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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)

ANNOUNCEMENT OF ANNUAL RESULTS FOR THE YEAR ENDED DECEMBER 31, 2024

The Board is pleased to announce the audited consolidated results of the Group for the year ended December 31, 2024, together with the audited comparative figures for the year ended December 31, 2023.

FINANCIAL HIGHLIGHTS

	2024	2023	Flux
	RMB'000	RMB'000	%
Revenue	1,933,045	1,540,493	25.5%
Gross profit	1,273,657	759,185	67.8%
Research and development expenses	(1,206,134)	(1,030,966)	17.0%
Loss for the year	(266,766)	(574,134)	-53.5%
Adjusted loss for the year ¹	(118,481)	(450,788)	-73.7%
	As at	As at	
	December 31,	December 31,	Flux
	2024	2023	%
Cash and financial assets ²	3,075,651	2,528,342	21.6%
Total equity	3,308,661	2,329,497	42.0%

¹ Calculated by deducting equity-settled share-based payment from loss for the year.

² Comprises cash and cash equivalents, restricted deposits, financial assets measured at fair value through profit or loss, and financial assets measured at amortized cost.

BUSINESS HIGHLIGHTS

Since the beginning of 2024, we have made encouraging progress in our business:

- **Key developments of our ADC and novel DC assets:**

- o We have 11 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®) 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);
 - 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.

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 significant statistically 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.

In March 2024, sac-TMT was granted Breakthrough Therapy Designation by the NMPA for the first-line treatment of unresectable locally advanced, recurrent or metastatic PD-L1 negative TNBC. We have initiated a Phase 3 registrational study of sac-TMT monotherapy versus investigator-choice chemotherapy for 1L advanced TNBC.

- o **HR+/HER2- BC.** A Phase 3 registrational study for 2L+ HR+/HER2- locally advanced or metastatic BC is in progress.

In June 2023, sac-TMT was granted Breakthrough Therapy Designation by the NMPA for the treatment of patients with locally advanced or metastatic HR+/HER2- BC who have previously received at least 2L systemic chemotherapy.

- 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.

In October 2024, the NDA for sac-TMT for the treatment of adult patients with EGFR-mutant locally advanced or metastatic NSCLC who progressed after treatment with EGFR-TKI therapy was accepted by the NMPA, and was included in the priority review and approval process. In January 2023, sac-TMT was granted Breakthrough Therapy Designation by the NMPA for EGFR-mutant locally advanced or metastatic NSCLC following treatment with an EGFR-TKI.

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®)³ 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.
- 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.

³ 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 12 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, such as:
 - *2024 ASCO Annual Meeting.*
 - Results from the Phase 3 OptiTROP-Breast01 study of sac-TMT in patients with previously treated locally recurrent or metastatic TNBC;
 - Results from the Phase 2 OptiTROP-Lung01 study of sac-TMT in combination with KL-A167 (an anti-PD-L1 mAb) as first-line treatment for patients with advanced NSCLC;
 - *2024 ESMO Congress.*
 - Efficacy and safety of sac-TMT plus pembrolizumab in patients with recurrent or metastatic CC;
 - Safety and efficacy of sac-TMT monotherapy in patients with previously treated advanced EC and OC from a Phase 2 study;
 - Exploratory analysis of patients with or without prior PD-(L)1 inhibitors in Phase 3 OptiTROP-Breast01 study of sac-TMT versus chemotherapy for previously treated advanced TNBC;
 - *2024 AACR Annual Meeting.*
 - Updated efficacy and safety results for sac-TMT in patients with previously treated advanced NSCLC from a Phase 2 study;
 - Preliminary efficacy and safety results for sac-TMT in patients with previously treated advanced gastric or GEJ cancer from a Phase 2 study; and

■ *2025 ASCO GU Cancers Symposium.*

- 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.

o Our Core Product trastuzumab botidotin (HER2 ADC, also known as A166) (舒泰莱®):

- 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.

o Others:

- **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.
- **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.
- **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 1 clinical trial in China is ongoing.

- **SKB518, SKB535/MK-6204 and SKB445.** SKB518, SKB535 and SKB445 are novel ADC drugs with potential FIC targets. The Phase 1 clinical trials for each of them are ongoing in China. The Company has entered into a license and collaboration agreement with MSD to develop SKB535. It was announced on the official website of the NMPA that SKB535 is the first pilot project approved by the NMPA through the optimized clinical trial review scheme for innovative drugs, and the review and approval time is 21 days.
 - **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 tumor bone metastasis. In January 2025, an IND application for SKB107 was accepted by the NMPA.
- **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 (科泰萊®).* (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 (达泰萊®).* 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) (科泰萊®).** 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.

1L 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, 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%.

3L+ NPC

Based on an open-label, multi-center, Phase 2 clinical study in patients with recurrent or metastatic NPC who have failed after prior 2L+ systematic therapies, the median follow-up time was 21.7 months, 132 patients entered FAS totally, the IRC-assessed ORR was 26.5%, the DoR was 12.4 months and the median OS was 16.2 months. Meanwhile, tagitanlimab showed a manageable safety profile, where the incidence of grade 3 immune-related adverse events (irAEs) was 3.9% and no grade 3 above irAE was observed. These study results have been published in *The Lancet Regional Health – Western Pacific*, a journal by The Lancet.

- 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 safety, tolerance and immunogenicity compared with 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.
- o **SKB378/WIN378 (TSLP mAb).** We completed Phase 1 clinical trial 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, is preparing for Phase 2 trial.
- o **SKB336 (FXI/FXI α 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[®]) in the China market and file an NDA for A400 in 2025.

We have set up a fully-fledged commercialization team to prepare and implement the marketing and commercialization of our strategic products and established a departmental structure within the Company, consisting of various departments such as Marketing, Commercial and Marketing Access, Medical Affairs, Sales, and Strategic Planning and Commercial Excellence. 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.

