Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.
四川科倫博泰生物醫藥股份有限公司

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

(Stock Code: 6990)

INTERIM RESULTS ANNOUNCEMENT FOR THE SIX MONTHS ENDED JUNE 30, 2024

The Board is pleased to announce the unaudited condensed consolidated interim results of the Group for the six months ended June 30, 2024, together with comparative figures for the six months ended June 30, 2023. The independent auditor of the Company has carried out a review of the interim financial information in accordance with the Hong Kong Standard on Review Engagements 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". Unless otherwise defined herein, capitalized terms used in this announcement shall have the same meanings as those defined in the Prospectus.

FINANCIAL HIGHLIGHTS

	Six months ended June 30,		
	2024	2023	Period to period change
	RMB'000	*RMB'000*	
	(Unaudited)	(Unaudited)	
Revenue	**1,382,791**	1,046,226	32.2%
Gross profit	**1,076,690**	675,660	59.4%
Research and development expenses	**652,337**	490,347	33.0%
Profit/(loss) for the period	**310,226**	(31,130)	N/A
Adjusted profit/(loss) for the period[1]	**385,636**	33,017	1,068.0%
	As at June 30, 2024	As at December 31, 2023	
Cash and financial assets[2]	**2,885,166**	2,488,349	15.9%

[1] *Calculated by deducting equity-settled share-based payment from profit/(loss) for the period.*

[2] *Comprises cash and cash equivalents, financial assets measured at fair value through profit or loss, and financial assets measured at amortized cost.*

BUSINESS HIGHLIGHTS

- **Key developments of our Core Product sac-TMT (sacituzumab tirumotecan) (formerly SKB264/MK-2870):**

  - **TNBC.** In December 2023, the NDA for sac-TMT in adult patients with unresectable locally advanced or metastatic TNBC who have received at least two prior systemic therapies (including at least one of them in the advanced or metastatic setting) was accepted by the CDE of the NMPA. The NDA was included in the priority review and approval process of the CDE in November 2023. 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 chemotheraphy for 1L advanced TNBC.

    The results from the phase 3 study of sac-TMT in patients with previously treated locally recurrent or metastatic TNBC presented at the 2024 ASCO Annual Meeting in May 2024 showed that sac-TMT demonstrated a significant statistically and clinically meaningful improvement in PFS and OS over chemotherapy. The median PFS was 6.7 months (95% CI, $p<0.00001$) with sac-TMT, and 2.5 months (95% CI, $p<0.00001$) with chemotherapy, and sac-TMT had a 68% lower risk of disease progression or death. The median OS was not reached ($p=0.0005$) with sac-TMT. The ORR was 45.4% with sac-TMT compared to 12% with chemotherapy. The subset of patients with high TROP2 expression had a higher median PFS of 8.3 months and ORR of 52.1% with sac-TMT.

  - **HR+/HER2- BC.** We initiated a phase 3 registrational study for 2L+ HR+/HER2- locally advanced or metastatic BC and commenced patient enrollment.

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

  - **EGFR-mutant NSCLC.** Registrational studies for 2L and 3L EGFR-mutant locally advanced or metastatic NSCLC are in progress.

    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. On August 14, 2024, it was announced on the official website of the CDE that NDA for sac-TMT monotherapy in adult patients with locally advanced or metastatic EGFR-mutant NSCLC who experience progression following treatment with an EGFR-TKI and platinum-based chemotherapy was planned to be included in the priority review and approval process of the CDE. On August 19, 2024, the NDA based on the positive results from the pivotal OptiTROP-Lung03 study of sac-TMT was accepted by the CDE of NMPA of China.

    Updated efficacy results from a phase 2 study of sac-TMT in patients with previously treated advanced NSCLC presented at the 2024 AACR Annual Meeting in April 2024 showed that for the subgroup of patients with EGFR-mutant NSCLC (which progressed on or after previous EGFR-TKI treatment and 50% of which also failed at least one line of chemotherapy), sac-TMT demonstrated an ORR of 60.0%, median PFS of 11.5 months and median OS of 22.7 months.

- **EGFR-wild type NSCLC.** We initiated a phase 3 registrational study on sac-TMT in combination with pembrolizumab (KEYTRUDA®) versus pembrolizumab for first-line treatment of patients with PD-L1 positive locally advanced or metastatic NSCLC. KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA. We have received approval from the CDE to initiate a phase 3 study on sac-TMT for first-line treatment of patients with PD-L1 negative non-squamous NSCLC.

  The results from the phase 2 study of sac-TMT in combination with KL-A167 as first-line treatment of patients with advanced NSCLC presented at the 2024 ASCO Annual Meeting showed that for patients who received sac-TMT plus KL-A167 Q3W, ORR was 48.6%, DCR was 94.6% and median PFS was 15.4 months; for patients who received sac-TMT plus KL-A167 Q2W, ORR was 77.6%, DCR was 100% and median PFS was not reached at the cutoff time.

  Updated efficacy results from a phase 2 study of sac-TMT in patients with previously treated advanced NSCLC presented at the 2024 AACR Annual Meeting in April 2024 showed that for the subgroup of patients with EGFR-wild type NSCLC (who had received a median of 3 prior regimens of therapy including anti-PD-(L)1 inhibitors), sac-TMT demonstrated an ORR of 26.3%, median PFS of 5.3 months and median OS of 14.1 months.

- **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, among others.

  Preliminary efficacy and safety results for sac-TMT from a phase 2 study of patients with previously treated advanced gastric or GEJ cancer (among which 50% had received one prior line of therapy (2L), 50% had received ≥ 2 prior lines of therapy (3L+) and 83.3% had received prior anti-PD-1/L1 inhibitors) presented at the 2024 AACR Annual Meeting showed an ORR of 22.0% and DCR of 80.5%.

