other receivables), based on the invoice date, is as follows:

	<b>As at June 30, 2025 RMB'000</b>	<b>As at December 31, 2024 RMB'000</b>
Within 3 months (inclusive)	<b>202,042</b>	57,842
	<hr/> <hr/>	<hr/> <hr/>

Trade debtors are due within 60 days from the date of billing.

## 7. TRADE AND OTHER PAYABLES

	As at June 30, 2025 RMB'000	As at December 31, 2024 RMB'000
Trade payables	297,871	246,687
Other payables	9,264	2,539
Bills payable	39,453	35,810
Accrued payroll and benefits	106,313	156,341
Other taxes payable	4,247	5,455
	<u>457,148</u>	<u>446,832</u>

As at the end of each reporting period, the ageing analysis of trade payables and bills payable (which are included in trade and other payables), based on the invoice date, is as follows:

	As at June 30, 2025 RMB'000	As at December 31, 2024 RMB'000
Within 1 year	290,479	214,208
1 to 2 years	13,074	53,439
2 to 3 years	31,177	13,993
More than 3 years	2,594	857
	<u>337,324</u>	<u>282,497</u>

## 8. CAPITAL, RESERVES AND DIVIDENDS

### (a) Capital and reserves

On June 12, 2025, the Company issued an aggregate of 5,918,000 new H shares at an offering price of HK\$331.8 per share pursuant to a placing agreement entered into by the Company and the placing agents. The net proceeds (after deducting the commissions and expenses) from the placing amounted to approximately HK\$1,943.0 million (equivalent to RMB1,777,434 thousand<sup>7</sup>).

Accordingly, the Company recorded RMB5,918 thousand in share capital and the remaining RMB1,771,516 thousand in capital reserves.

### (b) Dividends

The directors of the Company did not propose the distribution of any interim dividend during the Reporting Period.

<sup>7</sup> Based on the exchange rate of HK\$1: RMB0.91481 published by the State Administration of Foreign Exchange of the PRC on June 12, 2025 for illustration purpose.

## MANAGEMENT DISCUSSION AND ANALYSIS

### I. BUSINESS REVIEW

#### OVERVIEW

We are a biopharmaceutical company committed to the research and development (R&D), manufacturing and commercialization of novel drugs in oncology, immunology and other therapeutic areas. We have two ADC drugs as our Core Products, namely, sac-TMT and trastuzumab botidotin. Sac-TMT is a novel TROP2 ADC positioned as a monotherapy and part of combination therapies. Trastuzumab botidotin is a differentiated HER2 ADC positioned as a monotherapy to treat advanced HER2+ solid tumors. As at the date of this announcement, we were developing more than 30 candidates in our pipeline, including our Core Product, sac-TMT, tagitanlimab and Cetuximab N01, which have received marketing authorization in China from the NMPA. With the recognition of projects with competitive advantages and market value, and the aim to allocate our existing R&D resources to such projects, our pipeline mainly consists of oncology drug candidates as well as drug candidates for non-oncology diseases and conditions such as autoimmune, metabolism and other disease areas.

Supported by three in-house developed technology platforms with proprietary know-how in ADCs and novel DCs, biologics (mAbs and bsAbs) and small molecule drugs and validated by our clinical-stage drug candidates, our pipeline is diverse and synergistic in drug modalities, mechanisms, and indication coverage. Notably, we are one of the first movers in the development of ADCs, with over a decade of accumulated experience in ADC development. We are one of the first biopharmaceutical companies in China, and one of the few globally, to establish an in-house developed ADC and novel DC platform, OptiDCTM. Our drug development capabilities are further bolstered by cGMP-compliant, end-to-end manufacturing capabilities and a comprehensive quality management system. Furthermore, we are well-positioned to expand our commercialization infrastructure and market access, leveraging our Controlling Shareholder Kelun Pharmaceutical's decades-long experience, industry connections and extensive network.

The clinical value of our pipeline and our drug development capabilities are recognized by the strategic partnerships we have forged worldwide to unlock the global market potential of key assets. We have entered into license and collaboration agreements with MSD to develop multiple ADC assets for cancer treatment. According to Frost & Sullivan, we are the first China-based company to license internally discovered and developed ADC candidates to a top-ten biopharmaceutical multinational corporation. We have also entered into collaboration and license agreements with other partners, such as Ellipses Pharma and Windward Bio. Our strategic partnerships are not only testaments to our R&D and business development capabilities, but also key drivers of our continued innovation, global influence and long-term growth.

## OUR PIPELINE

Our pipeline targets the world's prevalent or hard-to-treat cancers, such as BC, NSCLC, GI cancers (including GC and CRC) and gynecological tumors, as well as non-oncology diseases and conditions affecting a large and underserved population. As at the date of this announcement, we had established a pipeline of over 30 candidates, including sac-TMT, tagitanlimab and Cetuximab N01 which have received marketing authorization in China from the NMPA, and over 10 clinical-stage drug candidates. We have also assembled a diverse portfolio of preclinical assets to further enrich our expanding pipeline targeting medical needs.

### Our oncology franchise

Our oncology franchise features diversified treatment modalities and targets different mechanisms to comprehensively treat prevalent or hard-to-treat cancers in China and worldwide, anchored by the following clinical-stage assets:

- ***ADC and novel DC:***
  - o ***Sac-TMT (sacituzumab tirumotecan) (also known as SKB264/MK-2870) (佳泰莱®)***, one of our Core Products, a novel TROP2 ADC with differentiated payload-linker strategy;
  - o ***Trastuzumab botidotin (also known as A166) (舒泰莱®)<sup>1</sup>***, another Core Product, a differentiated HER2 ADC in NDA registration stage to treat advanced HER2+ solid tumors;
  - o ***SKB315***, a novel CLDN18.2 ADC targeting advanced solid tumors;
  - o ***SKB410/MK-3120***, a novel Nectin-4 ADC targeting advanced solid tumors;
  - o ***SKB571/MK-2750***, a novel bsADC primarily targeting various solid tumors such as LC and CRC etc.;
  - o ***SKB518, SKB535/MK-6204 and SKB445***, novel ADC drugs with potential FIC targets;
  - o ***SKB500 and SKB501***, novel ADC drugs with verified targets but differentiated payload-linker strategies; and
  - o ***SKB107***, a RDC targeting bone metastases in solid tumors.

<sup>1</sup> Trade name to be approved by NMPA.

- ***Other modalities (Immunotherapies and Targeted Therapies):***
  - o ***Tagitanlimab (also known as A167) (科泰莱®)***, our PD-L1 mAb, the backbone of our immunotherapy franchise;
  - o ***Cetuximab N01 (also known as A 140) (达泰莱®)***, a recombinant EGFR human-mouse chimeric mAb that can inhibit the growth and survival of EGFR-expressing tumor cells;
  - o ***A400***, a novel next-generation selective RET inhibitor for NSCLC, MTC and other solid tumors with a high prevalence of RET alterations; and
  - o ***A296***, a novel second-generation small molecule STING agonist with a differentiating molecular design, and is positioned as a combination therapy to be used with our other immunotherapy assets.

***Sac-TMT (sacituzumab tirumotecan, TROP2 ADC) (also known as SKB264/MK-2870) (佳泰莱®)***

Sac-TMT, one of our Core Products, is a novel TROP2 ADC targeting advanced solid tumors in which we have proprietary intellectual property rights. TROP2 is frequently overexpressed across a broad spectrum of cancers, especially in highly prevalent or hard-to-treat cancers such as BC, NSCLC, GI cancer, gynecological cancer and many other solid tumor types. Being the first domestically developed TROP2 ADC in China, sac-TMT utilizes a differentiated drug design to improve ADC stability and maintain ADC bioactivity, thus enhancing its tumor targeting ability and reducing its off-target and on-target off-tumor toxicity, potentially leading to a broader therapeutic window.

Sac-TMT is developed with a novel linker to conjugate the payload, a belotecan-derivative topoisomerase I inhibitor with a DAR of 7.4. Sac-TMT specifically recognizes TROP2 on the surface of tumor cells by recombinant anti-TROP2 humanized monoclonal antibodies, which is then endocytosed by tumor cells and releases KL610023 intracellularly. KL610023, as a topoisomerase I inhibitor, induces DNA damage to tumor cells, which in turn leads to cell-cycle arrest and apoptosis. In addition, it also releases KL610023 in the tumor microenvironment. Given that KL610023 is membrane permeable, it can enable a bystander effect, or in other words kill adjacent tumor cells. The design was to achieve a more effective balance between stability in circulation and targeted-release of the ADC payload in tumor cells.

We are actively advancing a multi-strategy clinical development plan to explore sac-TMT's potential as a monotherapy and combination therapies to treat various types of advanced solid tumors in Greater China. Meanwhile, MSD is advancing the global clinical development of sac-TMT outside of Greater China.



## *Within Greater China*

Based on our retained rights to develop and commercialize sac-TMT and other TROP2 ADCs within Greater China, we have continued to advance our clinical development plan for sac-TMT in Greater China.

**TNBC.** In November 2024, we received marketing authorization in China from the NMPA for sac-TMT in adult patients with unresectable locally advanced or metastatic TNBC who have received at least two prior systemic therapies (at least one of them for advanced or metastatic setting). Sac-TMT is the first domestically developed ADC with global intellectual property rights to receive complete marketing authorization in China.

Our results from the Phase 3 study of sac-TMT in patients with previously treated locally recurrent or metastatic TNBC were presented at the ASCO Annual Meeting in May 2024. Sac-TMT demonstrated a statistically significant and clinically meaningful improvement in PFS and OS. The median PFS, as assessed by BICR, was 6.7 months (95% CI: 5.5, 8.0) with sac-TMT and 2.5 months (95% CI: 1.7, 2.7) with chemotherapy, and HR was 0.32 (95% CI: 0.24, 0.44,  $p < 0.00001$ ), and the risk of disease progression or death was reduced by 68%. The median OS was not reached with sac-TMT (95% CI: 11.2, NE) and 9.4 months with chemotherapy (95% CI: 8.5, 11.7), HR was 0.53 (95% CI: 0.36, 0.78,  $p = 0.0005$ ), and the risk of death was reduced by 47%. ORR was 45.4% with sac-TMT compared to 12% with chemotherapy. The subset of patients with high TROP2 expression (H-score  $> 200$ ) had a higher median PFS (8.3 months) and ORR (52.1%) with sac-TMT.

We have initiated a Phase 3 registrational study of sac-TMT monotherapy versus investigator-choice chemotherapy for 1L advanced TNBC.

**HR+/HER2- BC.** In May 2025, the NDA for sac-TMT for the treatment of adult patients with unresectable locally advanced or metastatic HR+/HER2- BC who have received prior endocrine therapy and other systemic treatments in the advanced or metastatic setting was accepted by the NMPA, and was included in the priority review and approval process. A Phase 3 registrational study of sac-TMT versus investigator's choice of chemotherapy for treatment of patients with unresectable locally advanced, recurrent or metastatic HR+/HER2- BC who received prior endocrine therapy is in progress.