- **Highlights of our License and Collaboration Arrangements.**
 - o ***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 12 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 Sac-TMT plus pembrolizumab versus TPC in TNBC who received neoadjuvant therapy 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);
- LC.
 - o 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 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.

In the third quarter of 2024, we were informed by MSD regarding an exclusive option to exercise SKB571/MK-2750. MSD has paid US\$37.5 million to the Company in connection with the option to exercise, and the Company is eligible to receive further milestone payments conditional upon the achievement of specified development and sales milestones and tiered royalties on net sales of SKB571/MK-2750 if commercialized. The Company retains the right to develop, use, manufacture and commercialize SKB571/MK-2750 in 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 December 31, 2024, a total of 33 clinical sites in the United States, Europe and UAE were set up for A400/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 to us and Harbour BioMed under the license agreement shall be paid in equal amounts to us and Harbour BioMed.

The Company has received upfront and milestone payments totaling US\$147.5 million (equivalent to approximately RMB1,060.3 million⁵) from partners with regard to multiple collaborated pipelines in 2024 and up to the date of this announcement.

- **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 June 2024, the Company was awarded "Excellence in ESG Governance Performance Award" by Ming Pao, a media brand under Media Chinese International Limited.
- **Placing of New H Shares.** On May 16, 2024, the placing of 3,648,600 H Shares to multiple placees at the placing price of HK\$150.00 per Share was completed. The net proceeds from the Placing amounted to approximately HK\$541.4 million.
- **Subscription of New Domestic Shares.** On December 17, 2024, the subscription of 4,423,870 Domestic Shares by Kelun Pharmaceutical at the subscription price of RMB136.21 per Share was completed. The net proceeds from the Subscription is approximately RMB601.4 million.

⁵ Based on the exchange rate of US\$1: RMB7.1884 published by the State Administration of Foreign Exchange of the PRC on December 31, 2024 for illustration purpose.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS
for the year ended December 31, 2024
(Expressed in Renminbi (“RMB”))

		2024	2023
	<i>Note</i>	<i>RMB’000</i>	<i>RMB’000</i>
Revenue	4	1,933,045	1,540,493
Cost of sales		<u>(659,388)</u>	<u>(781,308)</u>
Gross profit		1,273,657	759,185
Other net income	5	139,755	89,809
Selling and distribution expenses		(182,717)	(19,534)
Administrative expenses		(163,310)	(181,877)
Research and development expenses		<u>(1,206,134)</u>	<u>(1,030,966)</u>
Loss from operations		(138,749)	(383,383)
Finance costs		<u>(3,796)</u>	<u>(84,309)</u>
Loss before taxation		(142,545)	(467,692)
Income tax	6	<u>(124,221)</u>	<u>(106,442)</u>
Loss for the year attributable to equity shareholders of the Company		<u>(266,766)</u>	<u>(574,134)</u>
Loss per share	7		
Basic and diluted (<i>RMB</i>)		<u>(1.20)</u>	<u>(2.84)</u>

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

for the year ended December 31, 2024

(Expressed in RMB)

	2024	2023
<i>Note</i>	<i>RMB'000</i>	<i>RMB'000</i>
Loss for the year	(266,766)	(574,134)
Other comprehensive income for the year (after tax)		
<i>Item that may be reclassified subsequently to profit or loss:</i>		
<i>Exchange differences on translation of financial statements of overseas subsidiaries</i>	<u>3,537</u>	<u>4,793</u>
Other comprehensive income for the year	<u>3,537</u>	<u>4,793</u>
Total comprehensive income for the year attributable to equity shareholders of the Company	<u>(263,229)</u>	<u>(569,341)</u>

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

(Expressed in RMB)

		As at December 31,	
		2024	2023
	Note	RMB'000	RMB'000
Non-current assets			
Property, plant and equipment		594,822	607,783
Right-of-use assets		163,283	84,950
Intangible assets		2,579	1,336
Other non-current assets		14,512	8,199
		<u>775,196</u>	<u>702,268</u>
Current assets			
Inventories	8	110,506	63,032
Trade and other receivables	9	303,728	214,761
Amounts due from related parties		2,921	1,352
Financial assets measured at fair value through profit or loss ("FVPL")		1,448,319	633,705
Financial assets measured at amortized cost		283,979	325,870
Restricted deposits		6,850	39,993
Cash and cash equivalents		1,336,503	1,528,774
		<u>3,492,806</u>	<u>2,807,487</u>
Current liabilities			
Trade and other payables	10	446,832	523,477
Amounts due to related parties		8,792	21,429
Contract liabilities	11	312,375	510,692
Lease liabilities		41,842	54,406
		<u>809,841</u>	<u>1,110,004</u>
Net current assets		<u>2,682,965</u>	<u>1,697,483</u>
Total assets less current liabilities		<u>3,458,161</u>	<u>2,399,751</u>

	<i>Note</i>	As at December 31,	
		2024	2023
		<i>RMB'000</i>	<i>RMB'000</i>
Non-current liabilities			
Lease liabilities		84,905	5,513
Deferred income		64,595	64,741
		<u>149,500</u>	<u>70,254</u>
NET ASSETS		<u>3,308,661</u>	<u>2,329,497</u>
CAPITAL AND RESERVES			
Share capital	12	227,268	219,196
Reserves		3,081,393	2,110,301
TOTAL EQUITY		<u>3,308,661</u>	<u>2,329,497</u>

CONSOLIDATED STATEMENT OF CHANGES IN EQUITY
for the year ended December 31, 2024
(Expressed in RMB)