- **Key developments of our Core Product A166 (trastuzumab botidotin):**

  - A166 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 in May 2023.

  - We are conducting a phase 3 trial in China for 2L+ advanced HER2+ BC, as well as multiple ongoing phase 1b clinical trials in China for other advanced HER2+ solid tumors which are making steady progress.

- **Key developments of our other ADC products:**

  - **SKB315.** We have carried out certain activities in support of MSD's global clinical development, including a phase 1a clinical trial of SKB315 in patients with advanced solid tumors in China.

  - **SKB410/MK-3120.** We are carrying out certain activities in support of MSD's global clinical development, including a phase 1a clinical trial of SKB410 in patients with advanced solid tumors in China.

- o **SKB518.** In June 2024, we received a clinical trial notice approving the IND application from the NMPA for SKB518. Patient enrollment of a phase 1 study is ongoing.

- **Key developments of our other Key Products:**

  - o **A167 (tagitanlimab).** We filed an NDA with the NMPA in November 2021 to market A167 as a 3L+ treatment for RM-NPC. In May 2024, an NDA for the phase 3 registrational study of A167 as a 1L treatment of NPC was accepted by the NMPA.

  - o **A140.** The NDA for the use of A140 for the treatment of RAS wild-type mCRC and HNSCC was accepted by the NMPA in September 2023.

  - o **A400.** We commenced pivotal trials for 1L & 2L+ advanced RET+ NSCLC and patient enrollment is in progress.

- **Key developments of our other products:**

  - o **A223.** We completed patient enrollment for phase 2 trials in patients with moderate-to-severe RA and are conducting a phase 2 trial in patients with severe AA in China.

  - o **A277.** We are conducting a phase 2 trial in patients with CKD-aP in China.

  - o **SKB378.** We completed phase 1 clinical trial in healthy subjects in China.

  - o **SKB336.** We completed phase 1 clinical trial in healthy subjects in China.

  - o **A296.** We initiated a phase 1 trial in China. The phase 1 trial is in dose escalation phase and making steady progress.

- **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 our Core Products, sac-TMT (佳泰莱®) and A166 (舒泰莱®), and our Key Products, A167 (科泰莱®) and A140 (达泰莱®)[3], in the China market in the second half of 2024 or the first half of 2025. We have set up a fully-fledged commercialization team to prepare and implement the marketing and commercialization of our strategic products. We have established a departmental structure within the Company, consisting of various departments such as Marketing, Access and Distribution, 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 also continue to pursue a flexible strategy to capture the commercial value in major international markets, through forging synergistic license and collaboration opportunities worldwide.

[3] *Trade name to be determined by NMPA approval.*

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

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

    - ***Sac-TMT***: We have granted MSD an exclusive, royalty-bearing and sub-licensable license to develop, use, manufacture and commercialize sac-TMT outside Greater China and retain the right to develop, manufacture and commercialize sac-TMT within Greater China. As of June 30, 2024, MSD has initiated ten ongoing phase 3 global clinical studies of sac-TMT as a monotherapy or with pembrolizumab or other agents for several indications:

      - *TNBC.* Sac-TMT plus pembrolizumab versus TPC in TNBC who received neoadjuvant therapy and did not achieve a pathological complete response (pCR) at surgery;

      - *HR+/HER2- BC*. 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);

      - *NSCLC.*

        - 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 and 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;

      - *EC*. Sac-TMT monotherapy versus chemotherapy for the treatment of EC who have received prior platinum-based chemotherapy and immunotherapy;

      - *CC*. Sac-TMT monotherapy versus TPC as second-line treatment for participants with recurrent or metastatic CC; and

§ *GEA*. Sac-TMT in 3L+ advanced/metastatic gastroesophageal adenocarcinoma.

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 ***Early-stage ADC assets***: In addition to sac-TMT, we are also collaborating with MSD on certain early-stage clinical and preclinical ADC assets to continuously explore favorable ADC pipeline portfolios. On one hand, we aim to cover a wide range of tumor indications through our ADC pipelines with different targets, while on the other hand, we aim to apply differentiated payload-linker strategies for ADC assets with different targets to achieve better efficacy and/or differentiated safety profiles, and explore the combination of ADCs with different strategies. 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 licensed and option ADCs for mainland China, Hong Kong and Macau.

Based on the above strategy, we have been adjusting and optimizing our scope of collaboration with MSD regarding the early-stage pipelines from time to time, to gradually form a favorable early-stage licensing pipeline portfolio which complements sac-TMT and other late-stage ADC pipelines from the perspective of our partner's global commercialization in the future. We were informed recently by MSD with regard to an exclusive option exercise of SKB571. MSD shall pay US$37.5 million to the Company in connection with the option 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 if commercialized. The Company will retain the right to develop, use, manufacture and commercialize SKB571 in mainland China, Hong Kong and Macau. At the same time of exercising the option in respect of SKB571, MSD returned to the Company the global rights to develop, use, manufacture and commercialize SKB315, and the Company is not obliged to return any upfront and milestone payments received from MSD in respect of this asset. In addition, we plan to submit IND applications for other preclinical ADC assets already under licensed collaboration with MSD in the near future, and continue to explore new collaboration opportunities with MSD.