**EGFR-mutant NSCLC.** In March 2025, we received marketing authorization in China from the NMPA for sac-TMT for the treatment of adult patients with EGFR mutant-positive locally advanced or metastatic non-squamous NSCLC following progression on EGFR-TKI therapy and platinum-based chemotherapy. Sac-TMT monotherapy demonstrated a statistically significant and clinically meaningful improvement in ORR, PFS and OS compared with docetaxel. This is the first TROP2 ADC drug approved for marketing in LC globally.

Our results from the pivotal study of sac-TMT in patients with previously treated advanced EGFR-mutant NSCLC were presented at the ASCO Annual Meeting in June 2025. Sac-TMT achieved statistically significant clinical outcomes compared to docetaxel: confirmed ORR (BIRC: 45.1% vs 15.6%, one-sided  $p=0.0004$ ); PFS (BIRC: median 6.9 vs 2.8 months,  $HR=0.30$ , one-sided  $p<0.0001$ ; INV: median 7.9 vs 2.8 months,  $HR=0.23$ ); with 36.4% of patients in docetaxel group crossed over to receive sac-TMT, median OS was NR for both groups ( $HR=0.49$ , one-sided  $p=0.007$ ). The median OS analysed by pre-specified RPSFT model adjusted for crossover was 9.3 months for docetaxel and NR for sac-TMT ( $HR=0.36$ ).

In addition, a Phase 3 registrational study of sac-TMT combined with osimertinib as first-line treatment of locally advanced or metastatic non-squamous EGFR-mutant NSCLC is in progress.

*EGFR-wild type NSCLC.* Two Phase 3 registrational studies of sac-TMT, namely (i) sac-TMT in combination with pembrolizumab (KEYTRUDA®)<sup>2</sup> versus pembrolizumab for first-line treatment of patients with PD-L1 positive locally advanced or metastatic NSCLC, and (ii) sac-TMT in combination with pembrolizumab versus chemotherapy combined with pembrolizumab as first-line treatment for patients with PD-L1 negative locally advanced or metastatic non-squamous NSCLC are in progress.

In June 2025, sac-TMT in combination with tagitanlimab was granted Breakthrough Therapy Designation by the NMPA for the first-line treatment of locally advanced or metastatic non-squamous NSCLC without actionable genomic alterations.

*Other indications.* We are actively exploring the potential of sac-TMT both as a monotherapy and in combination with other therapies for treating other solid tumors, including GC, EC, CC, OC, UC, CRPC and HNSCC.

### *Global clinical development*

In May 2022, we licensed to MSD the exclusive rights to develop, use, manufacture and commercialize sac-TMT in all territories outside of Greater China (which includes Mainland China, Hong Kong, Macao, and Taiwan). As of the date of this announcement, MSD is progressing 14 ongoing Phase 3 global, multi-center clinical studies for sac-TMT for several types of cancer including BC, LC, gynecological cancer and GI cancer. We are also collaborating with MSD on several global Phase 2 basket studies for sac-TMT as monotherapy or in combination with other agents for multiple solid tumors and those studies are ongoing.

<sup>2</sup> Pembrolizumab (KEYTRUDA®) is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

### *Clinical data readout*

We presented clinical data on studies of sac-TMT at various academic conferences and published in journals, such as:

- *2025 ASCO GU Cancers Symposium.*
  - o Efficacy and safety results from the Phase 1/2 KL264-01/MK-2870-001 study (NCT04152499) of sac-TMT monotherapy in patients with unresectable, locally advanced or metastatic UC who progressed on or after prior anti-cancer therapies;
- *2025 ASCO Annual Meeting.*
  - o Sac-TMT in patients with previously treated advanced EGFR-mutated NSCLC: Results from the randomized OptiTROP-Lung03 study;
  - o Sac-TMT as first-line treatment for unresectable locally advanced/metastatic TNBC: Initial results from the Phase 2 OptiTROP-Breast05 study;
  - o Sac-TMT in combination with tagitanlimab (anti-PD-L1) in first-line advanced NSCLC: Non-squamous cohort from the Phase 2 OptiTROP-Lung01 study;
  - o Sac-TMT in patients with previously treated locally advanced or metastatic NSCLC harboring uncommon EGFR mutations: Preliminary results from a Phase 2 Study;
- *The British Medical Journal.*
  - o Sac-TMT versus docetaxel for previously treated EGFR-mutated advanced NSCLC: multicentre, open label, randomised controlled trial (OptiTROP-Lung03);
- *Nature Medicine.*
  - o Sac-TMT in previously treated metastatic TNBC: a randomized Phase 3 trial (OptiTROP-Breast01);
  - o Sac-TMT in advanced NSCLC with or without EGFR mutations: Phase 1/2 and Phase 2 trials; and

- *Journal of Hematology & Oncology.*
  - o Results of a phase 1/2 study of sac-TMT in patients with unresectable locally advanced or metastatic solid tumors refractory to standard therapies.

In addition, we will present results from a few clinical studies of sac-TMT at 2025 ESMO Congress to be held in Berlin, Germany from October 17 to 21, 2025, local time.

**SACITUZUMAB TIRUMOTECAN (SAC-TMT) FOR THE TREATMENT OF OTHER INDICATIONS NOT YET APPROVED MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.**

***Trastuzumab Botidotin (HER2 ADC, also known as A166) (舒泰莱®)<sup>3</sup>***

Trastuzumab botidotin, another of our Core Products, is a differentiated HER2 ADC in NDA registration stage to treat advanced HER2+ solid tumors. It is positioned to target multiple cancer indications with high prevalence and medical needs, including BC, with the potential to be one of the first domestically developed ADCs for HER2+ BC in China.

Trastuzumab botidotin is an innovative HER2 ADC developed by the Company, which conjugates a novel, monomethyl auristatin F (MMAF) derivative (a highly cytotoxic tubulin inhibitor, Duo-5) via a stable, enzyme-cleavable linker to a HER2 monoclonal antibody with a DAR of 2. Trastuzumab botidotin specifically binds to HER2 on the surface of tumor cells and is internalized by tumor cells, releasing the toxin molecule Duo-5 inside the cell. Duo-5 induces tumor cell cycle arrest in the G2/M Phase, leading to tumor cell apoptosis. After targeting HER2, trastuzumab botidotin can also inhibit the HER2 signaling pathway; it has ADCC activity.

Trastuzumab botidotin has met the primary endpoints of its pivotal Phase 2 trial for 3L+ advanced HER2+ BC based on results from the primary analysis, and the NDA was accepted by the NMPA in May 2023. In January 2025, an NDA for the treatment of adult patients with HER2+ unresectable or metastatic BC who have received at least one prior anti-HER2 therapy was accepted by the CDE of the NMPA. At a pre-specified interim analysis, trastuzumab botidotin monotherapy demonstrated a statistically significant and clinically meaningful improvement in the primary endpoint of PFS as assessed by the BICR compared with T-DM1. We have also initiated an open, multi-center Phase 2 clinical study of trastuzumab botidotin in the treatment of HER2+ unresectable or metastatic BC that previously received a topoisomerase inhibitor ADC.

<sup>3</sup> *Trade name to be approved by NMPA.*

## **TRASTUZUMAB BOTIDOTIN MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.**

### ***SKB315 (CLDN18.2 ADC)***

SKB315 is configured with a proprietary, in-house developed humanized CLDN18.2 mAb and a differentiated payload-linker design. The early-stage clinical data of SKB315 demonstrates promising efficacy and acceptable safety profile in GC with mid and high CLDN18.2 expression. We are conducting a Phase 1b clinical trial of SKB315 and have initiated the exploration in combination with immunotherapy for the treatment of GC/GEJC. Results of a Phase 1 study of SKB315 will be presented at 2025 ESMO Congress in October 2025.

### ***SKB410/MK-3120 (Nectin-4 ADC)***

SKB410 is a novel Nectin-4 ADC targeting advanced solid tumors and utilizing a differentiated payload-linker strategy. SKB410 has shown promising Phase 1 clinical data. MSD, as the sponsor, has launched the global Phase 1/2 clinical trial of SKB410/MK-3120.

### ***SKB571/MK-2750***

SKB571 is a novel bsADC that primarily targets various solid tumors such as LC and CRC etc. being developed in collaboration with MSD. The Phase 2 clinical trial in China is to be initiated.

### ***SKB518, SKB535/MK-6204 and SKB445***

SKB518, SKB535 and SKB445 are novel ADC drugs with potential FIC targets. The Phase 2 clinical trial for SKB518 and the Phase 1 clinical trials for SKB535 and SKB445 are ongoing in China. The Company has entered into a license and collaboration agreement with MSD to develop SKB535.

### ***SKB500 and SKB501***

SKB500 and SKB501 are novel ADC drugs with verified targets but differentiated payload-linker strategies. In November and December 2024, we received a clinical trial notice approving the IND application of SKB501 and SKB500, respectively, for advanced solid tumors from the NMPA.

## **SKB107**

SKB107 is a RDC drug jointly developed by us and the Affiliated Hospital of Southwest Medical University (西南醫科大學附屬醫院) targeting bone metastases in solid tumors. In March 2025, an IND application for SKB107 was approved by the NMPA and the Phase 1 study is ongoing.

**SKB315, SKB410/MK-3120, SKB571/MK-2750, SKB518, SKB535/MK-6204, SKB445, SKB500, SKB501 AND SKB107 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.**

## ***Tagitanlimab (PD-L1 mAb, also known as A167) (科泰萊®)***

Tagitanlimab is a humanized mAb that targets PD-L1, an important immune checkpoint protein. Targeting PD-L1 and its receptor PD-1 have become the cornerstone of cancer immunotherapy, with PD-(L)1 mAbs now widely recognised as a front-line cancer immunotherapy agent. To further elicit the anti-tumor activity of PD-(L)1 mAbs, the market has witnessed encouraging clinical development advancement of PD-(L)1 mAbs-based combination strategies in recent years, with an aim to achieve synergistic efficacies, boost response rates, overcome heterogeneity across patients, and relieve treatment resistance.

We have developed tagitanlimab as the backbone of our immunotherapy franchise, not only as a monotherapy but, more importantly, to be used in combination with our ADCs and other oncology assets.

In December 2024, we received marketing authorization in China from NMPA for tagitanlimab for the treatment of patients with recurrent or metastatic NPC who have failed after prior 2L+ chemotherapy. In January 2025, we received marketing authorization of tagitanlimab used in combination with cisplatin and gemcitabine for the first-line treatment of patients with recurrent or metastatic NPC in China from NMPA. Tagitanlimab is the first PD-L1 mAb globally to receive authorization for the first-line treatment of NPC. Moreover, we are actively exploring tagitanlimab's potential as an early-line treatment in combination with our ADC assets to maximize the clinical value of our oncology franchise.