	<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>
Balance at January 1, 2023		107,370	147,877	749	(3,482,182)	(3,226,186)
Changes in equity for 2023						
Loss for the year		–	–	–	(574,134)	(574,134)
Exchange differences on translation of financial statements of an overseas subsidiary		–	–	4,793	–	4,793
Total comprehensive income		–	–	4,793	(574,134)	(569,341)
Issuance of new shares	12	59,937	2,598,744	–	–	2,658,681
Issuance of ordinary shares by initial public offering and over-allotment, net of issuing costs	12	25,813	1,336,861	–	–	1,362,674
Issuance of shares with preferential rights to investors		26,076	1,297,399	–	–	1,323,475
Recognition of financial liabilities recognized for preferential rights issued to investors		–	(1,323,475)	–	–	(1,323,475)
Reclassification of financial liabilities recognized for preferential rights issued to investors to equity		–	1,980,323	–	–	1,980,323
Equity-settled share-based payment		–	123,346	–	–	123,346
Balance at December 31, 2023		<u>219,196</u>	<u>6,161,075</u>	<u>5,542</u>	<u>(4,056,316)</u>	<u>2,329,497</u>
Balance at January 1, 2024		219,196	6,161,075	5,542	(4,056,316)	2,329,497
Changes in equity for 2024						
Loss for the year		–	–	–	(266,766)	(266,766)
Exchange differences on translation of financial statements of an overseas subsidiary		–	–	3,537	–	3,537
Total comprehensive income		–	–	3,537	(266,766)	(263,229)
Issuance of new shares		8,072	1,086,036	–	–	1,094,108
Equity-settled share-based payment		–	148,285	–	–	148,285
Balance at December 31, 2024		<u>227,268</u>	<u>7,395,396</u>	<u>9,079</u>	<u>(4,323,082)</u>	<u>3,308,661</u>

CONSOLIDATED CASH FLOW STATEMENT
for the year ended December 31, 2024
(Expressed in RMB)

	<i>Note</i>	2024 RMB'000	2023 RMB'000
Operating activities			
Net cash (used in)/generated from operating activities		(429,770)	59,559
Investing activities			
Payment for the purchase of property, plant and equipment		(77,460)	(80,982)
Proceeds from disposal of property, plant and equipment		30	5
Payment for intangible assets		(3,659)	(1,268)
Payment for investment in financial assets measured at FVPL		(3,210,000)	(2,060,000)
Proceeds from redemption of financial assets measured at FVPL		2,416,933	1,436,828
Payment for investment in financial assets measured at amortized cost		(103,102)	(320,000)
Proceeds from disposals of financial assets measured at amortized cost		155,253	—
Net cash used in investing activities		(822,005)	(1,025,417)
Financing activities			
Repayment of bank loans		—	(100,000)
Repayment of other borrowings from Sichuan Kelun Pharmaceutical Co.,Ltd.(“ Kelun Pharmaceutical ”)		—	(294,040)
Proceeds from issuance of new shares		1,094,108	158,681
Proceeds from issuance of shares with preferential rights		—	1,323,475
Issuance of ordinary shares by initial public offering and over-allotment, net of issuing costs		—	1,370,939
Interest paid		—	(563)
Capital element of lease rentals paid		(54,601)	(66,762)
Interest element of lease rentals paid		(2,288)	(9,449)
Net cash generated from financing activities		1,037,219	2,382,281
Net (decrease)/increase in cash and cash equivalents		(214,556)	1,416,423
Cash and cash equivalents at January 1		1,528,774	92,960
Effect of foreign exchange rate changes		22,285	19,391
Cash and cash equivalents at December 31		1,336,503	1,528,774

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

(Expressed in RMB unless otherwise indicated)

1 STATEMENT OF COMPLIANCE

These financial statements have been prepared in accordance with all applicable IFRS Accounting Standards, which collective term includes all applicable individual International Financial Reporting Standards, International Accounting Standards (“**IASs**”) and Interpretations issued by the International Accounting Standards Board (“**IASB**”) and the disclosure requirements of the Hong Kong Companies Ordinance. These financial statements also comply with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (“**Stock Exchange**”). Material accounting policies adopted by the Company and its subsidiaries (together referred to as the “**Group**”) are disclosed below.

The IASB has issued certain amendments to IFRS Accounting Standards that are first effective or available for early adoption for the current accounting period of the Group.

2 BASIS OF PREPARATION OF THE FINANCIAL STATEMENTS

The consolidated financial statements for the year ended December 31, 2024 comprise the Group.

Items included in these consolidated financial statements of each entity in the Group are measured using the currency that best reflects the economic substance of the underlying events and circumstances relevant to the entity (“**functional currency**”).

RMB, the United States dollars (“**USD**”) and Hong Kong dollars (“**HKD**”) are the functional currencies for the Company and Company’s subsidiaries established in Mainland China, the United States and Hong Kong.

The consolidated financial statements are presented in RMB, rounded to nearest thousands, which is the presentation currency.

The measurement basis used in the preparation of the financial statements is the historical cost basis except that financial assets measured at fair value through profit or loss are stated at fair value as explained.

The preparation of financial statements in conformity with IFRS Accounting Standards requires management to make judgements, estimates and assumptions that affect the application of policies and reported amounts of assets, liabilities, income and expenses. The estimates and associated assumptions are based on historical experience and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis of making the judgements about carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates.

The estimates and underlying assumptions are reviewed on an ongoing basis. Revisions to accounting estimates are recognized in the period in which the estimate is revised if the revision affects only that period, or in the period of the revision and future periods if the revision affects both current and future periods.

3 CHANGES IN ACCOUNTING POLICIES

None of these amendments had a material effect on how the Group’s results and financial position for the current or prior year have been prepared or presented. The Group has not applied any new standard or interpretation that is not yet effective for the current accounting period.

4 REVENUE

The principal activities of the Group are the research and development, manufacturing and commercialization of novel drugs in oncology, immunology and other therapeutic areas.