SKB571 is a novel bsAb ADC that primarily targets various solid tumors such as lung cancer and gastrointestinal tumors. Through a scientific selection of target combinations and a differentiated design of bsAb molecules, it is designed to enhance tumor targeting and help overcome tumor heterogeneity, thereby improving efficacy. By utilizing the high hydrophilicity drug-linker strategy of the OptiDC™ platform, this asset not only possesses a uniform DAR value but also exhibits good in vivo pharmacokinetic properties. Preclinical studies have demonstrated promising anti-tumor efficacy and a good safety profile of this asset in multiple patient-derived xenograft (PDX) models and cynomolgus monkeys, respectively. An IND application for this asset is expected to be submitted in the near future.

The early-stage clinical data of SKB315 demonstrates positive efficacy and acceptable safety profile in GC with high CLDN18.2 expression, and we expect to present relevant data at upcoming academic conferences. Given the significant population of GC patients in China, we have confidence in the market prospects of SKB315 in China. We will continue to expedite its development in China and explore suitable expansion into overseas markets.

The Company has received milestone payments totaling US$90.0 million (equivalent to approximately RMB641.4 million[4]) from MSD with regard to multiple collaborated pipelines in the first half of this year.

- ***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. A400 is known as EP0031 by Ellipses Pharma.

  In November 2023, A400/EP0031 was granted Orphan Drug Designation by the FDA for the treatment of RET fusion-positive solid tumors. In March 2024, 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. Clinical trial applications of A400/EP0031 were approved by the UAE agency in April 2024. As of June 30, 2024, a total of 25 clinical sites in the United States and Europe were set up for A400/EP0031.

- **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 (equivalent to approximately RMB491.6 million[5]).

[4] *Based on the exchange rate of US$1: RMB7.1268 published by the State Administration of Foreign Exchange of the PRC on June 28, 2024 for illustration purpose.*

[5] *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.*

- **Subscription of New Domestic Shares.** 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. The estimated net proceeds from the Subscription is expected to be approximately RMB601.1 million, equivalent to approximately HK$661.9 million[6]. The independent Shareholders approved the Subscription at the 2023 annual general meeting of the Company on June 20, 2024. As at the date of this announcement, the Company is in the process of obtaining the required regulatory approvals for the Subscription and completion of the Subscription has not taken place.

[6] *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.*

INTERIM RESULTS

Consolidated statement of profit or loss
for the six months ended June 30, 2024 – unaudited
(Expressed in Renminbi ("RMB"))

	Note	Six months ended June 30, **2024**	2023
		RMB'000	*RMB'000*
Revenue	3	**1,382,791**	1,046,226
Cost of sales		**(306,101)**	(370,566)
Gross profit		**1,076,690**	675,660
Other net income		**94,395**	24,120
Administrative expenses		**(65,839)**	(89,424)
Selling and distribution expenses		**(41,151)**	–
Research and development expenses		**(652,337)**	(490,347)
Profit from operations		**411,758**	120,009
Finance costs		**(2,507)**	(78,732)
Profit before taxation		**409,251**	41,277
Income tax	4	**(99,025)**	(72,407)
Profit/(loss) for the period attributable to equity shareholders of the Company		**310,226**	(31,130)
Earnings/(loss) per share	5		
Basic and diluted (RMB)		**1.41**	(0.17)

Consolidated statement of profit or loss and other comprehensive income for the six months ended June 30, 2024 – unaudited
(Expressed in RMB)

	Note	Six months ended June 30, 2024	2023
		RMB'000	*RMB'000*
Profit/(loss) for the period		**310,226**	(31,130)
Other comprehensive income for the period (after tax)			
Item that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of financial statements of an overseas subsidiary		**1,337**	9,277
Other comprehensive income for the period		**1,337**	9,277
Total comprehensive income for the period attributable to equity shareholders of the Company		**311,563**	(21,853)

Consolidated statement of financial position
at June 30, 2024 – unaudited
(Expressed in RMB)

	Note	**As at June 30, 2024** ***RMB'000***	As at December 31, 2023 *RMB'000*
Non-current assets			
Property, plant and equipment		**600,385**	607,783
Right-of-use assets		**63,435**	84,950
Intangible assets		**2,453**	1,336
Other non-current assets		**10,491**	8,199
		676,764	702,268
Current assets			
Inventories		**60,912**	63,032
Trade and other receivables	6	**197,676**	214,761
Amounts due from related parties		**1,866**	1,352
Financial assets measured at fair value through profit or loss ("FVPL")		**371,543**	633,705
Financial assets measured at amortized cost		**383,327**	325,870
Restricted deposits	7	**12,306**	39,993
Cash and cash equivalents	7	**2,130,296**	1,528,774
		3,157,926	2,807,487
Current liabilities			
Trade and other payables	8	**490,103**	523,477
Amounts due to related parties		**26,629**	21,429
Contract liabilities		**2,686**	510,692
Lease liabilities		**34,353**	54,406
		553,771	1,110,004
Net current assets		**2,604,155**	1,697,483
Total assets less current liabilities		**3,280,919**	2,399,751

Consolidated statement of financial position
at June 30, 2024 – unaudited (continued)
(Expressed in RMB)

	Note	**As at June 30, 2024** ***RMB'000***	As at December 31, 2023 *RMB'000*
Non-current liabilities			
Lease liabilities		**3,886**	5,513
Deferred income		**67,848**	64,741
		71,734	70,254
NET ASSETS		**3,209,185**	2,329,497
CAPITAL AND RESERVES			
Share capital	9	**222,845**	219,196
Reserves	9	**2,986,340**	2,110,301
TOTAL EQUITY		**3,209,185**	2,329,497

Consolidated statement of changes in equity
for the six months ended June 30, 2024 – unaudited
(Expressed in RMB)