Based on a randomized, double-blinded, placebo controlled, multi-center, Phase 3 clinical study which evaluates the efficacy and safety results of tagitanlimab in combination with cisplatin and gemcitabine versus placebo in combination with cisplatin and gemcitabine for the treatment of recurrent or metastatic NPC, as presented at the ASCO Annual Meeting in May 2025, tagitanlimab used in combination with cisplatin and gemcitabine for the first-line treatment of recurrent or metastatic NPC has better PFS, higher ORR and extended DoR

compared with chemotherapy, and has benefitted all patients regardless of PD-L1 expression. The median PFS for tagitanlimab in combination with chemotherapy is not reached compared to 7.9 months for placebo in combination with chemotherapy (HR=0.47, 95% CI: 0.33-0.66,  $p<0.0001$ ), and the risk of disease progression and death is reduced by 53%; ORR is 81.7% vs 74.5%; median DoR is 11.7 vs 5.8 months (HR=0.48, 95% CI: 0.32-0.70), which is nearly double compared to the placebo arm; the beneficial trend for OS of tagitanlimab in combination with chemotherapy has already been observed (HR=0.62, 95% CI: 0.32-1.22), and its risk of death is reduced by 38%.

**TAGITANLIMAB FOR THE TREATMENT OF OTHER INDICATIONS NOT YET APPROVED MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.**

***Cetuximab N01 (EGFR mAb, also known as A140) (达泰莱®)***

Cetuximab N01 is a recombinant anti-EGFR human-mouse chimeric mAb that can inhibit the growth and survival of EGFR-expressing tumor cells.

In February 2025, we received marketing authorization in China from the NMPA for Cetuximab N01 Injection used in combination with FOLFOX or FOLFIRI regimens for first-line treatment of RAS wild-type mCRC.

As demonstrated by a large-scale domestic Phase 3 clinical study conducting a head-to-head comparison of Cetuximab N01 Injection with Cetuximab Solution for Injection (Erbix<sup>®</sup>), the Cetuximab N01 combination chemotherapy was clinical equivalent in ORR (Cetuximab N01 vs Cetuximab Solution for Injection (Erbix<sup>®</sup>): 71.0% vs 77.5%; ORR ratio is 0.93 [95% CI: 0.87, 0.99]), and Cetuximab N01 did not demonstrate any clinically meaningful or statistically significant differences in DoR and PFS compared with Cetuximab Solution for Injection (Erbix<sup>®</sup>) (median PFS: 10.9 months vs 10.8 months, HR: 1.03 [95% CI: 0.83, 1.28]; median DoR: 10.2 months vs 9.5 months). As for safety, this study has sufficiently proven that the Cetuximab N01 combination chemotherapy is comparable in terms of safety, tolerance and immunogenicity to the Cetuximab Solution for Injection (Erbix<sup>®</sup>) combination chemotherapy.

**CETUXIMAB N01 FOR THE TREATMENT OF OTHER INDICATIONS NOT YET APPROVED MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.**

***A400/EP0031 (RET inhibitor)***

A400, a next-generation selective RET inhibitor, is positioned to be the first domestically developed next-generation selective RET inhibitor for treating RET+ solid tumors in China.



RET alterations have been reported to be a major oncogenic driver in about 2% of all cancers, most notably in NSCLC and MTC, the first two indications that A400 is designed to target. Although two first-generation selective RET inhibitors were approved in China for RET+ solid tumors as at December 31, 2024, their therapeutic benefits are limited, in part, by acquired RET drug-resistant mutations and safety issues such as hypertension and hematological toxicity, underscoring the need for novel selective RET inhibitors with improved safety and better efficacy against drug resistant mutations. A400 is designed with a novel proprietary molecular structure to address selective RET inhibitor resistance while maintaining target selectivity, efficacy and safety with reduced manufacturing cost and difficulty.

Through our collaboration and license agreement, Ellipses Pharma is progressing their Phase 2 clinical study globally outside of China.

#### *Within Greater China*

We are currently conducting pivotal clinical study for both 1L and 2L+ advanced RET+ NSCLC as well as a Phase 1b/2 clinical study for RET+ MTC and solid tumor. We expect to file an NDA for A400 in 2025.

Our results from the Phase 1 study of A400 in patients with advanced RET-mutant MTC were presented at the ASCO Annual Meeting in May 2025. The confirmed ORR was 63.0% and the DCR was 100% for overall population. The confirmed ORR was 56.3% (9/16) and 62.5% (5/8) in patients with prior MKI or treatment naïve, respectively. Median DoR was not reached, with the longest duration still ongoing at 25.8 months. Similarly, median PFS was not reached, with the 24-month PFS rate of 77.8%.

#### *Global collaboration with Ellipses Pharma*

In March 2021, we granted Ellipses Pharma, a U.K.-based international oncology drug development company, an exclusive license to develop, manufacture and commercialize A400 outside Greater China and certain Asian countries.

In March 2024, it was announced that A400/EP0031 was granted Fast Track designation by the FDA for the treatment of RET-fusion positive NSCLC. In April 2024, A400/EP0031 was cleared by the FDA to progress into Phase 2 clinical development.

## **A400 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.**

### ***A296 (STING agonist)***

A296 is a novel second-generation small molecule STING agonist with a differentiating molecular design. It has the potential to invigorate anti-tumor immunity in “cold” tumors that are unresponsive to existing immune checkpoint inhibitors and is positioned as a combination therapy to be used with our other immunotherapy assets. The Phase 1 trial is making steady progress.

## **A296 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.**

### **Our non-oncology franchise**

Our non-oncology franchise covers a range of diseases and conditions with large patient populations and medical needs, with a primary focus on immune-mediated diseases, including moderate-to-severe asthma and thromboembolic disorders.

### ***SKB378 (TSLP mAb)***

SKB378 is potentially one of the first domestically developed anti-TSLP mAbs in China for treating patients with moderate-to-severe asthma. SKB378 is a novel, recombinant fully human mAb that potently binds to the TSLP ligand and inhibits the TSLP mediated signaling pathway by blocking the interaction between TSLP and TSLP receptor. This is a well-validated cytokine that plays a key role in the development and progression of a wide array of immunological conditions, including asthma and COPD where inhibition has demonstrated benefit in a wide array of inflammatory phenotypes. SKB378 has been engineered to achieve an extended half-life and effector silencing and is subcutaneously administered.

### ***Within Greater China***

We received IND approval for moderate-to-severe asthma from the NMPA in February 2022, and we have completed Phase 1 clinical trial in healthy subjects in China. In January 2025, an IND application for SKB378 for the treatment of COPD was approved by the NMPA.

### ***Global collaboration with Windward Bio***

In January 2025, it was announced that we and Harbour BioMed had entered into an exclusive license agreement with Windward Bio, under which we and Harbour BioMed granted Windward Bio an exclusive license for the research, development, manufacturing

and commercialization of SKB378/WIN378 globally (excluding Greater China and several Southeast and West Asian countries). SKB378/WIN378 started as a co-development project jointly conducted by the Company and Harbour BioMed (also known as HBM9378), with both parties equally sharing global rights. Windward Bio has launched the Phase 2 POLARIS trial in patients with asthma.

**SKB378 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.**

***SKB336 (FXI/FXIa mAb)***

SKB336 is a novel FXI/FXIa mAb designed as an anticoagulant for preventing and treating thromboembolic disorders. Thromboembolic disorders are prevalent and potentially fatal conditions in which abnormally formed blood clots block blood vessels. The current mainstay anticoagulant therapies put patients at increased risks of severe and potentially life-threatening bleeding complications as their targets are also required for normal coagulation, leaving a need for novel effective anticoagulation agents with limited risk of bleeding. In published preclinical studies, FXI/FXIa deficiencies led to clot instability and prevented the occlusion of blood vessels, suggesting that targeting FXI/FXIa is potentially a safe and effective strategy for preventing and treating thromboembolic disorders.

We received IND approval from the NMPA in July 2021 for preventing and treating thromboembolic disorders. We have completed Phase 1 trial in China.

**SKB336 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.**

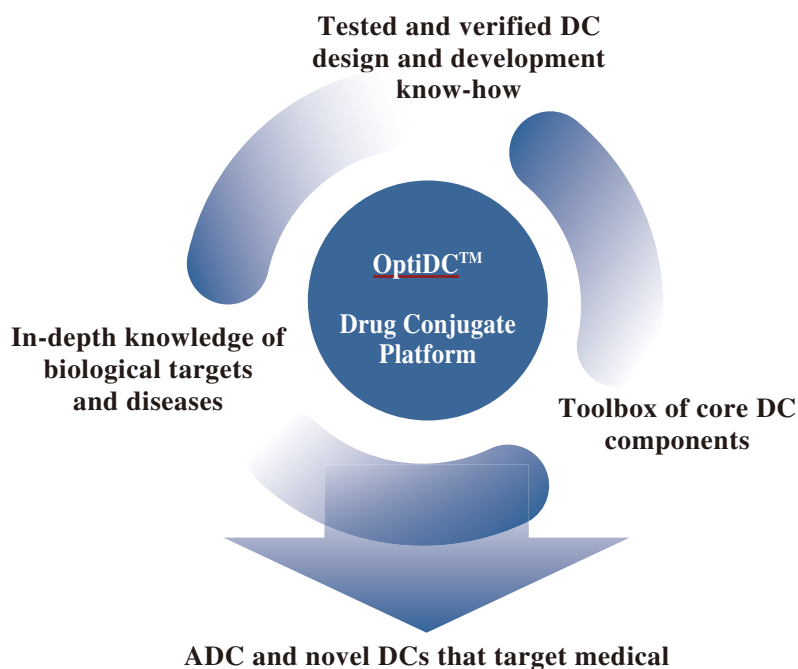
Apart from the above, we will continue to develop novel non-oncology drug candidates to address highly prevalent chronic diseases currently without effective treatments, including autoimmune and metabolic diseases.

**OUR TECHNOLOGY PLATFORMS**

We have established three core platforms specializing in ADCs and novel DCs, biologics and small molecule technologies that serve as the foundation of our discovery and development of innovative medicines for medical needs in selected disease areas, such as oncology, autoimmune diseases and metabolic diseases. These platforms cover the entire R&D process for different drug modalities and work in tandem to allow cross-functional synergies at crucial stages of drug development.

- ***ADC and novel DC Platform.*** We are one of the first movers in the development of ADCs, with over a decade of accumulated experience in ADC development. According to Frost & Sullivan, we are one of the first biopharmaceutical companies in China, and one of the few globally, to establish an in-house developed ADC and novel DC platform, which supports our systematic development of ADCs and novel DCs across their entire lifecycle. Our ADC and novel DC platform, OptiDCTM, is supported by three capability pillars – in-depth knowledge of biological targets and diseases, tested and verified DC design and development know-how, and a toolbox of core DC components. Through over a decade of development, we have developed a toolbox of core DC components which gives us the versatility to engineer customized ADC and novel DCs optimized for different biological targets to address medical needs in a broad range of indications. We have honed our expertise in ADC and novel DC process development, manufacturing and quality management, which we believe is crucial in bringing our ADCs and novel DCs from bench to bedside. Notably, our ADC and novel DC platform is tested and verified through preclinical studies and clinical trials with thousands of patients enrolled.