Disaggregation of revenue

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

	Year ended December 31,	
	2024	2023
	RMB'000	RMB'000
Revenue from contracts with customers within the scope of IFRS 15		
Revenue from license and collaboration agreements	1,863,071	1,531,699
Revenue from provision of research and development service	18,276	8,794
Revenue from sales of pharmaceutical products	51,698	–
	<u>1,933,045</u>	<u>1,540,493</u>

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

	Year ended December 31,	
	2024	2023
	RMB'000	RMB'000
Disaggregated by timing of revenue recognition		
Point in time	1,107,697	814,568
Over time	825,348	725,925
	<u>1,933,045</u>	<u>1,540,493</u>

5 OTHER NET INCOME

	Year ended December 31,	
	2024	2023
	RMB'000	RMB'000
Interest income from bank deposits	23,917	39,316
Interest income on financial assets measured at amortised cost	10,260	5,870
Net foreign exchange gains	17,791	16,085
Government grants	67,102	20,578
Net loss on disposal of property, plant and equipment	(146)	(1,488)
Net realized and unrealized gain on financial assets measured at FVPL	21,547	10,533
Others	(716)	(1,085)
	<u>139,755</u>	<u>89,809</u>

6 INCOME TAX IN THE CONSOLIDATED STATEMENT OF PROFIT OR LOSS

	Year ended December 31,	
	2024	2023
	RMB'000	RMB'000
Current tax		
Provision for the year		
– The PRC Corporate Income Tax	–	–
– United States Withholding Tax	124,221	106,442
	124,221	106,442

(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 October 16, 2023 and is entitled to preferential income tax of 15% from 2023 to 2025.

(ii) Hong Kong Profit Tax

The provision for Hong Kong Profits Tax for 2024 is calculated at 16.5% (2023: 16.5%) of the estimated assessable profits for the year. There were no assessable profits generating from the subsidiary incorporated in Hong Kong of the Group during the year ended as at December 31, 2024.

(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.

7 LOSS PER SHARE

(a) Basic loss per share

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

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

	Year ended December 31,	
	2024	2023
	RMB'000	RMB'000
Loss for the year attributable to ordinary equity shareholders	(266,766)	(574,134)
Allocation of loss for the year attributable to financial instruments issued to investors	—	51,925
Loss for the year attributable to ordinary equity shareholders of the Company for the purpose of basic loss per share	<u>(266,766)</u>	<u>(522,209)</u>

(ii) Weighted average number of shares

	Year ended December 31,	
	2024	2023
Issued ordinary shares at January 1	219,195,499	107,369,609
Effect of issuance of new shares	2,452,086	94,518,344
Effect of the financial instruments issued to investors	—	(18,258,773)
Weighted average number of ordinary shares at December 31	<u>221,647,585</u>	<u>183,629,180</u>

(b) Diluted loss per share

The Group had no potentially dilutive ordinary shares in issue during the year ended December 31, 2024.

As the Group incurred losses for the year ended December 31, 2023, the potential ordinary shares were not included in the calculation of diluted loss per share as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the year ended December 31, 2023 was the same as basic loss per share.

8 INVENTORIES

	As at December 31,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Raw materials	78,655	57,922
Low-value consumables	5,000	5,110
Work in progress	24,848	–
Finished goods	2,003	–
	<u>110,506</u>	<u>63,032</u>

9 TRADE AND OTHER RECEIVABLES

	As at December 31,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Trade receivables	57,842	–
Other receivables	12,083	16,294
Value Added Tax (“VAT”) recoverable	171,243	106,802
Prepaid Tax	2,085	35,648
Prepayments	60,475	56,017
	<u>303,728</u>	<u>214,761</u>

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

	As at December 31,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Within 3 months	<u>57,842</u>	<u>–</u>
	<u>57,842</u>	<u>–</u>

10 TRADE AND OTHER PAYABLES

	As at December 31,	
	2024	2023
	RMB'000	RMB'000
Trade payables	246,687	315,501
Other payables	2,539	3,029
Bills payable	35,810	67,449
Accrued payroll and benefits	156,341	133,773
Other taxes payable	5,455	3,725
	<u>446,832</u>	<u>523,477</u>

As of the end of the years, 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 December 31,	
	2024	2023
	RMB'000	RMB'000
Within 1 year	214,208	365,199
1 to 2 years	53,439	16,798
2 to 3 years	13,993	349
More than 3 years	857	604
	<u>282,497</u>	<u>382,950</u>

11 CONTRACT LIABILITIES

	As at December 31,	
	2024	2023
	RMB'000	RMB'000
Receipts in advance	<u>312,375</u>	<u>510,692</u>

When the Group receives upfront payments before the provision of research and development service, this will give rise to contract liabilities at the start of a contract, until the revenue recognized from provision of research and development service exceeds the amount of the upfront payments. The amount of the upfront payments was negotiated on a case-by-case basis with the respective customers.

Movements in contract liabilities

	2024	2023
	RMB'000	RMB'000
Balance at January 1	510,692	163,976
Decrease in contract liabilities as a result of recognising revenue during the year that was included in the contract liabilities at the beginning of the year	(510,692)	(163,578)
Increase in contract liabilities as a result of receipts in advance	<u>312,375</u>	<u>510,294</u>
Balance at December 31	<u>312,375</u>	<u>510,692</u>

All of contract liabilities are expected to be recognized as income within one year.

12 SHARE CAPITAL

As at December 31, 2023 and 2024, the Company has 219,196,000 shares and 227,268,000 shares registered with par value of RMB1 for each share, respectively.

On May 16, 2024, the Company issued an aggregate of 3,649,000 new H shares at an offering price of HK\$150 per share pursuant to a placing agreement entered into by the Company and the placing agents (the “**Placing**”).

The net proceeds (after deducting the commissions and expenses) from the Placing amounted to approximately HK\$541.4 million (equivalent to RMB492,715,000), of which RMB3,649,000 was recorded in share capital and the remaining RMB489,066,000 was recorded in capital reserves.

On December 17, 2024, the Company issued an aggregate of 4,423,000 domestic shares at an offering price of HK\$150 per share pursuant to a subscription agreement entered into by the Company and its ultimate controlling party, Sichuan Kelun Pharmaceutical Co., Ltd. (“**Kelun Pharmaceutical**”) (the “**Subscription**”).

The net proceeds (after deducting the commissions and expenses) from the Subscription amounted to approximately HK\$661.9 million (equivalent to RMB601,393,000), of which RMB4,423,000 was recorded in share capital and the remaining RMB596,970,000 was recorded in capital reserves.