	Share capital *RMB'000*	Capital reserves *RMB'000*	Exchange reserves *RMB'000*	Accumulated losses *RMB'000*	Total *RMB'000*
Balance at January 1, 2023	107,370	147,877	749	(3,482,182)	(3,226,186)
Changes in equity for the six months ended June 30, 2023					
Loss for the period	–	–	–	(31,130)	(31,130)
Exchange differences on translation of financial statements of an overseas subsidiary	–	–	9,277	–	9,277
Total comprehensive income	–	–	9,277	(31,130)	(21,853)
Issuance of new shares	59,937	2,598,744	–	–	2,658,681
Issuance of shares with preferential rights	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)
Equity-settled share-based payment	–	64,147	–	–	64,147
Balance at June 30, 2023 and July 1, 2023	193,383	2,784,692	10,026	(3,513,312)	(525,211)

Consolidated statement of changes in equity
for the six months ended June 30, 2024 – unaudited (continued)
(Expressed in RMB)

	Share capital *RMB'000*	Capital reserves *RMB'000*	Exchange reserves *RMB'000*	Accumulated losses *RMB'000*	Total *RMB'000*
Balance at July 1, 2023	193,383	2,784,692	10,026	(3,513,312)	(525,211)
Changes in equity for the six months ended December 31, 2023					
Loss for the period	–	–	–	(543,004)	(543,004)
Exchange differences on translation of financial statements of an overseas subsidiary	–	–	(4,484)	–	(4,484)
Total comprehensive income	–	–	(4,484)	(543,004)	(547,488)
Issuance of ordinary shares by initial public offering and over-allotment, net of issuing costs	25,813	1,336,861	–	–	1,362,674
Reclassification of financial liabilities recognized for preferential rights issued to investors to equity	–	1,980,323	–	–	1,980,323
Equity-settled share-based payment	–	59,199	–	–	59,199
Balance at December 31, 2023	219,196	6,161,075	5,542	(4,056,316)	2,329,497

	Note	Share capital *RMB'000*	Capital reserves *RMB'000*	Exchange reserves *RMB'000*	Accumulated losses *RMB'000*	Total *RMB'000*
Balance at January 1, 2024		219,196	6,161,075	5,542	(4,056,316)	2,329,497
Changes in equity for the six months ended June 30, 2024						
Profit for the period		–	–	–	310,226	310,226
Exchange differences on translation of financial statements of an overseas subsidiary		–	–	1,337	–	1,337
Total comprehensive income		–	–	1,337	310,226	311,563
Issuance of new shares	9	3,649	489,066	–	–	492,715
Equity-settled share-based payment		–	75,410	–	–	75,410
Balance at June 30, 2024		222,845	6,725,551	6,879	(3,746,090)	3,209,185

Condensed consolidated statement of cash flows
for the six months ended June 30, 2024 – unaudited
(Expressed in RMB)

	Note	Six months ended June 30, 2024 ***RMB'000***	2023 *RMB'000*
Operating activities			
Net cash (used in)/generated from operating activities		**(68,912)**	471,080
Investing activities			
Payment for the purchase of property, plant and equipment		**(35,218)**	(32,130)
Proceeds from disposal of property, plant and equipment		**16**	3
Payment for intangible assets		**(2,194)**	(1,137)
Payment for investment in financial assets measured at FVPL		**(950,000)**	(1,380,000)
Proceeds from redemption of financial assets measured at FVPL		**1,219,427**	651,635
Payment for investment in financial assets measured at amortized cost		**(103,102)**	(270,000)
Proceeds from disposals of financial assets measured at amortized cost		**50,801**	–
Net cash generated from/(used in) investing activities		**179,730**	(1,031,629)
Financing activities			
Proceeds from issuance of new shares	9	**492,847**	158,681
Capital element of lease rentals paid		**(20,368)**	(37,663)
Interest element of lease rentals paid		**(2,454)**	(5,590)
Repayment of bank loans		**–**	(100,000)
Repayment of other borrowings from Sichuan Kelun Pharmaceutical Co., Ltd.		**–**	(294,040)
Proceeds from issuance of shares with preferential rights		**–**	1,323,475
Interest paid		**–**	(563)
Net cash generated from financing activities		**470,025**	1,044,300
Net increase in cash and cash equivalents		**580,843**	483,751
Cash and cash equivalents at January 1		**1,528,774**	92,960
Effect of foreign exchange rate changes		**20,679**	10,550
Cash and cash equivalents at June 30		**2,130,296**	587,261

NOTES TO THE UNAUDITED INTERIM FINANCIAL REPORT

(Expressed in thousands of RMB, unless otherwise indicated)

1 BASIS OF PREPARATION

This interim financial report has been prepared in accordance with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, including compliance with Hong Kong Accounting Standard ("HKAS") 34, *Interim financial reporting*, issued by the Hong Kong Institute of Certified Public Accountants ("HKICPA"). It was authorised for issue on August 19, 2024.

The interim financial report has been prepared in accordance with the same accounting policies adopted in the 2023 annual financial statements except for the accounting policy changes that are expected to be reflected in the 2024 annual financial statements. Details of any changes in accounting policies are set out in note 2.

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

This interim financial report contains condensed consolidated financial statements and selected explanatory notes. The notes include an explanation of events and transactions that are significant to an understanding of the changes in financial position and performance of the Group since the 2023 annual financial statements. The condensed consolidated interim financial statements and notes thereon do not include all of the information required for a full set of financial statements prepared in accordance with IFRS Accounting Standards.