By leveraging our experience and data from drug discovery, translational medicine, process development and clinical studies over years of implementing our DC design strategies, we deploy a multi-pronged strategy to advance our ADC and novel DC platform. For oncology diseases, we are developing ADCs as a replacement for chemo-based cancer therapies, by (i) developing ADCs targeting novel targets with monoclonal, biparatopic and bispecific antibodies; (ii) expanding cytotoxic agents beyond common topoisomerase and tubulin inhibitors, and (iii) optimizing our conjugation technologies to enable precise control of the positioning and number of conjugated payloads including dual payloads. We are also developing novel DCs to replace non-chemo-based cancer therapies by developing ADC derivatives with innovative compound structure and diversified payloads other than cytotoxins such as RDCs, iADCs and DACs, etc. Beyond oncology diseases, we are developing ADCs with non-cytotoxic payloads for other disease indications such as autoimmune disease.



- **Biologics Platform.** Our extensive biologics platform enables the creation and refinement of cutting-edge mAb/bsAb medicines across the entire drug development lifecycle – from target biology to clinical-grade biologics. By integrating advanced technologies and workflows, including single B cell screening, next-generation sequencing, and high-throughput screening and analysis, the platform accelerates the generation of innovative antibodies with desired properties. Leveraging AI-powered epitope prediction, physiochemical profiling, and precision antibody engineering, we guide the antibody discovery toward specific epitopes with enhanced therapeutic potential. This approach addresses challenges associated with complex targets, improves druggability, and ensures optimal functional characteristics. Antibody discovery platforms drive the development of mAbs/bsAbs and ADCs and novel DCs for treating cancer, autoimmune diseases and metabolic diseases, and possess end-to-end antibody development capabilities ranging from antibody discovery and optimization to bioprocessing and scale-up manufacturing.
- **Small Molecule Platform.** Our small molecule platform is driven by the integration of medicinal chemistry, CADD (computer-aided drug design) and AIDD technologies, such as molecular docking, pharmacophore modeling, FEP (free energy perturbation) calculations, ADMET (absorption, distribution, metabolism, elimination and toxicity) prediction, and de novo molecule generation. These capabilities enable us to be highly efficient in compound optimization in early-stage research, which help rationalize and accelerate our preclinical drug discovery. We are also exploring state-of-the-art technologies such as PROTAC to navigate challenging protein targets.

## RESEARCH AND DEVELOPMENT

Our in-house R&D capabilities, built on three technology platforms, give us control and visibility over our R&D process, reduce our reliance on CROs and enable us to ensure the quality and efficiency of our drug development programs.

Our R&D team comprises industry veterans with extensive experience of driving drug development programs at leading biopharmaceutical companies. We have a comprehensive in-house R&D engine covering drug discovery, translational medicine, process development and clinical research.

- ***Drug Discovery.*** Our drug discovery team plays a fundamental role in our development of innovative drugs to address medical needs. Our discovery team comprises medicinal chemists, computational chemists, protein scientists, biologists, immunologists and is led by experts with years of experience working at multinational corporations. Through bringing over 10 drug candidates into clinical development, we have accumulated in-depth know-how and streamlined our drug discovery workflows for ADCs and novel DCs, biologics and small molecules. Our research platform supports in-house capabilities covering target validation, mechanism study, candidate design and selection (including computer-aided approaches), with a goal to consistently design and engineer differentiated drug candidates with high clinical values to enrich our pipeline.
- ***Translational Medicine.*** Our translational medicine scientists work closely to facilitate the bridging of our drug discovery and preclinical studies with clinical needs, with an aim to bring differentiated drug candidates to market. Their interdisciplinary research encompasses a wide range of studies from AI, pharmacology, drug metabolism and pharmacokinetics, toxicology to biomarker development. Our translational medicine team plays a key role in improving the success rates, time-efficiency and cost-effectiveness of our clinical trials.
- ***Process Development.*** Our process development team is responsible for developing a quality, scalable, and robust process for our ADC and novel DC, antibody and small molecule drugs. They have extensive experience in process optimization and scale-up, analytical method development and validation, quality criteria establishment, and technology transfer for clinical and commercial manufacturing. We are guided by a quality-by-design concept to scientifically design process performance characteristics, which underlies our consistent, high quality manufacturing of drug products.

- **Clinical Research.** We have a robust clinical research team located across our four clinical centers in Beijing, Shanghai, Chengdu and the U.S. Our clinical scientists are highly experienced at formulating clinical development plans, selecting indications, and determining regulatory pathways. Their rich experience in regulatory communication, both in China and overseas, also plays a key role in advancing our clinical development plans towards successful commercialization.

We have introduced AI into several R&D processes to further improve R&D efficiency. For instance, AI-assisted sequence prediction and binding site prediction of antibodies have been realized, while AIDD technology is one of the drivers of our small molecule platform. For translational medicine, through the use of commercial AI databases, the gene pathway analysis and toxicity mechanism prediction of innovative targets have been optimized, and the risk control methods of innovative R&D have been improved.

## OUR LICENSE AND COLLABORATION ARRANGEMENTS

While we are primarily engaged in in-house drug development, we also believe that an open and collaborative mindset is crucial to the success of our global strategy. Along each step of our drug development plans – from drug discovery to commercialization – we proactively pursue external collaborations, licensing arrangements and other strategic partnerships to create synergies with our pipeline and technology platforms.

Set forth below is a summary of our key license and collaboration agreements:

- **Collaboration with MSD.** We have entered into license and collaboration agreements with MSD to develop multiple ADC assets for cancer treatment.
  - o **Sac-TMT:** We have granted MSD an exclusive, royalty-bearing and sub-licensable license to develop, use, manufacture and commercialize sac-TMT outside Greater China. We retain the right to develop and commercialize sac-TMT within Greater China. As of the date of this announcement, MSD has initiated 14 ongoing Phase 3 global clinical studies of sac-TMT as a monotherapy or with pembrolizumab or other agents for several types of cancer. The following studies are sponsored and led by MSD:
    - BC.
      - Adjuvant sac-TMT plus pembrolizumab versus TPC in TNBC who received neoadjuvant pembrolizumab plus chemotherapy and did not achieve a pCR at surgery;



- Sac-TMT as a monotherapy and in combination with pembrolizumab versus TPC in participants with previously untreated locally recurrent unresectable or metastatic TNBC expressing PD-L1 at CPS<10;
- Sac-TMT as a single agent and in combination with pembrolizumab versus TPC in participants with unresectable locally advanced or metastatic HR+/HER2- BC (after one or more lines of ET);
- Sac-TMT followed by carboplatin/paclitaxel versus chemotherapy, both in combination with pembrolizumab as neoadjuvant therapy for high-risk, early-stage TNBC or HR-low positive/HER2-negative BC;

➤ LC.

- Adjuvant sac-TMT plus pembrolizumab versus pembrolizumab in adult participants with resectable NSCLC not achieving a pCR after receiving neoadjuvant pembrolizumab with platinum-based doublet chemotherapy followed by surgery;
- Sac-TMT in combination with pembrolizumab versus pembrolizumab monotherapy in the first-line treatment of participants with metastatic NSCLC expressing PD-L1 greater than or equal to 50 percent;
- Sac-TMT monotherapy versus standard chemotherapy for the treatment of previously treated advanced or metastatic NSCLC with EGFR mutations or other genomic alterations (after 1 or 2 prior lines of EGFR-TKI and 1 platinum-based therapy after progression on or after EGFR-TKI);
- Sac-TMT versus pemetrexed and carboplatin combination therapy in participants with EGFR-mutated, advanced non-squamous NSCLC who have progressed on prior EGFR-TKI;
- Sac-TMT in combination with pembrolizumab versus pembrolizumab as maintenance treatment in the first-line treatment of metastatic squamous NSCLC after induction treatment with pembrolizumab plus carboplatin and paclitaxel or nab-paclitaxel;



➤ Gynecological cancer.

- Sac-TMT monotherapy versus chemotherapy for the treatment of EC who have received prior platinum-based chemotherapy and immunotherapy;
- Sac-TMT in combination with pembrolizumab versus pembrolizumab alone as treatment in participants with mismatch repair proficient EC;
- Sac-TMT monotherapy versus TPC as second-line treatment for participants with recurrent or metastatic CC;
- Sac-TMT in patients with platinum-sensitive recurrent OC who have received 2L chemotherapy; and

➤ GI cancer. Sac-TMT in 3L+ advanced/metastatic GEA.

We are also collaborating with MSD on several global Phase 2 basket studies for sac-TMT as monotherapy or in combination with other agents for multiple solid tumors and those studies are ongoing.

- o **Other ADC assets:** In addition to sac-TMT, we are also collaborating with MSD on certain ADC assets including SKB410/MK-3120, SKB571/MK-2750, SKB535/MK-6204, etc. to continuously explore favorable ADC pipeline portfolios. Through our ADC pipelines, we aim to cover a wide range of tumor indications via different targets, to apply differentiated payload-linker strategies for ADC assets with different targets to achieve better efficacy and/or differentiated safety profiles, and through various strategies, to explore ADCs in combination. We have granted MSD exclusive global licenses to research, develop, manufacture and commercialize multiple ADC assets and exclusive options to obtain additional licenses to certain other ADC assets. We retain the right to research, develop, manufacture and commercialize certain licenses and option ADCs for mainland China, Hong Kong and Macau.
- **Collaboration with Ellipses Pharma.** In March 2021, we entered into a collaboration and license agreement with Ellipses Pharma, under which we granted Ellipses Pharma an exclusive, revenue sharing, royalty-bearing, sub-licensable license to develop, manufacture and commercialize A400. A400 is known as EP0031 by Ellipses Pharma. The license includes all countries excluding Greater China, North Korea, South Korea, Singapore, Malaysia and Thailand.

In March 2024, it was announced that A400/EP0031 was granted Fast Track designation by the FDA for the treatment of RET-fusion positive NSCLC. In April 2024, A400 was cleared by the FDA to progress into Phase 2 clinical development. As of June 30, 2025, a total of 36 clinical sites in the United States, Europe and UAE were set up for EP0031.

- ***Collaboration with Windward Bio.*** In January 2025, it was announced that we and Harbour BioMed had entered into an exclusive license agreement with Windward Bio, under which we and Harbour BioMed granted Windward Bio an exclusive license for the research, development, manufacturing and commercialization of SKB378/WIN378<sup>4</sup> globally (excluding Greater China and several Southeast and West Asian countries).

In return, we and Harbour BioMed are eligible to receive a total of up to US\$970 million upfront and milestone payments as well as single to double-digit tiered royalties on net sales of SKB378/WIN378. The US\$45 million upfront and near-term payments include both cash consideration and equity in the parent company of Windward Bio. Subject to the terms and conditions of the license agreement, we and Harbour BioMed are also eligible to receive additional payment from Windward Bio if Windward Bio undergoes a near-term change of control or enters into a sublicense agreement with a third party. The payments to be made by Windward Bio under the license agreement shall be paid in equal amounts to us and Harbour BioMed.

In May 2025, it was announced that the Company had received an upfront payment from Windward Bio in line with the terms of the license agreement including: (i) a cash payment, which was received in February 2025, and (ii) an equity interest in the parent company of Windward Bio, which was settled in May 2025 upon satisfaction of relevant regulatory approvals in mainland China and other closing conditions.