13 DIVIDEND

No dividend has been paid or declared by the Company for the year ended December 31, 2024 (2023: Nil).

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 for treating various advanced solid tumors. 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, and our Key Products, 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, 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 platform, OptiDC™. 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 targeting advanced solid tumors;
 - o **Trastuzumab botidotin (also known as A166) (舒泰莱®)**, 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 tumor bone metastases.

• **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 A140) (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 significant statistically 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.

In March 2024, sac-TMT was granted Breakthrough Therapy Designation by the NMPA for the first-line treatment of unresectable locally advanced, recurrent or metastatic PD-L1 negative TNBC. We have initiated a Phase 3 registrational study of sac-TMT monotherapy versus investigator-choice chemotherapy for 1L advanced TNBC.

HR+/HER2- BC. A Phase 3 registrational study for 2L+ HR+/HER2- locally advanced or metastatic BC is in progress.

In June 2023, sac-TMT was granted Breakthrough Therapy Designation by the NMPA for the treatment of patients with locally advanced or metastatic HR+/HER2- BC who have previously received at least 2L systemic chemotherapy.

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.

In October 2024, the NDA for sac-TMT for the treatment of adult patients with EGFR-mutant locally advanced or metastatic NSCLC who progressed after treatment with EGFR-TKI therapy was accepted by the NMPA and was included in the priority review and approval process. In January 2023, sac-TMT was granted Breakthrough Therapy Designation by the NMPA for EGFR-mutant locally advanced or metastatic NSCLC following treatment with an EGFR-TKI. In August 2024, based on the positive results from the pivotal OptiTROP-Lung03 study of sac-TMT, the NDA was accepted by the CDE of the NMPA, and was included in the priority review and approval process.

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®)¹ 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.

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 12 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.

¹ 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, such as:

- *2024 ASCO Annual Meeting.*
 - o Results from the Phase 3 OptiTROP-Breast01 study of sac-TMT in patients with previously treated locally recurrent or metastatic TNBC;
 - o Results from the Phase 2 OptiTROP-Lung01 study of sac-TMT in combination with KL-A167 (an anti-PD-L1 mAb) as first-line treatment for patients with advanced NSCLC;
- *2024 ESMO Congress.*
 - o Efficacy and safety of sac-TMT plus pembrolizumab in patients with recurrent or metastatic CC;
 - o Safety and efficacy of sac-TMT monotherapy in patients with previously treated advanced EC and OC from a Phase 2 study;
 - o Exploratory analysis of patients with or without prior PD-(L)1 inhibitors in Phase 3 OptiTROP-Breast01 study of sac-TMT versus chemotherapy for previously treated advanced TNBC;
- *2024 AACR Annual Meeting.*
 - o Updated efficacy and safety results for sac-TMT in patients with previously treated advanced NSCLC from a Phase 2 study;
 - o Preliminary efficacy and safety results for sac-TMT in patients with previously treated advanced gastric or GEJ cancer from a Phase 2 study; and
- *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.

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®)

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.

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.

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.

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 1 clinical trial in China is ongoing.

SKB518, SKB535/MK-6204 and SKB445

SKB518, SKB535 and SKB445 are novel ADC drugs with potential FIC targets. The Phase 1 clinical trials for each of them are ongoing in China. The Company has entered into a license and collaboration agreement with MSD to develop SKB535. It was announced on the official website of the NMPA that SKB535 is the first pilot project approved by the NMPA through the optimized clinical trial review scheme for innovative drugs, and the review and approval time is 21 days.

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 tumor bone metastasis. In January 2025, an IND application for SKB107 was accepted by the NMPA.

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) (科泰莱®)

Tagitanlimab is a humanized mAb that targets PD-L1, an important immune checkpoint protein. Targeting PD-L1 and its receptor PD-1 has 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.

1L 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, 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%.

3L+ NPC

Based on an open-label, multi-center, Phase 2 clinical study in patients with recurrent or metastatic NPC who have failed after prior 2L+ systematic therapies, the median follow-up time was 21.7 months, 132 patients entered FAS totally, the IRC-assessed ORR was 26.5%, the DoR was 12.4 months and the median OS was 16.2 months. Meanwhile, tagitanlimab showed a manageable safety profile, where the incidence of grade 3 immune-related adverse events (irAEs) was 3.9% and no grade 3 above irAE was observed. These study results have been published in *The Lancet Regional Health – Western Pacific*, a journal by The Lancet.

**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[®]), 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 safety, tolerance and immunogenicity compared with Cetuximab Solution for Injection (Erbix[®]) 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.

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 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, 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 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 is a co-development project jointly conducted by the Company and Harbour BioMed, with both parties equally sharing global rights. Windward Bio is preparing for Phase 2 trial.

SKB378 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

SKB336 (FXI/FXI α mAb)

SKB336 is a novel FXI/FXI α 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/FXI α deficiencies led to clot instability and prevented the occlusion of blood vessels, suggesting that targeting FXI/FXI α 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.

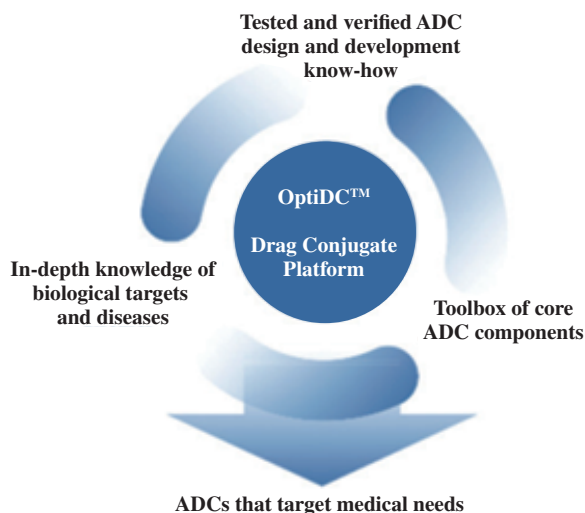
Apart from the above, we will continue to develop novel non-oncology drug candidates to address highly prevalent chronic diseases currently without effective treatments, including autoimmune and metabolic diseases.