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

2 CHANGES IN ACCOUNTING POLICIES

The Group has applied the following amendments to IFRS Accounting Standards issued by the International Accounting Standards Board to this interim financial report for the current accounting period:

- Amendments to IAS 1, *Presentation of financial statements: Classification of liabilities as current or non-current ("2020 amendments")*
- Amendments to IAS 1, *Presentation of financial statements: Non-current liabilities with covenants ("2022 amendments")*
- Amendments to IFRS 16, *Leases: Lease liability in a sale and leaseback*
- Amendments to IAS 7, *Statement of cash flows* and IFRS 7, *Financial instruments: Disclosures – Supplier finance arrangements*

The Group has not applied any new standard or interpretation that is not yet effective for the current accounting period. Impacts of the adoption of the amended IFRS accounting standards are discussed below:

Amendments to IAS 1, Presentation of financial statements ("2020 and 2022 amendments", or collectively the "IAS 1 amendments")

The IAS 1 amendments impact the classification of a liability as current or non-current, and are applied retrospectively as a package.

The 2020 amendments primarily clarify the classification of a liability that can be settled in its own equity instruments. If the terms of a liability could, at the option of the counterparty, result in its settlement by the transfer of the entity's own equity instruments and that conversion option is accounted for as an equity instrument, these terms do not affect the classification of the liability as current or non-current. Otherwise, the transfer of equity instruments would constitute settlement of the liability and impact classification.

The 2022 amendments specify that conditions with which an entity must comply after the reporting date do not affect the classification of a liability as current or non-current. However, the entity is required to disclose information about non-current liabilities subject to such conditions in a full set of financial statements.

Upon the adoption of the amendments, the Group has reassessed the classification of its liabilities as current or non-current and did not identify any material reclassification to be made.

Amendments to IFRS 16, Leases: Lease liability in a sale and leaseback

The amendments clarify how an entity accounts for a sale and leaseback after the date of the transaction. The amendments require the seller-lessee to apply the general requirements for subsequent accounting of the lease liability in such a way that it does not recognise any gain or loss relating to the right of use it retains. A seller-lessee is required to apply the amendments retrospectively to sale and leaseback transactions entered into after the date of initial application. The amendments do not have a material impact on these financial statements as the Group has not entered into any sale and leaseback transactions.

Amendments to IAS 7, Statement of cash flows and IFRS 7, Financial instruments: Disclosures – Supplier finance arrangements

The amendments introduce new disclosure requirements to enhance transparency of supplier finance arrangements and their effects on an entity's liabilities, cash flows and exposure to liquidity risk. The amendments do not have a material impact on these financial statements as the Group has not entered into any supplier finance arrangements.

3 REVENUE AND SEGMENT REPORTING

(a) Revenue

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

Disaggregation of revenue

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

	Six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
Revenue from contracts with customers within the scope of IFRS 15		
Revenue from license and collaboration agreements	**1,377,978**	1,040,171
Revenue from provision of research and development service	**4,813**	6,055
	1,382,791	1,046,226

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

	Six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
Disaggregated by timing of revenue recognition		
Point in time	**929,313**	759,992
Over time	**453,478**	286,234
	1,382,791	1,046,226

4 INCOME TAX

	Six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
Current tax		
Provision for the period		
– The PRC Corporate Income Tax	**–**	–
– Withholding Tax	**99,025**	72,407
	99,025	72,407

(i) PRC Corporate Income Tax

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

According to the PRC Corporate Income Tax Law and its relevant regulations, entities that qualified as high-technology enterprise are entitled to a preferential income tax rate of 15%. The Company obtained its certificate of high-technology enterprise on December 3, 2020 and October 16, 2023 respectively and is entitled to preferential income tax of 15% from 2020 to 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 period. There were no assessable profits generating from the subsidiary incorporated in Hong Kong of the Group during the six months ended June 30, 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税和防止偷漏税的協定), 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.

5 EARNINGS/LOSS PER SHARE

(a) Basic earnings/loss per share

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

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

	Six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
Profit/(loss) for the period attributable to ordinary equity shareholders	**310,226**	(31,130)
Allocation of earnings/loss for the period attributable to financial instruments issued to investors	**–**	5,753
Profit/(loss) for the period attributable to ordinary equity shareholders of the Company for the purpose of basic loss per share	**310,226**	(25,377)

(ii) Weighted average number of shares

	Six months ended June 30,	
	2024	2023
Issued ordinary shares at January 1	**219,195,499**	107,369,609
Effect of issuance of new shares	**902,126**	79,385,562
Effect of the financial instruments issued to investors	**–**	(34,515,234)
Weighted average number of ordinary shares at June 30	**220,097,625**	152,239,937

Effect of the financial instruments issued to investors represents the weighted average number of ordinary shares of the Company that are subject to redemption and excluded from the calculation of the basic loss per share.

(b) Diluted earnings/loss per share

The calculation of diluted earnings/loss per share is based on the profit/loss attributable to ordinary equity shareholders of the Company and the weighted average number of ordinary shares. The profit/loss attributable to ordinary equity shareholders of the Company used in diluted earnings/loss per share calculation were determined to be the same as those used in basic earnings/loss per share calculation for the period.

Accordingly, diluted earnings per share for the six months ended June 30, 2024 are the same as basic earnings per share.

6 TRADE AND OTHER RECEIVABLES

	As at June 30, 2024	As at December 31, 2023
	RMB'000	*RMB'000*
Trade receivables	**22,379**	–
Other receivables	**8,009**	16,294
Value Added Tax ("VAT") recoverable	**131,157**	106,802
Prepayments	**35,595**	56,017
Prepaid tax	**536**	35,648
	197,676	214,761

(a) Ageing analysis

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

	As at June 30, 2024	As at December 31, 2023
	RMB'000	*RMB'000*
Within 3 months (inclusive)	**22,379**	–

Trade debtors are due within 45 days from the date of billing.