## MANUFACTURING AND QUALITY MANAGEMENT

We believe a well-established manufacturing and quality management system serves as the cornerstone of our commercialization and underlies our ability to enhance our R&D capabilities and advance clinical development. Our manufacturing and quality management system is capable of supporting the production of antibodies, ADCs and their key drug substances and chemical pharmaceuticals (including radioactive pharmaceuticals). This system helps ensure the consistent, stable, and controllable quality of our clinical and commercialized products.

<sup>4</sup> SKB378 is known as HBM9378 in Harbour BioMed's pipeline and WIN378 in Windward Bio's pipeline.

- **Manufacturing.** Our main manufacturing site in Chengdu is one of the few facilities in China with cGMP-compliant, end-to-end capabilities covering the entire development lifecycle of ADCs, from cell culture and purification, for antibody production, syntheses of payloads and linkers, ADC conjugation to formulation, fill and finish. Our ADC manufacturing facilities have an annual production capacity of 50 batches (or 1.4 million vials) of freeze-dried ADCs or 100 batches (or 2 million vials) of injectable ADCs. Our antibody manufacturing facilities have an annual production capacity of 60 batches (or 750,000 vials) of freeze-dried formulation or 100 batches (or 2.6 million vials) of injectable solutions.
- **Quality Management.** We continuously promote the improvement of a comprehensive quality management system throughout the entire product lifecycle to ensure compliance with cGMP standards and regulatory developments in China, the United States, and Europe. The Company prioritizes quality, strengthens the segmented contract manufacturing management system for biological products, and achieves collaborative operations across multiple production sites and enterprises by dividing the production process into multiple stages. Through “standardized division of labor and refined management”, we enhance quality control, drive regulatory innovation, prioritize patients’ benefits, and improve supply chain security and drug accessibility. On June 26, 2025, our innovative ADC biological product, trastuzumab botidotin (舒泰莱®)<sup>5</sup>, received official approval from the NMPA to carry out the cross-provincial segmented production pilot program.

## COMMERCIALIZATION

We have received marketing authorization for sac-TMT (佳泰莱®), tagitanlimab (科泰莱®) and Cetuximab N01 (达泰莱®) and have commenced their commercialization. Based on the expected approval timeline of each late-stage project in our pipeline, subject to regulatory communications and marketing approval, we expect to launch trastuzumab botidotin (舒泰莱®)<sup>5</sup> in the China market and file an NDA for A400 in the second half of 2025.

The total commercial sales reached RMB309.8 million for the first half of 2025. Among them, the sales of sac-TMT (佳泰莱®) accounted for 97.6%. At the same time, all accounts receivables from sales of pharmaceutical products were collected within the payment period, ensuring efficient and stable cash flow.

Currently, our businesses have covered 30 provinces, over 300 prefectures and over 2,000 hospitals, where over 1,000 hospitals generated sales, and reached tens of thousands of healthcare professionals through various types of marketing campaigns to convey product and medical professional information. In addition, we have obtained authoritative endorsement

<sup>5</sup> Trade name to be approved by NMPA.

for our products from experts in clinical guidelines, such as “CSCO Diagnosis and Treatment Guidelines for Breast Cancer (2025 edition) (CSCO乳腺癌診療指南(2025年版))”, “CSCO Diagnosis and Treatment Guidelines for Non-Small Cell Lung Cancer (2025 edition) (CSCO非小細胞肺癌診療指南(2025年版))”, “CBCS&CSOBO Guidelines for Breast Cancer Diagnosis and Treatment (2025 Concise Edition) (CBCS&CSOBO乳腺癌診治指南與規範(2025年精要本))”, “Guidelines for Diagnosis and Treatment of Advanced Breast Cancer in China (2024 edition) (中國晚期乳腺癌規範診療指南(2024版))” and “Chinese Medical Association Clinical Practice Guidelines for Lung Cancer (中華醫學會肺癌臨床診療指南(2025版))”, providing further support for the commercialization process.

We have established a fully-fledged marketing team of over 350 people, dedicated to preparing and implementing the marketing and commercialization of our strategic products. Within the marketing team, we have established a departmental structure that includes marketing, sales, medical affairs, strategic planning and commercial excellence as well as marketing compliance functions. The commercialization team will continue to expand to capture more market opportunities in the future as more products and indications are launched and are included in the medical insurance. Currently, among the commercialized products and therapeutic areas, the business team is divided into breast cancer, lung cancer, and other tumors based on indications, and the synergy of the indications of commercialized products are conducive to the implementation of marketing and promotional activities.

In the first half of 2025, our products were promoted through our self-built marketing teams and sold primarily through DTP pharmacies. We have established stable relationships with multiple leading commercial and distribution groups, including 60+ Tier 1 distributors and 400+ DTP pharmacies. A hierarchical management system for pharmacy retail has been adopted and trainings have been provided to around 4,500 pharmacists in the first half of 2025. By organizing nationwide pharmacy trainings, the company has significantly enhanced the professionalism of terminal services and improved the ability to provide patients with medication guidance.

The Company has actively optimized its network strategy. In the first half of 2025, sac-TMT (佳泰萊®), tagitanlimab (科泰萊®) and Cetuximab N01 (達泰萊®) have been included in 29, 25 and 15 provincial networks, respectively, ensuring rapid market access through provincial procurement channels. We have been actively advancing the preparation work for the National Reimbursement Drug List (國家醫保藥品目錄) access of the relevant strategic products, including preparing for the value dossier and application materials of the relevant products. All of our commercialized products, including sac-TMT (佳泰萊®), tagitanlimab (科泰萊®) and Cetuximab N01 (達泰萊®), have passed the preliminary formal examination of National Reimbursement Drug List.

Meanwhile, to further reduce the burden of patients and implement the concept of inclusive healthcare, we have been proactively facilitating the enrollment of sac-TMT(佳泰萊®) in provincial and prefecture city level Inclusive Insurance (惠民保). As at the end of the Reporting Period, sac-TMT (佳泰萊®) has been enrolled in more than 7 provinces and 20 cities.

Globally, we will continue to pursue a flexible strategy to capture the commercial value in major international markets, through forging synergistic license and collaboration opportunities worldwide.

## **AWARDS AND RECOGNITION**

In May 2025, the Company was awarded “Asia’s Best Company” by FinanceAsia (亞洲金融).

In May 2025, the Company received a series of industry awards from Extel (formerly Institutional Investor Research) (前稱“機構投資者”), including “Most Honored Company”, “Best Company Board”, “Best CEO”, “Best CFO” and etc..

In May 2025, the Company was awarded “IRM OF CHINESE LISTED COMPANIES” by Securities Times (證券時報).

In July 2025, the Company was recognized with the “China Pharmaceutical Emerging Innovative Force Award” by the China National Pharmaceutical Industry Information Center (中國醫藥工業信息中心).

## **ENVIRONMENTAL, SOCIAL AND GOVERNANCE**

We have established a comprehensive three-tier ESG governance structure consisting of the Board of Directors, ESG Working Group and ESG Executive Body. Among them, the Board of Directors serves as the highest responsible and decision-making body for ESG management and information disclosure, guiding and supervising the Company’s ESG development. Through the establishment and continuous improvement of the ESG governance structure, the Company comprehensively enhances ESG performance ability and ensures the Company’s sustainable development. In May 2025, the company was awarded “Best ESG” by Extel (formerly Institutional Investor Research) (前稱“機構投資者”).

## **II. FINANCIAL REVIEW**

### **Overview**

The following discussion is based on, and should be read in conjunction with, the financial statements and the notes included elsewhere in this announcement.

## Revenue

During the Reporting Period, our revenue consisted of (i) revenue from our license and collaboration agreements (see “Our License and Collaboration Arrangements” above in this announcement for details); (ii) revenue from research and development services; and (iii) revenue from sales of pharmaceutical products. The following table sets forth the components of our revenue in absolute amounts for the period indicated:

	<b>Six months ended June 30,</b>	
	<b>2025</b>	<b>2024</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
<b>Revenue from contracts with customers within the scope of IFRS 15</b>		
Revenue from license and collaboration agreements	<b>628,015</b>	1,377,978
Revenue from provision of research and development service	<b>12,674</b>	4,813
Revenue from sales of pharmaceutical products	<b>309,756</b>	–
	<b><u>950,445</u></b>	<b><u>1,382,791</u></b>

The Group’s revenue for the six months ended June 30, 2025 was RMB950.4 million, representing a decrease of 31.3% compared to RMB1,382.8 million for the six months ended June 30, 2024. The decrease was mainly attributable to the decrease of milestone payments from license and collaboration agreements compared to the first half of 2024. Meanwhile, in the first half of 2025, the sales of pharmaceutical products contributed RMB309.8 million in revenue.

## Cost of Sales

During the Reporting Period, our cost of sales was primarily related to the R&D activities we conducted in accordance with our license and collaboration agreements, the R&D services we provided to Kelun Group and other third parties, and the production of our pharmaceutical products. Our cost of sales primarily consisted of (i) trial and testing expenses, primarily in relation to the engagement of CROs, clinical trial sites, principal investigators and other service providers for the R&D services we provided to other third parties in accordance with our license and collaboration agreements; (ii) employee salaries and benefits for R&D staff; and (iii) others, including cost of goods sold (COGS) of pharmaceutical products, tax and surcharge, costs of raw materials and other consumables, depreciation and amortization expenses in connection with the machinery and equipment used, transportation expenses, and office expenses and other miscellaneous expenses.



The following table sets forth a breakdown of our cost of sales in absolute amounts for the period indicated.

	<b>Six months ended June 30,</b>	
	<b>2025</b>	<b>2024</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
Staff costs	<b>29,123</b>	46,030
Trial and testing expenses	<b>227,006</b>	225,976
Others	<b>34,328</b>	34,095
	<hr/>	<hr/>
Total	<b>290,457</b>	306,101
	<hr/>	<hr/>

The Group's cost of sales for the six months ended June 30, 2025 was RMB290.5 million, representing a decrease of 5.1% compared to RMB306.1 million for the six months ended June 30, 2024. The decrease was mainly because staff costs participating in collaboration projects decreased in the first half of 2025.

### **Gross Profit and Gross Profit Margin**

Gross profit represents revenue less cost of sales. As a result of the aforementioned factors, the gross profit of the Group decreased by 38.7% from RMB1,076.7 million for the six months ended June 30, 2024 to RMB660.0 million for the six months ended June 30, 2025.

Our gross profit margin is calculated as gross profit divided by revenue. The gross profit margin of the Group decreased from 77.9% for the six months ended June 30, 2024 to 69.4% for the six months ended June 30, 2025.

### **Other Net Income**

During the Reporting Period, our other net income or expenses primarily consisted of (i) interest income from bank deposits; (ii) net foreign exchange gains or losses which primarily reflected the increased or decreased value of assets or liabilities denominated in foreign currencies we hold resulting from fluctuations in exchange rate; (iii) net realized and unrealized gain on financial assets measured at fair value through profit or loss (FVPL); (iv) government grants, mainly representing government subsidies from state and local government authorities in relation to our R&D activities and construction of our R&D and manufacturing facilities, which were one-off in nature and may vary from period to period; (v) interest income from financial assets measured at amortized cost; (vi) net gains or losses on disposal of property, plant and equipment; (vii) donations; and (viii) others.