OUR TECHNOLOGY PLATFORMS

We have established three core platforms specializing in ADCs, 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 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 platform, which supports our systematic development of ADCs across their entire lifecycle. Our ADC platform, OptiDC™, is supported by three capability pillars – in-depth knowledge of biological targets and diseases, tested and verified ADC design and development know-how, and a toolbox of core ADC components. Through over a decade of development, we have developed a toolbox of core ADC components which gives us the versatility to engineer customized ADCs optimized for different biological targets to address medical needs in a broad range of indications. We have honed our expertise in ADC process development, manufacturing and quality management, which we believe is crucial in bringing our ADCs from bench to bedside. Notably, our ADC 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 ADC design strategies, we deploy a multi-pronged strategy to advance our ADC 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 ADCs 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 possesses 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 (AI-driven drug design) 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, reduces 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, 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, 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 (AI-driven drug design) technologies 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 12 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.

- Sac-TMT plus pembrolizumab versus TPC in TNBC who received neoadjuvant therapy 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);

§ LC.

- 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 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.

In the third quarter of 2024, we were informed by MSD regarding an exclusive option to exercise SKB571/MK-2750. MSD has paid US\$37.5 million to the Company in connection with the option to exercise, and the Company is eligible to receive further milestone payments conditional upon the achievement of specified development and sales milestones and tiered royalties on net sales of SKB571/MK-2750 if commercialized. The Company retains the right to develop, use, manufacture and commercialize SKB571/MK-2750 in 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 December 31, 2024, a total of 33 clinical sites in the United States, Europe and UAE were set up for A400/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/WIN378³ globally (excluding Greater China and several Southeast and West Asian countries).

³ SKB378 is known as HBM9378 in Harbour BioMed's pipeline and WIN378 in Windward Bio's pipeline.

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 to us and Harbour BioMed under the license agreement shall be paid in equal amounts to us and Harbour BioMed.

The Company has received upfront and milestone payments totaling US\$147.5 million from partners with regard to multiple collaborated pipelines in 2024 and up to the date of this announcement.

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. This system helps ensure the consistent, stable, and controllable quality of our clinical and commercialized products.

- **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 operate a comprehensive quality management system which extends across all key stages of the R&D, manufacturing and commercialization processes. This system was established and refined in accordance with the rigorous regulations and guidelines in China, the U.S. and Europe. We pay close attention to the evolving cGMP standards and regulatory developments in these target markets and have been updating our internal procedures accordingly, striving for the highest international standards in 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, subject to regulatory communications and marketing approval, we expect to launch trastuzumab botidotin (舒泰莱®) in the China market and file an NDA for A400 in 2025.

We have set up a fully-fledged commercialization team to prepare and implement the marketing and commercialization of our strategic products and established a departmental structure within the Company, consisting of various departments such as Marketing, Commercial and Marketing Access, Medical Affairs, Sales, and Strategic Planning and Commercial Excellence. 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.

AWARDS AND RECOGNITION

In April 2024, the Company was awarded “ADC Pioneer Enterprise” by TONACEA.

In September 2024, 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).

In November 2024, the “Sichuan Province Biomacromolecule Drug Innovation Consortium” (四川省生物大分子藥物創新聯合體) was officially established. The consortium, led by Kelun Pharmaceutical, was jointly established by the Company, China Pharmaceutical University (中國藥科大學), Sichuan Provincial People’s Hospital (四川省人民醫院), the Affiliated Hospital of North Sichuan Medical College (川北醫學院附屬醫院), and other innovative and distinguished units to carry out technical breakthroughs in the field of biomacromolecules, focusing on “R&D + clinical + manufacturing + application” of biomacromolecule drugs.

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 June 2024, the Company was awarded “Excellence in ESG Governance Performance Award” by Ming Pao, a media brand under Media Chinese International Limited.

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 the 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:

	Year ended December 31,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Revenue from contracts with customers within the scope of IFRS 15		
Revenue from license and collaboration agreements	1,863,071	1,531,699
Revenue from provision of research and development service	18,276	8,794
Revenue from sales of pharmaceutical products	51,698	—
	<u>1,933,045</u>	<u>1,540,493</u>

The Group’s revenue for the year ended December 31, 2024 was RMB1,933.05 million, representing an increase of 25.5% compared to RMB1,540.5 million for the year ended December 31, 2023. The increase is mainly attributable to (i) the achievement of various R&D milestones in 2024; and (ii) the commencement of sales of pharmaceutical products in 2024.

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, and the R&D services we provided to Kelun Group and other third parties. 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; (ii) employee salaries and benefits for R&D staff; and (iii) others, including 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, 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.

	Year ended December 31,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Staff costs	95,098	107,778
Trial and testing expenses	493,053	469,846
Project cooperation expenses	–	92,726
Others	71,237	110,958
	<hr/>	<hr/>
Total	659,388	781,308
	<hr/>	<hr/>

The Group's cost of sales for the year ended December 31, 2024 was RMB659.39 million, representing a decrease of 15.6% compared to RMB781.3 million for the year ended December 31, 2023. The decrease is mainly because we did not incur project cooperation expenses and stamp taxes in 2024.

Gross Profit and Gross Profit Margin

Gross profit represents revenue less cost of sales. Gross profit margin represents gross profit as a percentage of revenue. As a result of the aforementioned factors, the gross profit of the Group increased by 67.8% from RMB759.2 million for the year ended December 31, 2023 to RMB1,273.7 million for the year ended December 31, 2024.

Our gross profit margin is calculated as gross profit divided by revenue. The gross profit margin of the Group increased from 49.3% for the year ended December 31, 2023 to 65.9% for the year ended December 31, 2024.

Other Net Income/Expenses

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; and (vii) others.