7 CASH AND CASH EQUIVALENTS

	Note	**As at June 30, 2024** ***RMB'000***	As at December 31, 2023 *RMB'000*
Cash at bank		**2,142,602**	1,568,767
Less: restricted bank deposits	(i)	**(12,306)**	(39,993)
Cash and cash equivalents in the consolidated statements of financial position		**2,130,296**	1,528,774

(i) Restricted bank deposits are pledged deposits for issuance of bills payable. The pledged deposits will be released upon the settlement of relevant bills payable.

8 TRADE AND OTHER PAYABLES

	As at June 30, 2024 ***RMB'000***	As at December 31, 2023 *RMB'000*
Trade payables	**223,209**	315,501
Bills payable	**173,683**	67,449
Accrued payroll and benefits	**88,011**	133,773
Other taxes payable	**3,707**	3,725
Other payables	**1,493**	3,029
	490,103	523,477

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

	As at June 30, 2024 ***RMB'000***	As at December 31, 2023 *RMB'000*
Within 1 year	**375,697**	365,199
1 to 2 years	**20,969**	16,798
2 to 3 years	**170**	349
More than 3 years	**56**	604
	396,892	382,950

9 CAPITAL, RESERVES AND DIVIDENDS

(a) Capital and reserves

On May 16, 2024, the Company issued an aggregate of 3,649,000 new H shares at an offer price of HK$150.0 per share pursuant to a Placing Agreement entered into by the Company and the placing agents. The net proceeds (after deducting the commissions and expenses) from the Placing amounted to approximately HK$541.4 million (equivalent to RMB492,715,000).

Accordingly, the Company recorded RMB3,649,000 in share capital and the remaining RMB489,066,000 in capital reserves.

(b) Dividends

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

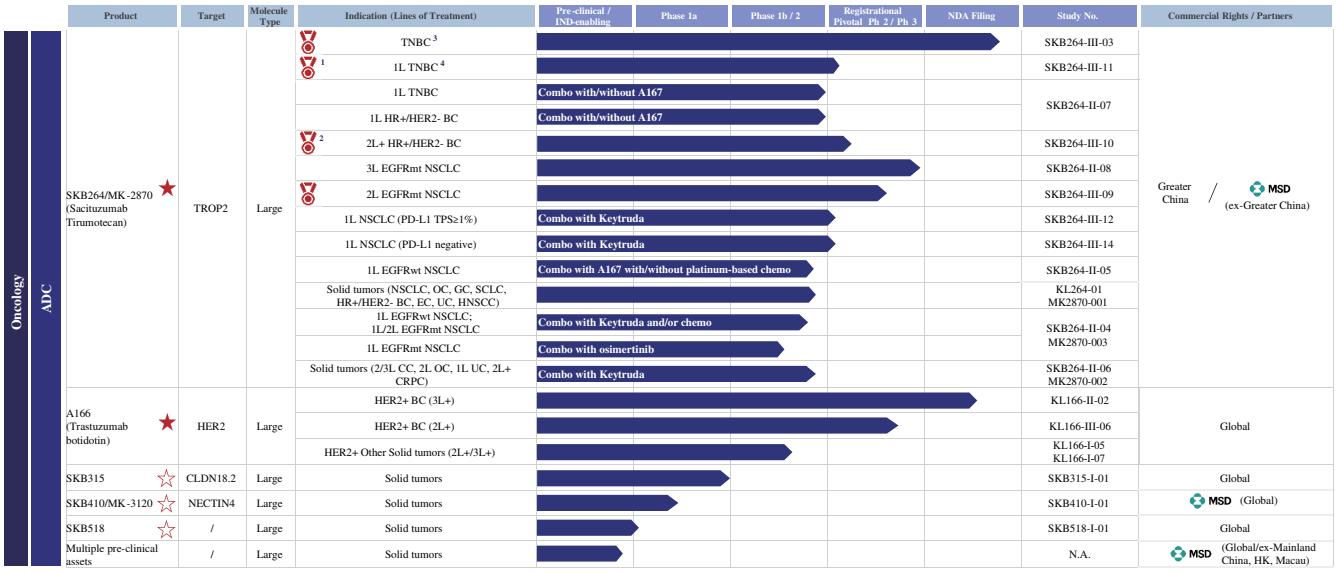
MANAGEMENT DISCUSSION AND ANALYSIS

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 antibody drug conjugate (ADC) drugs as our Core Products, namely, sac-TMT and A166. Sac-TMT is a novel NDA-stage TROP2 ADC positioned as a monotherapy and part of combination therapies for treating various advanced solid tumors. A166 is a differentiated NDA-stage HER2 ADC positioned as a monotherapy to treat advanced HER2-positive (HER2+) solid tumors. As at the date of this announcement, we were developing more than 30 candidates in our pipeline. 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.