The Group's other net income for the six months ended June 30, 2025 was RMB31.8 million, representing a decrease of RMB62.6 million compared to RMB94.4 million for the six months ended June 30, 2024, mainly due to a decrease in government subsidies.

### **Administrative Expenses**

During the Reporting Period, our administrative expenses primarily consisted of (i) staff costs, representing employee salaries and benefits, including the grant of restricted share units, for our administrative personnel; (ii) office and travel expenses in relation to our general operations; (iii) consulting service fees paid to agents, independent financial advisor and other professional service providers in the ordinary course of our business; and (iv) others, including depreciation and amortization expenses mainly associated with our office and equipment for administrative purposes, maintenance and repair expenses for office and equipment, recruitment expenses, and other miscellaneous expenses.

The following table sets forth a breakdown of our administrative expenses in absolute amounts for the periods indicated.

	<b>Six months ended June 30,</b>	
	<b>2025</b>	<b>2024</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
Staff costs	<b>60,799</b>	50,638
Consulting service fee	<b>3,727</b>	2,043
Office and travel expenses	<b>1,643</b>	3,189
Others	<b>7,675</b>	9,969
	<hr/>	<hr/>
Total	<b>73,844</b>	65,839
	<hr/> <hr/>	<hr/> <hr/>

The Group's administrative expenses for the six months ended June 30, 2025 was RMB73.8 million, representing an increase of 12.2% compared to RMB65.8 million for the six months ended June 30, 2024. The increase was primarily attributable to the increase in staff costs.

### **Selling and Distribution Expenses**

During the Reporting Period, our selling and distribution expenses primarily consisted of (i) costs of staff salaries and benefits associated with sales and marketing activities; and (ii) conference and marketing expenses related to business activities, administrative expenses and others.



The following table sets forth a breakdown of our selling and distribution expenses in absolute amounts for the periods indicated.

	<b>Six months ended June 30,</b>	
	<b>2025</b>	<b>2024</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
Staff costs	<b>94,753</b>	33,797
Conference, marketing, administrative expenses and others	<b>84,172</b>	7,354
Total	<b>178,925</b>	41,151

The Group's selling and distribution expenses for the six months ended June 30, 2025 was RMB178.9 million, representing an increase of 334.8% compared to RMB41.2 million for the six months ended June 30, 2024. The increase was primarily attributable to (i) the continuous expanding of our commercialization team; and (ii) increased costs and expenses relating to marketing activities for our products. Since a few of the Group's pharmaceutical products were approved for marketing and the Company officially launched commercial sales last November, the costs of marketing and academic promotional activities, etc., correspondingly increased in the first half of 2025. For further details of the commercialization of our products, please see the section headed "Commercialization" of this announcement.

### **Research and Development Expenses**

During the Reporting Period, our research and development expenses primarily consisted of (i) trial and testing expenses, primarily in relation to the engagement of CROs, clinical trial sites, principal investigators and other service providers; (ii) staff costs, representing employee salaries and benefits, including the grant of restricted share units, for our R&D personnel; (iii) raw materials costs in relation to research and development of our drug candidates; and (iv) others, such as depreciation, amortization and short-term lease expenses, utilities, maintenance and repair costs, and expenses incurred for the application and maintenance of intellectual property rights in relation to our R&D activities.

The following table sets forth a breakdown of our research and development expenses in absolute amounts for the periods indicated.

	<b>Six months ended June 30,</b>	
	<b>2025</b>	<b>2024</b>
	<b><i>RMB'000</i></b>	<b><i>RMB'000</i></b>
Staff costs	<b>201,672</b>	200,857
Trial and testing expenses	<b>289,511</b>	298,119
Raw materials	<b>53,298</b>	85,278
Others	<b>67,058</b>	68,083
	<hr/>	<hr/>
Total	<b>611,539</b>	652,337
	<hr/>	<hr/>

The Group's R&D expenses for the six months ended June 30, 2025 was RMB611.5 million, representing a decrease of 6.3% compared to RMB652.3 million for the six months ended June 30, 2024, mainly due to the reduction in the use of raw materials.

### **Finance Costs**

During the Reporting Period, our finance costs primarily consisted of (i) interest expenses on lease liabilities and (ii) interest expenses on discounting of bills payable.

The Group's finance costs for the six months ended June 30, 2025 was RMB3.0 million, representing an increase of 20.5% compared to RMB2.5 million for the six months ended June 30, 2024. The increase in finance costs was primarily attributable to the rise in interest expenses on lease liabilities.

### **Income Tax**

During the Reporting Period, our income tax consisted of current tax, withholding tax, and withholding tax refund. For the six months ended June 30, 2024 and 2025, we recorded income tax of RMB99.0 million and RMB-30.4 million, respectively.

## ***PRC***

Effective from January 1, 2008, the PRC statutory income tax rate is 25% under the enterprise income tax laws. Our subsidiaries in the PRC are subject to PRC income tax at 25% unless otherwise specified.

According to the enterprise income tax laws and its relevant regulations, entities that qualified as High and New Technology Enterprise are entitled to a preferential income tax rate of 15%. We obtained our certificate of High and New Technology Enterprise on December 3, 2020 and October 16, 2023 respectively and are entitled to preferential income tax of 15% from 2020 to 2026.

## ***United States***

Pursuant to U.S. income tax laws and regulations and the Agreement between the Government of the People's Republic of China and the United States of America for Avoidance of Double Taxation and the Prevention of Fiscal Evasion with respect to Taxes on Income (《中華人民共和國政府和美利堅合眾國政府關於對所得避免雙重徵稅和防止偷漏稅的協定》), we are subject to a 10% U.S. federal withholding tax, applied to certain payments made to us pursuant to the respective license and collaboration agreements.

In 2025, Internal Revenue Service refunded USD6,500 thousand (equivalent to RMB46,715 thousand) of withholding tax to the Company pursuant to relevant US federal income tax laws and regulations.

## ***Hong Kong***

The provision for Hong Kong Profits Tax for 2025 is calculated at 16.5% (2024: 16.5%) of the estimated assessable profits for the period. There were no assessable profits generating from the subsidiary incorporated in Hong Kong of the Group during the six months ended June 30, 2025.

## **Profit/Loss for the period**

As a result of the foregoing, our profit for the Reporting Period decreased by 146.8% from RMB310.2 million for the six months ended June 30, 2024 to RMB-145.2 million for the six months ended June 30, 2025.

The Group also uses adjusted loss for the year calculated by deducting equity-settled share-based payment from loss for the year as an additional financial measure which is not required by or presented in accordance with the IFRS. This non-IFRS measure has limitations as an analytical tool and may not be comparable to a similarly titled measure

presented by other companies. However, the Group believes that this non-IFRS measure is a reflection of its normal operating results by eliminating potential impacts of items that the management do not consider to be indicative of the Group's operating performance and thus provides useful and meaningful information to the Shareholders and the investing public.

## **Capital Management**

As part of our cash management policy, we believe that we can make better use of our cash by utilizing wealth management products to better utilize our idle own funds without interfering with our business operations or capital expenditures. To monitor and control the investment risks associated with our financial assets measured at FVPL and financial assets measured at amortized cost, we have adopted a comprehensive set of internal policies and guidelines to manage our investment in financial assets measured at FVPL and financial assets measured at amortized cost. We make investment decisions based on our estimated capital requirements and our annual budget, taking into account the duration, expected returns and risks of the wealth management product.

## **Liquidity and Capital Resources**

On June 12, 2025, the Company issued an aggregate of 5,918,000 new H Shares at a placing price of HK\$331.8 per H Share pursuant to a placing agreement entered into by the Company and the Placing Agents. The net proceeds from the Placing amounted to approximately HK\$1,943.0 million (equivalent to RMB1,777.4 million<sup>6</sup>).

During the Reporting Period, our cash and cash equivalents consisted of cash at bank, net of restricted bank deposits. We had cash and cash equivalents of RMB1,336.5 million and RMB3,102.8 million as at December 31, 2024 and June 30, 2025, respectively. The increase in our cash and cash equivalents primarily reflected the net proceeds from the Placing in June 2025.

As at December 31, 2024 and June 30, 2025, the balance of our financial assets measured at FVPL was RMB1,448.3 million and RMB852.3 million, respectively. As at December 31, 2024 and June 30, 2025, the balance of our financial assets measured at amortized cost was RMB284.0 million and RMB488.3 million, respectively. Such changes were primarily due to the purchase and maturity of wealth management products acquired by the Company.

<sup>6</sup> Based on the exchange rate of HK\$1: RMB0.91481 published by the State Administration of Foreign Exchange of the PRC on June 12, 2025 for illustration purpose.

## **Net Cash Used in Operating Activities**

Our primary uses of cash during the Reporting Period were to fund our research and development activities, the construction of our research and development and manufacturing facilities, and purchase of equipment, machinery and intangible assets. We used net cash of RMB373.2 million in operating activities for the six months ended June 30, 2025, compared to the net cash of RMB68.9 million used in operating activities for the six months ended June 30, 2024. The increase in cash used was primarily because of less payments received from MSD pursuant to our collaboration in the first half of 2025. During the Reporting Period, we financed our operations primarily through payments received in accordance with our license and collaboration agreements and proceeds from the Placing.

## **Borrowings and Gearing Ratio**

During the Reporting Period, the Company did not have any borrowings.

The gearing ratio is calculated by using interest-bearing borrowings and lease liabilities less cash and cash equivalents, divided by total equity and multiplied by 100%. As at June 30, 2024 and 2025, the Group had more cash and cash equivalents than interest-bearing borrowings and lease liabilities and thus, gearing ratio is not applicable.

## **Net Current Assets**

The Group's net current assets as at June 30, 2025 were RMB4,402.3 million, representing an increase of 64.1% compared to net current assets of RMB2,683.0 million as at December 31, 2024 primarily because of the net proceeds from the Placing.

## **Currency Risk**

We are exposed to currency risk primarily through sales and purchases which give rise to cash and cash equivalents and amounts due to related parties that are denominated in a foreign currency, i.e., a currency other than the functional currency of the operations to which the transactions related. The currencies giving rise to this risk is primarily U.S. dollars. Any significant exchange rate fluctuations of U.S. dollars against RMB may have a financial impact on us. Our management monitors our foreign currency risk exposure and will review and adjust our hedging measures in accordance with our needs.

## **Pledge of Shares**

We do not have any pledging of shares by our Controlling Shareholders.

## **Significant Investments, Material Acquisitions and Disposals**

As at June 30, 2025, we did not hold any significant investments. For the Reporting Period, we did not have material acquisitions or disposals of subsidiaries, associates and joint ventures.

## **Capital Expenditure**

For the six months ended June 30, 2025, the Group's total capital expenditure amounted to approximately RMB27.1 million, which was mainly used in purchasing R&D instruments and equipment.

## **Charge on Assets**

As at June 30, 2025, there was no charge on assets of the Group.

## **Contingent Liabilities**

As at June 30, 2025, we did not have any contingent liabilities.

## **Employees and Remuneration Policies**

As at June 30, 2025, we had 1,870 employees in total.