The Group's other net income or expenses for the year ended December 31, 2024 was RMB139.8 million, representing an increase of RMB50.0 million compared to RMB89.8 million for the year ended December 31, 2023, mainly due to an increase 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.

	Year ended December 31,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Staff costs	124,987	117,982
Consulting service fee	7,446	6,730
Office and travel expenses	9,192	9,323
Listing expenses	—	27,346
Others	21,685	20,496
	<hr/>	<hr/>
Total	163,310	181,877
	<hr/>	<hr/>

The Group's administrative expenses for the year ended December 31, 2024 was RMB163.3 million, representing a decrease of 10% compared to RMB181.9 million for the year ended December 31, 2023. The decrease was primarily attributable to the absence of listing expenses in 2024.

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; (ii) conference and marketing expenses related to business activities, and administrative expenses; and (iii) other expenses, such as transportation expenses etc.

	Year ended December 31,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Staff costs	91,807	17,258
Conference, marketing and administrative expenses	84,863	1,541
Others	6,047	735
	<hr/>	<hr/>
Total	182,717	19,534
	<hr/>	<hr/>

The Group's selling and distribution expenses for the year ended December 31, 2024 was RMB182.7 million, compared to RMB19.5 million for the year ended December 31, 2023. Such expenses are primarily attributable to (i) the recruitment of staff into our commercialization team and (ii) pre-launch and post-launch marketing activities for our product sac-TMT, as we are expanding our commercialization team and conducting marketing activities for our commercialization needs.

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.

	Year ended December 31,	
	2024	2023
	<i>RMB'000</i>	<i>RMB'000</i>
Staff costs	390,898	316,917
Trial and testing expenses	531,817	527,306
Raw materials	155,742	73,618
Others	127,677	113,125
	<hr/>	<hr/>
Total	<u>1,206,134</u>	<u>1,030,966</u>

The Group's R&D expenses for the year ended December 31, 2024 was RMB1,206.1 million, representing an increase of 17.0% compared to RMB1,031.0 million for the year ended December 31, 2023, mainly due to (i) an increase in staff costs; (ii) an increase in raw materials. Such increases were primarily due to the increased investments in the on-going R&D projects of the Group.

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 year ended December 31, 2024 was RMB3.8 million, representing a decrease of 95.5% compared to RMB84.3 million for the year ended December 31, 2023. The decrease in finance costs was primarily because, following the completion of the debt-to-equity conversion and initial public offering of the Company and the repayment of bank loans by the Company in 2023, the Company did not incur any interest expenses on the borrowings from Kelun Pharmaceutical, financial instruments issued to investors (representing the Shares issued to Series A Investors and Series B Investors) and bank loans in 2024.

Income Tax

During the Reporting Period, our income tax consisted of current tax and withholding tax. For the year ended December 31, 2023 and 2024, we recorded income tax of RMB106.4 million and RMB124.2 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%. The Company obtained its certificate of high-technology enterprise on October 16, 2023 and is entitled to preferential income tax of 15% from 2023 to 2025.

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.

Hong Kong

The provision for Hong Kong Profits Tax for 2024 is calculated at 16.5% (2023: 16.5%) of the estimated assessable profits for the year. There were no assessable profits generating from the subsidiary incorporated in Hong Kong of the Group during the year ended December 31, 2024.

Profit/Loss for the period

As a result of the foregoing, our loss for the Reporting Period decreased by 53.5% from RMB574.1 million for the year ended December 31, 2023 to RMB266.8 million for the year ended December 31, 2024.

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 May 8, 2024, the Company entered into a placing agreement with the Placing Agents, pursuant to which the Placing Agents conditionally agreed to procure the placing of, as agent of the Company, or failing which to purchase itself, 3,648,600 H Shares to multiple placees at the placing price of HK\$150.00 per Share. Completion of the Placing took place on May 16, 2024. 3,648,600 H Shares were successfully placed by the Placing Agents to multiple placees at the placing price pursuant to the terms and conditions of the placing agreement. The net proceeds from the Placing amounted to approximately HK\$541.4 million.

On May 8, 2024, the Company entered into a subscription agreement with Kelun Pharmaceutical (as subscriber), pursuant to which Kelun Pharmaceutical conditionally agreed to subscribe for and the Company conditionally agreed to allot and issue a total of 4,423,870 Domestic Shares at the subscription price of RMB136.21 per Share, equivalent to HK\$150.00 per Share, which is the same as the placing price of the Placing. The independent Shareholders approved the subscription at the 2023 annual general meeting of the Company on June 20, 2024. The Subscription was completed on December 17, 2024. The net proceeds from the Subscription is approximately RMB601.4 million (equivalent to approximately HK\$662.29 million⁴).

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 RMB1,528.8 million and RMB1,336.5 million as at December 31, 2023 and December 31, 2024, respectively. The decrease in our cash and cash equivalents primarily reflected our investment on financial assets.

As at December 31, 2023 and December 31, 2024, the balance of our financial assets measured at FVPL was RMB633.7 million and RMB1,448.3 million, respectively. As at December 31, 2023 and December 31, 2024, the balance of our financial assets measured at amortized cost was RMB325.9 million and RMB284.0 million, respectively. Such increase was primarily because of the acquisition of wealth management products by the Company.

Net Cash Used in/Generated from 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 RMB429.8 million in operating activities for the year ended December 31, 2024, compared to the net cash of RMB59.6 million generated from operating activities for the year ended December 31, 2023. The decrease in cash was primarily because of the increased investments in the on-going R&D projects of the Group and less payments received from MSD pursuant to our collaboration. 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 and the Subscription.

⁴

Based on the exchange rate of HK\$1: RMB0.90806 published by the State Administration of Foreign Exchange of the PRC on May 7, 2024 for illustration purpose.

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 December 31, 2023 and December 31, 2024, 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 December 31, 2024 were RMB2,683.0 million, representing an increase of 58.1% compared to RMB1,697.5 million as at December 31, 2023 primarily because of the net proceeds from the Placing and the Subscription and milestone payments received from MSD pursuant to our collaboration.