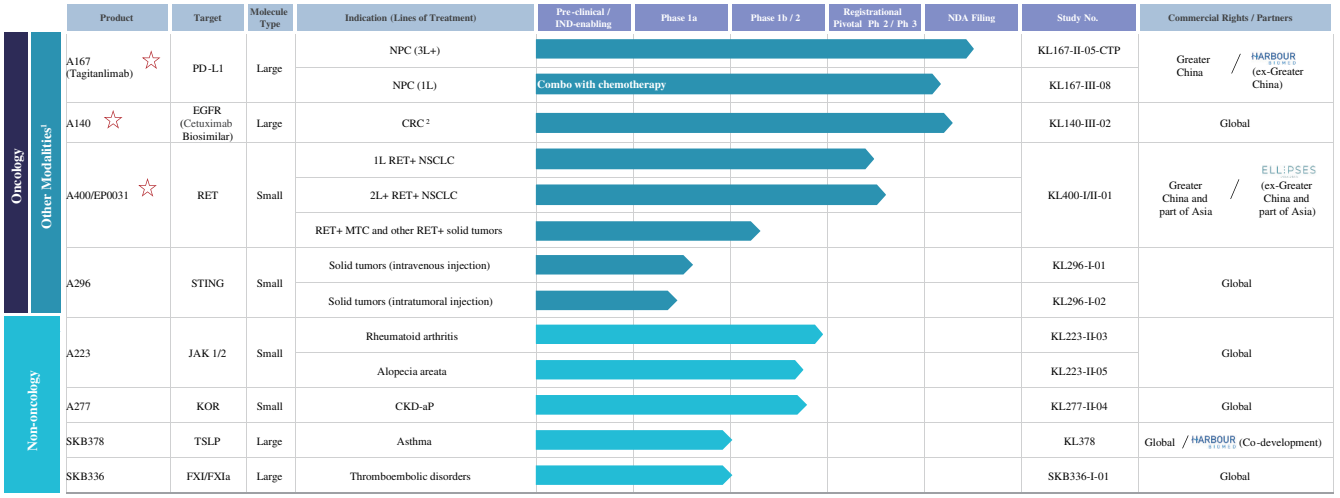
The pipeline chart below summarizes the development status of our main clinical-stage drug candidates and selected pre-clinical assets as at the date of this announcement.



Abbreviations: TNBC: triple-negative breast cancer; BC: breast cancer; NSCLC: non-small-cell lung cancer; NPC: nasopharyngeal cancer; GC: gastric cancer; OC: ovarian cancer; SCLC: small-cell lung cancer; UC: urothelial cancer; HNSCC: head and neck squamous cell carcinoma; EC: endometrial cancer; CC: cervical cancer; CRPC: castration-resistant prostate cancer; CRC: colorectal cancer; MTC: medullary thyroid cancer

Note: [1] In March 2024, SKB264 was granted Breakthrough Therapy Designation for first-line treatment of unresectable locally advanced, recurrent or metastatic PD-L1 negative TNBC; [2] In June 2023, SKB264 was granted Breakthrough Therapy Designation for locally advanced or metastatic HR+/HER2- BC who have previously received at least 2L systematic chemotherapy; [3] Used 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); [4] including participants whose tumor are PD-L1 negative, or PD-L1 positive and have relapsed after prior anti-PD-(L)1 inhibitor.

★ Core Products ☆ Key Products Breakthrough Designation



Abbreviations: TNBC: triple-negative breast cancer; BC: breast cancer; NSCLC: non-small-cell lung cancer; NPC: nasopharyngeal cancer; GC: gastric cancer; OC: ovarian cancer; SCLC: small-cell lung cancer; UC: urothelial cancer; HNSCC: head and neck squamous cell carcinoma; EC: endometrial cancer; CC: cervical cancer; CRPC: castration-resistant prostate cancer; CRC: colorectal cancer; MTC: medullary thyroid cancer

Note: [1] Including immunotherapy and targeted therapies; [2] No phase 2 clinical trial is required for biosimilar drug candidates in China.

★ Core Products ☆ Key Products Breakthrough Designation

WE MAY NOT BE ABLE TO SUCCESSFULLY DEVELOP AND/OR MARKET OUR CORE PRODUCTS, OR ANY OF OUR DRUG CANDIDATES.

Supported by three in-house developed technology platforms with proprietary know-how in ADCs, biologics (monoclonal antibodies (mAbs) and bispecific antibodies (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 current good manufacturing practice (cGMP)-compliant, end-to-end manufacturing capabilities and a comprehensive quality control 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 three license and collaboration agreements with MSD to develop multiple ADC assets for cancer treatment including clinical-stage ADC assets (including the Group's Core Product sac-TMT and Key Products SKB410) and preclinical ADC assets. 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. 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 breast cancer (BC), non-small cell lung cancer (NSCLC), gastrointestinal (GI) cancers (including gastric cancer (GC) and colorectal cancer (CRC)), 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 over 10 clinical-stage drug candidates. We have also assembled a diverse portfolio of preclinical assets, including multiple (of which the majority are ADC and ADC-derivative assets) proposed for Investigational New Drug (IND) filing in 2024, 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:***
  - ***Sac-TMT (sacituzumab tirumotecan) (formerly SKB264/MK-2870)***, one of our Core Products, a novel TROP2 ADC targeting advanced solid tumors;
  - ***A166 (trastuzumab botidotin),*** another Core Product, a differentiated HER2 ADC in NDA registration stage to treat advanced HER2+ solid tumors;
  - ***SKB315***, a novel CLDN18.2 ADC targeting advanced solid tumors;
  - ***SKB410/MK-3120***, a novel Nectin-4 ADC targeting advanced solid tumors; and
  - ***SKB518***, a novel ADC drug targeting advanced solid tumors;
- ***Other modalities (Immunotherapies and Targeted Therapies):***
  - ***A167 (tagitanlimab)***, our PD-L1 mAb, which is expected to be the backbone of our immunotherapy franchise;
  - ***A140***, a biosimilar of EGFR mAb cetuximab, which has the potential to be the first cetuximab biosimilar approved in China;
  - ***A400***, a novel next-generation selective RET inhibitor, which is positioned to be the first domestically developed next-generation selective RET inhibitor for NSCLC, MTC and other solid tumors with a high prevalence of RET alterations; and
  - ***A296***, a novel second-generation small molecule stimulator of interferon genes (STING) agonist with a differentiating molecular design, which 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.