We enter into individual employment contracts with our employees covering matters such as salaries, bonuses, employee benefits, workplace safety, confidentiality obligations, work product assignment clause and grounds for termination. The remuneration package of our employees includes salary and bonus, which are generally determined by their qualifications, performance review, and seniority. We also offer share incentives and promotion opportunities to motivate our employees.

### III. PROSPECTS

In 2025, we continue to deepen the reform of our R&D innovation. Focusing on our strengths, we strive to increase efficiency, strengthen external cooperation, benchmark with the highest industry standards, enhance scientific decision-making capability, and maintain and expand our leading advantage in key technology areas such as pioneering projects and ADCs. Having established a product market-oriented mindset and facing unmet clinical needs, we have been developing innovative drugs with differentiated advantages and potential for internationalization in a targeted manner. Leveraging the application of big data and artificial intelligence, we have been strengthening our research capabilities on biology/small molecule and translational medicine to increase the success rate of innovative drug R&D. We will also enhance international cooperation on innovative drugs, accelerate cultivation of new competitive advantages and integrate into the innovative global drug network at a higher level to realize the value of innovative drugs in a broader space.

Specifically, we intend to pursue the following development strategies: (i) advancing our differentiated pipelines targeting indications with significant medical needs; (ii) innovating on optimized payload-linker strategies, novel DC designs and structures, and expanded application to non-oncology diseases; (iii) enhancing our end-to-end drug development capabilities and advancing towards commercialization; (iv) expanding global footprints and strategic partnerships to maximize the value of our pipelines; and (v) optimizing our operation system to become a leading global biopharmaceutical company.

#### **(i) Advancing our differentiated pipelines targeting indications with significant medical needs**

In the second half of 2025, our main goal is to advance our pipeline of over 10 clinical-stage drug candidates. We plan to accelerate the clinical development process of our clinical stage drug candidates. We expect to continue to strengthen the establishment of our ADC and novel DC pipelines, promote the joint management of projects under collaboration with our partners and receive further milestone payments.

Guided by our indication-oriented approach, we will continue to advance our clinical-stage and preclinical oncology assets to target cancer indications with high prevalence and medical needs, notably BC, NSCLC, GI cancers and gynecological tumors. We will also continue to build and expand our differentiated non-oncology drug portfolio to target indications with significant disease burden and medical needs including autoimmune and metabolic diseases, leveraging our competitive ADC and novel DC, biologics and small-molecule technology platforms.

**(ii) Innovating on optimized payload-linker strategies, novel DC designs and structures, and expanded application to non-oncology diseases**

We are establishing ADC and novel DC designs to further advance our OptiDC™ portfolio via a multi-pronged strategy, including:

***Further replacement of chemo-based cancer therapies.***

- Developing ADCs targeting novel targets and target combinations, such as (i) biparatopic antibodies that target different, non-overlapping binding sites on a single antigen to improve efficacy by promoting cellular uptake of an ADC; (ii) bsAbs that target two different antigens co-expressed on the same cancer cells to improve binding specificity toward cancer cells and reduce off-tumor toxicity; and (iii) TAA-IO bsAbs to enhance anti-tumor effect by simultaneously targeting TAA on tumor cells and IO antigen.
- Expanding payloads beyond common cytotoxic agents. In addition to new topoisomerase and tubulin inhibitors with optimized drug-like properties, DNA-damaging reagents and other novel cytotoxic agents and their combinations (dual-payload ADCs) are developed to deal with drug resistance and suboptimal therapeutic index of current ADC-based therapies.
- Optimizing our conjugation technologies to enable precise control of the positioning and number of conjugated payloads including dual payloads. To match the needs of constructing ADCs with appropriate drug load and types, and conjugating sites, we have developed site-specific conjugating technologies that allow precise control of DAR value, and this is realized via a practical and cost-effective CMC process without complicated antibody engineering or modification.

***Expansion into non-chemo-based cancer therapies.***

- Developing novel DCs with diversified mechanisms of action other than cytotoxic mechanism, such as (i) RDCs that carry radioactive isotopes to cancer cells and represent a promising strategy to overcome drug resistance associated with traditional cytotoxin-based ADCs; (ii) iADCs that carry immune-modulators that stimulate innate and adaptive immune response to provide a robust and long-term anti-tumor effect; and (iii) DACs with targeted protein degraders that offer enhanced safety than cytotoxins by inducing specific protein degradation in tumor cells.



***Exploration beyond cancer.***

- In addition to ADCs for treating cancers, we are developing ADCs configured with various novel, non-cytotoxic payload strategies for non-oncology diseases, such as ADCs with GR modulators as payloads to treat autoimmune diseases.

**(iii) Enhancing our end-to-end drug development and commercialization capabilities**

***R&D.*** In addition to expanding our drug portfolio, we are dedicated to optimizing our R&D platforms and developing novel technologies to support the R&D of next-generation drugs. We continue to enhance our R&D capabilities by bringing in experienced professionals from around the world. In addition, we are paying close attention to AI-enabled drug discovery and plan to continue introducing AI into several R&D processes to further improve R&D efficiency, including novel target validation, drug discovery, synthesis pathway generation, prediction of drug properties and indication selection, and so on.

***Manufacturing and Quality Management.*** We will continue to expand our cGMP facilities to support commercialization needs. Going forward, we will continue to enhance our manufacturing capabilities, through expanding our in-house capacity or through collaborating with industry-recognized contract manufacturing organizations. Meanwhile, we strive to upgrade and improve our comprehensive quality management system, benchmarking against the highest international standards adopted by pharmaceutical multinational corporations, to ensure patient safety and regulatory compliance.

**Commercialization.** We have received marketing authorization for sac-TMT (佳泰莱®), tagitanlimab (科泰莱®) and Cetuximab N01 (达泰莱®) and have commenced their commercialization. Based on the expected approval timeline of each late-stage project in our pipeline, and subject to regulatory communications and marketing approval, we expect to launch our Core Product trastuzumab botidotin (舒泰莱®)<sup>7</sup> in the China market and file an NDA for A400 in the second half of 2025. We have set up a fully-fledged commercialization team to prepare and implement the marketing and commercialization of our strategic products and have established a departmental structure within the Company, consisting of various departments such as marketing, sales, distribution and market access, medical affairs, and strategic planning and commercial excellence, among others, as well as marketing compliance and KA functions. We will continue to refine our commercialization strategies for each late-stage drug candidate, first prioritizing therapeutic areas with medical needs in China, such as BC, NSCLC and GI cancers, while offering synergistic treatment options enabled by our diverse pipeline to optimize patient outcome. Globally, we will continue to pursue a flexible strategy to capture the commercial value in major international markets, through forging synergistic license and collaboration opportunities worldwide.

**(iv) Expanding global footprints and strategic partnerships to maximize the value of our pipelines**

Following the success of our existing license and collaboration agreements, we are actively exploring new partnership opportunities globally. In the near to medium term, we plan to continue adopting the out-licensing collaboration model and fully leverage our partners' global clinical development and commercialization capabilities to bring our products to the global market. In the long term, we will leverage the out-licensing collaborations to fully learn from our partners' expertise in global clinical development and commercialization, explore more diversified "going overseas" pathways, gradually conduct and promote international multi-center, registrational clinical studies and establish a commercialization system. By doing so, our products can benefit from a wider range of patients worldwide, enjoy greater global market value and further enhance corporate value. Meanwhile, we are closely monitoring global opportunities to in-license new drug candidates and innovative technologies that could bring strategic synergies to our pipeline and technology platforms. We are also committed to enhancing our collaborations with key opinion leaders, top hospitals and academic institutions, in China and globally, to ensure our timely access to cutting-edge research and support our existing and future pipeline.

<sup>7</sup> Trade name to be approved by NMPA.

**(v) Optimizing our operation system to become a leading global biopharmaceutical company**

We are continuously reviewing and optimizing our internal procedures, particularly our R&D management process, to enhance operational efficiency and support our growth as a fully-fledged biopharmaceutical company. We also aim to attract and recruit outstanding scientific, marketing and managerial personnel to join our talent pool, in order to maintain our competitiveness in a rapidly evolving industry.

Meanwhile, we are actively seeking opportunities to expand our global footprint and raise international brand awareness. As our business continues to grow, we will adhere to our mission to address major medical needs in China and globally, and to bring world-class treatments, and a healthier and happier life, to all patients.

**PURCHASE, SALE OR REDEMPTION OF THE COMPANY'S SECURITIES**

None of the Company or any of its subsidiaries has made any purchase, sale or redemption of the listed securities of the Company (including sale of treasury shares) during the six months ended June 30, 2025.

As at 30 June 2025, the Company did not hold any treasury shares.

**CORPORATE GOVERNANCE**

The Company recognizes the importance of good corporate governance for enhancing the management of the Company as well as preserving the interests of the shareholders as a whole. The Company has adopted corporate governance practices based on the principles and code provisions as set out in the CG Code as contained in Appendix C1 to the Listing Rules as its own code of corporate governance practices.

The Company has strictly complied with the CG Code during the six months ended June 30, 2025.

The Board will continue to review and monitor its code of corporate governance practices of the Company with an aim to maintaining a high standard of corporate governance.

## **MODEL CODE FOR SECURITIES TRANSACTIONS**

The Company has adopted the Model Code as set out in Appendix C3 to the Listing Rules as its code of conduct regarding dealings in the securities of the Company by the Directors, the Supervisors (from the beginning of the Reporting Period until the abolishment of the Supervisory Committee on June 20, 2025) and the Group's employees who, because of his/her office or employment, is likely to possess inside information in relation to the Group or the Company's securities.

Upon specific enquiry, all Directors confirmed that they have complied with the Model Code during the six months ended June 30, 2025, and all Supervisors confirmed that they have complied with the Model Code from the beginning of the Reporting Period until the abolishment of the Supervisory Committee on June 20, 2025. In addition, the Company is not aware of any non-compliance with the Model Code by the senior management of the Group during the six months ended June 30, 2025.

## **PLACING OF NEW H SHARES**

The placing of 5,918,000 H Shares to not less than six placees at the placing price of HK\$331.80 per Share was completed on June 12, 2025. The net proceeds from the Placing amounted to approximately HK\$1,943.0 million.

For further details, please refer to the Company's announcements dated June 5, 2025 and June 12, 2025.

## **COMPLETION OF H SHARE FULL CIRCULATION**

The conversion of an aggregate of 25,421,196 Domestic Shares of the Company (the "Converted H Shares") was completed on April 25, 2025 and the listing of the Converted H Shares on the Stock Exchange commenced on April 28, 2025.

For further details, please refer to the Company's announcement dated April 25, 2025.

## **EVENTS AFTER THE REPORTING PERIOD**

The Company is not aware of any material subsequent events from June 30, 2025 to the date of this announcement.

## **REVIEW OF INTERIM RESULTS**

The Audit Committee comprises three independent non-executive Directors, namely Dr. LI Yuedong, Dr. TU Wenwei and Dr. ZHENG Qiang. The chairman of the Audit Committee is Dr. LI Yuedong who holds the appropriate qualification as required under Rules 3.10(2) and 3.21 of the Listing Rules. The Audit Committee has reviewed the unaudited interim condensed consolidated financial information of the Group for the six months ended June 30, 2025 with the management and the auditor of the Company. The Audit Committee considered that the interim results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company and internal control with senior management of the Company.