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 December 31, 2024, 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 year ended December 31, 2024, the Group's total capital expenditure amounted to approximately RMB81.1 million, which was mainly used in purchasing R&D instruments and equipment and factory construction.

Charge on Assets

As at December 31, 2024, there was no charge on assets of the Group.

Contingent Liabilities

As at December 31, 2024, we did not have any contingent liabilities.

Employees and Remuneration Policies

As at December 31, 2024, we had 1,837 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.

Future Investment Plans and Expected Funding

As of the date of this announcement, we are strategically pursuing investment and/or acquisition opportunities to drive our long-term growth, and will make further announcements in accordance with the Listing Rules, where applicable, if any investments and acquisition opportunities materialize.

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 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, 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 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) tumor-associated-immuno-oncology bispecific antibodies (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 capabilities and advancing towards commercialization

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®) in the China market and file an NDA for A400 in 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, Commercial and Marketing Access, Medical Affairs, Sales, and Strategic Planning and Commercial Excellence. 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. We take a two-pronged business development approach to drive both our near- and long-term growth: for clinical-stage assets, we focus on forging partnerships with multinational corporations and leading domestic companies to accelerate our development timelines and maximize the commercial value of our pipeline; for early-stage assets and drug discovery, we seek co-development opportunities that enable us to explore new therapeutic areas and cutting-edge modalities and augment our technology platforms. 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 will consider whether to retain the Greater China commercial rights of, or fully out-license, our assets as we evaluate opportunities on a case by case basis. 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.

(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.

CORPORATE GOVERNANCE AND OTHER INFORMATION

Compliance with the Corporate Governance Code

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 year ended December 31, 2024.

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 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 and Supervisors confirmed that they have complied with the Model Code during the year ended December 31, 2024. In addition, the Company is not aware of any non-compliance with the Model Code by the senior management of the Group during the year ended December 31, 2024.

Purchase, Sale or Redemption of the Company's Securities

Save for the Placing and the Subscription, 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 year ended December 31, 2024.

The Company has not made any sales of treasury shares on the Stock Exchange during the year ended December 31, 2024. As at December 31, 2024, the Company did not hold any treasury shares.

Completion of H Share Full Circulation

The conversion of an aggregate of 1,157,778 Domestic Shares and Unlisted Foreign Shares of the Company (the “**Converted H Shares**”) was completed on September 17, 2024 and the listing of the Converted H Shares on the Stock Exchange commenced on September 19, 2024.

For further details, please refer to the Company's announcement dated September 17, 2024.

Audit Committee

The Audit Committee comprises three independent non-executive Directors, namely Dr. LI Yuedong, Dr. TU Wenwei and Dr. JIN Jinping. 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 annual financial results of the Group for the year ended December 31, 2024 with the management and the auditor of the Company. The Audit Committee considered that the annual financial 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.

Scope of Work of the Company's Auditors

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

Final Dividend

The Board has resolved not to recommend the payment of a final dividend for the year ended December 31, 2024 (2023: Nil).

2024 AGM

An announcement containing information in relation to the latest registration date and the period of closure of the share register of the Company for attending the 2024 AGM of the Company will be published separately when the date of the 2024 AGM of the Company is fixed.

Publication of Annual Results Announcement and Annual Report

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

The annual report of the Company for the year ended December 31, 2024 containing all the information required by the Listing Rules will be despatched to the Shareholders who requested for printed copies and published on the websites of the Stock Exchange and the Company in due course.

DEFINITIONS

“2024 AGM”	the 2024 annual general meeting of the Company
“AACR”	American Association for Cancer Research
“ADC(s)”	antibody drug conjugate(s)
“ADCC”	antibody-dependent cell-mediated cytotoxicity
“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
“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 annual 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 Shareholder(s)”	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, 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 trastuzumab botidotin
“CRC”	colorectal cancer
“CRO”	contract research organization
“CRPC”	castration-resistant prostate cancer
“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)
“Director(s)”	the director(s) of the Company or any one of them
“Domestic Share(s)”	ordinary shares in the share capital of our Company, with a nominal value of RMB1.00 each, which are subscribed for and paid up in RMB

“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/FXI α ”	factor XI, a type of blood protein playing a role in aiding the blood to clot. Factor XI α , one of the enzymes of the coagulation cascade. FXI is the zymogen form of FXI α
“GC”	gastric cancer
“GEA”	gastroesophageal adenocarcinoma
“GEJ”	gastroesophageal junction
“GI”	gastrointestinal
“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\$”	Hong Kong dollars and cents respectively, 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)
“IND”	investigational new drug or investigational new drug application, also known as clinical trial application in China or the U.S.
“IRC”	independent review committee
“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
“Key Products”	SKB315, SKB410/MK-3120, SKB518, tagitanlimab, Cetuximab N01 and A400/EP0031
“LC”	lung cancer
“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 antibodies
“mCRC”	metastatic colorectal cancer

“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
“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” or “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 3,648,600 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 May 8, 2024
“Placing Agents”	Goldman Sachs (Asia) L.L.C., Citigroup Global Markets Limited and J.P. Morgan Securities (Asia Pacific) Limited
“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 year ended December 31, 2024
“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
“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
“Subscription”	the subscription of 4,423,870 new Domestic Shares by Kelun Pharmaceutical (as subscriber) pursuant to the terms and conditions of the subscription agreement entered into between the Company and the Kelun Pharmaceutical on May 8, 2024
“subsidiary(ies)”	has the meaning ascribed thereto under the Listing Rules
“Supervisor(s)”	supervisor(s) of the Company
“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
“Unlisted Foreign Share(s)”	unlisted ordinary Share(s) issued by the Company, with a nominal value of RMB1.00 each, which are subscribed for in a currency other than RMB
“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, March 24, 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, Mr. ZENG Xuebo and Mr. LI Dongfang as non-executive Directors, and Dr. ZHENG Qiang, Dr. TU Wenwei, Dr. JIN Jinping, and Dr. LI Yuedong as independent non-executive Directors.