The independent auditor of the Company, namely KPMG, has carried out a review of the interim financial information in accordance with the Hong Kong Standard on Review Engagements 2410 “Review of Interim Financial Information Performed by the Independent Auditor of the Entity”.

## **INTERIM DIVIDEND**

The Board does not recommend the payment of an interim dividend for the six months ended June 30, 2025 (June 30, 2024: nil).

## **PUBLICATION OF INTERIM RESULTS ANNOUNCEMENT AND INTERIM REPORT**

This announcement is published on the websites of the Company (<https://kelun-biotech.com>) and the Stock Exchange (<http://www.hkexnews.hk>).

The 2025 interim report will be made available on the websites of the Company and the Stock Exchange in due course.

## DEFINITIONS

“ADC(s)”	antibody drug conjugate(s)
“ADCC”	antibody-dependent cell-mediated cytotoxicity
“AIDD”	AI-driven drug design
“Articles of Association”	the articles of association of the Company
“ASCO”	American Society of Clinical Oncology
“associate(s)”	has the meaning ascribed thereto under the Listing Rules
“Audit Committee”	the audit committee of the Board
“BC”	breast cancer
“BICR”	blinded independent central review
“Board of Directors” or “Board”	the board of Directors
“bsAb(s)”	bispecific antibodies
“bsADC”	bispecific ADC(s)
“CBCS”	China Anti-Cancer Association Committee of Breast Cancer Society
“CC”	cervical cancer
“CDE”	Center for Drug Evaluation
“CG Code”	the “Corporate Governance Code” as contained in Appendix C1 to the Listing Rules
“cGMP”	current good manufacturing practice

“China” or “PRC”	the People’s Republic of China, which for the purpose of this interim results announcement and for geographical reference only, excludes Hong Kong, Macau and Taiwan
“CLDN18.2”	claudin 18.2, a member of the Claudin protein family
“CMC”	chemistry, manufacturing and controls, also commonly referred to as process development, which covers the various procedures used to assess the physical and chemical characteristics of drug products, and to ensure their quality and consistency during manufacturing
“Company”, “our Company”, “the Company”, “we” or “us”	Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (四川科倫博泰生物醫藥股份有限公司), a joint stock company established in the PRC with limited liability on November 22, 2016 and the H Shares of which are listed on the Stock Exchange (stock code: 6990) and which includes its subsidiaries (from time to time) where the context so requires
“Controlling Shareholders”	has the meaning ascribed to it under the Listing Rules and unless the context otherwise requires, refers to Kelun Pharmaceutical, Kelun International Development Co., Limited (科倫國際發展有限公司), the Employee Incentive Platforms and Mr. LIU Gexin
“COPD”	chronic obstructive pulmonary disease
“Core Products”	has the meaning ascribed thereto in Chapter 18A of the Listing Rules; for the purpose of this announcement, our Core Products refer to sac-TMT and A166
“CRC”	colorectal cancer
“CRO”	contract research organization
“CRPC”	castration-resistant prostate cancer
“CSCO”	Chinese Society of Clinical Oncology
“CSOBO”	Chinese Medical Association Chinese Society of Oncology – Breast Oncology

“DAC(s)”	degrader-antibody conjugate(s)
“DAR”	drug-to-antibody ratio, the average number of drugs conjugated to the antibodies
“DC(s)”	drug conjugate(s)
“DCR”	disease control rate, the total proportion of patients who demonstrate a response to treatment, equal to the sum of complete responses (CR), partial responses (PR) and stable disease (SD)
“Director(s)”	the director(s) of the Company
“DoR”	duration of response
“EC”	endometrial carcinoma
“EGFR”	epidermal growth factor receptor
“Ellipses Pharma”	Ellipses Pharma Limited
“Employee Incentive Platforms”	Chengdu Kelun Huicai Enterprise Management Center Limited Partnership (成都科倫匯才企業管理中心(有限合夥)), Chengdu Kelun Huide Enterprise Management Center Limited Partnership (成都科倫匯德企業管理中心(有限合夥)), Chengdu Kelun Huineng Enterprise Management Center Limited Partnership (成都科倫匯能企業管理中心(有限合夥)), and Chengdu Kelun Huizhi Enterprise Management Center Limited Partnership (成都科倫匯智企業管理中心(有限合夥))
“ESMO”	european society for medical oncology
“ET”	endocrine therapy
“FAS”	full analysis set
“FDA”	the United States Food and Drug Administration
“FIC”	first-in-class



“first/second/third-line” or “1/2/3L”	the first/second/third line treatment
“Frost & Sullivan”	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., an independent market, research and consulting company
“FXI/FXIa”	factor XI, a type of blood protein playing a role in aiding the blood to clot. Factor XIa, one of the enzymes of the coagulation cascade. FXI is the zymogen form of FXIa
“GC”	gastric cancer
“GEA”	gastroesophageal adenocarcinoma
“GEJC”	gastroesophageal junction cancer
“GI”	gastrointestinal
“GMP”	the Good Manufacturing Practice of Medical Devices (《醫療器械生產質量管理規範》)
“GP”	gemcitabine and cisplatin
“Greater China”	the PRC, Hong Kong, Macau and Taiwan
“Group”, “our Group” or “the Group”	the Company and its subsidiaries
“GU”	genitourinary
“H Share(s)”	overseas listed foreign share(s) in the ordinary share capital of the Company with nominal value of RMB1.00 each, which are listed on the Stock Exchange
“Harbour BioMed”	Harbour BioMed Therapeutics Limited, an indirect wholly owned subsidiary of HBM Holdings Limited (和鉑醫藥控股有限公司), a company listed on the Stock Exchange (stock code: 02142)
“HER2”	human epidermal growth factor receptor 2

“HK\$” or “HKD”	Hong Kong dollars, the lawful currency of Hong Kong
“HNSCC”	head and neck squamous cell carcinoma
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“HR”	hormone receptor
“iADC(s)”	immunostimulatory ADC(s)
“IFRS”	International Financial Reporting Standards
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China or the U.S.
“INV”	investigator
“JAK1/2”	Janus kinase 1 or Janus kinase 2
“Kelun Pharmaceutical”	Sichuan Kelun Pharmaceutical Co., Ltd. (四川科倫藥業股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 002422), one of our Controlling Shareholders
“KOR”	kappa-opioid receptor, one major type of opioid receptor, which are ubiquitously distributed in the central and peripheral nervous system, with a major role in the induction, transmission and perception of sensations such as pain and itch
“Listing Rules”	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
“mAb(s)”	monoclonal antibody(ies)
“Macau”	the Macau Special Administrative Region of the PRC
“Main Board”	the stock exchange (excluding the option market) operated by the Stock Exchange, which is independent from and operated in parallel with Growth Enterprise Market of the Stock Exchange

“mCRC”	metastatic colorectal cancer
“MKI”	multikinase inhibitor
“Model Code”	the “Model Code for Securities Transactions by Directors of Listed Issuers” set out in Appendix C3 to the Listing Rules
“MSD”	Merck Sharp & Dohme LLC together with its affiliates
“MTC”	medullary thyroid cancer
“NDA”	new drug application
“NMPA”	the National Medical Products Administration (國家藥品監督管理局) and its predecessor, the China Food and Drug Administration (國家食品藥品監督管理總局)
“NPC”	nasopharyngeal cancer
“NR”	not reached
“NSCLC”	non-small cell lung cancer
“OC”	ovarian cancer
“ORR”	objective response rate, the proportion of patients with a complete response or partial response to treatment
“OS”	overall survival, the length of time from either the date of diagnosis or the start of treatment for a disease that patients diagnosed with the disease are still alive, used in clinical trials as a measurement of a drug’s effectiveness
“pCR”	pathological complete response
“PD-1”	programmed cell death protein 1
“PD-L1”	PD-1 ligand 1
“PD-(L)1”	PD-1 or PD-L1

“PFS”	progression-free survival, the length of time during and after the treatment that a patient lives without the disease getting worse
“Placing”	the placing of 5,918,000 new H Shares by the Placing Agents on the terms and subject to the conditions of the placing agreement entered into between the Company and the Placing Agents on June 5, 2025
“Placing Agents”	Goldman Sachs (Asia) L.L.C. and Citigroup Global Markets Limited
“Prospectus”	the prospectus issued by the Company dated June 29, 2023
“PROTAC”	proteolysis targeting chimera, a heterobifunctional small molecule composed of two active domains and a linker, capable of removing specific unwanted proteins
“RAS”	rat sarcoma virus
“RDC(s)”	radionuclide drug conjugate(s)
“Reporting Period”	the six months ended June 30, 2025
“RET”	rearranged during transfection, a proto-oncogene, i.e., a gene that promotes cancer formation when altered by mutations or rearrangements. RET alterations have been reported to be a major oncogenic driver in about 2% of all cancers, most notably in NSCLC and MTC
“RMB”	Renminbi, the lawful currency of the PRC
“RPSFT”	rank-preserving structural failure time
“Share(s)”	ordinary shares in the share capital of our Company with a nominal value of RMB1.00 each
“Shareholder(s)”	holder(s) of the Shares

“STING”	stimulator of interferon genes
“Stock Exchange”	The Stock Exchange of Hong Kong Limited
“subsidiary(ies)”	has the meaning ascribed thereto under the Listing Rules
“substantial shareholder(s)”	has the meaning ascribed thereto under the Listing Rules
“Supervisor(s)”	member(s) of the supervisory committee of the Company, which was abolished on June 20, 2025
“Supervisory Committee”	the supervisory committee of the Company, which was abolished on June 20, 2025
“TAA”	tumor-associated antigen, an antigen with elevated level on tumor cells and lower levels on normal cells
“TAA-IO bsAbs”	tumor-associated-immuno-oncology bispecific antibodies, a type of bispecific antibodies with dual targeting ability against a certain tumor-associated antigen on tumor cells and a certain immune-oncology antigen involved in antitumor immune response, such as an immune checkpoint protein
“TKI”	tyrosine kinase inhibitor
“TNBC”	triple-negative breast cancer
“TPC”	treatment of physician’s choice
“TROP2”	human trophoblast cell-surface antigen 2, which is a transmembrane protein frequently over-expressed in many types of solid tumors
“TSLP”	thymic stromal lymphopoietin
“UC”	urothelial cancer
“US” or “U.S.” or “United States”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction

“US\$” or “USD”	United States dollars, the lawful currency of the United States
“Windward Bio”	Windward Bio AG
“%”	per cent

By order of the Board  
**Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.**  
**LIU Gexin**  
*Chairman of the Board and Non-executive Director*

Hong Kong, 18 August 2025

*As at the date of this announcement, the Board comprises Mr. LIU Gexin as the chairman of the Board and non-executive Director, Dr. GE Junyou as executive Director, Mr. LIU Sichuan, Mr. LAI Degui, Mr. FENG Hao, Ms. LIAO Yihong and Mr Zeng Xuebo as non-executive Directors, and Dr. ZHENG Qiang, Dr. TU Wenwei, Dr. JIN Jinping, and Dr. LI Yuedong as independent non-executive Directors.*