Sac-TMT (sacituzumab tirumotecan) (formerly SKB264/MK-2870)

Sac-TMT, one of our Core Products, is a novel human trophoblast cell-surface antigen 2 (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, and many other solid tumor types. Positioned to be the first domestically developed TROP2 ADC in China to be commercialized, 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 drug-to-antibody-ratio (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:

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 August 2023, we announced that the randomized, controlled, open-label, multi-center phase 3 clinical trial of sac-TMT versus investigator selected regimens in patients with unresectable locally advanced, recurrent or metastatic triple-negative breast cancer (TNBC) who have failed second-line or above prior standard of care met the primary endpoint of progression-free survival as assessed by the independent review committee. Based on the results from the interim analysis, the Company submitted the new drug application (NDA) for sac-TMT to the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China. The NDA was included in the priority review and approval process of the CDE in November 2023 and the NDA was accepted in December 2023.

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-1 ligand 1 (PD-L1) negative TNBC. We have initiated a phase 3 registrational study of sac-TMT monotherapy versus investigator-choice chemotherapy for 1L advanced TNBC.

Our results from the phase 3 study of sac-TMT in patients with previously treated locally recurrent or metastatic TNBC were presented at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting in May 2024. Sac-TMT demonstrated a significant statistically and clinically meaningful improvement in progression-free survival (PFS) and overall survival (OS) over chemotherapy. The median PFS, as assessed by BICR, was 6.7 months (95% CI, 5.5 to 8.0, $p<0.00001$) with sac-TMT and 2.5 months (95% CI, 1.7 to 2.7, $p<0.00001$) with chemotherapy, and sac-TMT had a 68% lower risk of disease progression or death. The median OS, as assessed by BICR, was not reached ($p=0.0005$) with sac-TMT. Objective response rate (ORR) was 45% with sac-TMT compared to 12% with chemotherapy. The subset of patients with high TROP2 expression (TROP H-score > 200) had a higher median PFS of 8.3 months and ORR of 52.1% with sac-TMT.

HR+/HER2- BC. We initiated a phase 3 registrational study for 2L+ HR+/HER2- locally advanced or metastatic BC and commenced patient enrollment.

Sac-TMT was granted Breakthrough Therapy Designation by the NMPA for locally advanced or metastatic hormone receptor positive (HR+) and human epidermal growth factor receptor 2-negative (HER2-) BC who have previously received at least 2L systemic chemotherapy in June 2023.

Data from a phase 1/2 clinical trial evaluating sac-TMT for previously-treated patients with HR+/HER2- BC was presented at the 2023 European Society for Medical Oncology (ESMO) Congress on October 22, 2023 and showed that sac-TMT had an ORR of 36.8%, disease control rate (DCR) of 89.5% and median PFS of 11.1 months.

EGFR-mutant NSCLC. We commenced registrational studies for 3L epidermal growth factor receptor (EGFR)-mutant locally advanced or metastatic NSCLC which are making steady progress. A phase 3 study led by the Company evaluating sac-TMT in patients with 2L EGFR mutant NSCLC in China is ongoing.

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-tyrosine kinase inhibitor (TKI). On August 14, 2024, it was announced on the official website of the CDE that NDA for sac-TMT monotherapy in adult patients with locally advanced or metastatic EGFR-mutant NSCLC who experience progression following treatment with an EGFR-TKI and platinum-based chemotherapy was planned to be included in the priority review and approval process of the CDE. On August 19, 2024, the NDA based on the positive results from the pivotal OptiTROP-Lung03 study of sac-TMT was accepted by the CDE of NMPA of China.

Efficacy results from a phase 2 study of sac-TMT in patients with previously treated advanced NSCLC presented at the 2024 American Association for Cancer Research (AACR) Annual Meeting showed that for the subgroup of patients with EGFR-mutant NSCLC (which progressed on or after previous EGFR-TKI treatment and 50% of which also failed at least one line of chemotherapy), sac-TMT demonstrated an ORR of 60.0% and median PFS of 11.5 months.

EGFR-wild type NSCLC. We initiated a phase 3 registrational study on sac-TMT in combination with pembrolizumab (KEYTRUDA®) versus pembrolizumab for first-line treatment of patients with PD-L1 positive locally advanced or metastatic NSCLC in June 2024. KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA. We have received approval from the CDE to initiate a phase 3 study on sac-TMT for first-line treatment of patients with PD-L1 negative non-squamous NSCLC.

Our results from the phase 2 study of sac-TMT in combination with KL-A167 as first-line treatment for patients with advanced NSCLC presented at the 2024 ASCO Annual Meeting showed that for patients who received sac-TMT plus KL-A167 Q3W, ORR was 48.6%, DCR was 94.6% and median PFS was 15.4 months; for patients who received sac-TMT plus KL-A167 Q2W, ORR was 77.6%, DCR was 100% and median PFS was not reached at the cutoff time.

Updated efficacy results from a phase 2 study of sac-TMT in patients with previously treated advanced NSCLC presented at the 2024 AACR Annual Meeting in April 2024 showed that for the subgroup of patients with EGFR-wild type NSCLC (who had received a median of 3 prior regimens of therapy including anti-PD-(L)1 inhibitors), sac-TMT demonstrated an ORR of 26.3%, median PFS of 5.3 months and median OS of 14.1 months.

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, endometrial carcinoma (EC), cervical cancer (CC), ovarian cancer (OC), urothelial cancer (UC), castration-resistant prostate cancer (CRPC) and head and neck squamous cell carcinoma (HNSCC), among others.

Preliminary efficacy and safety results for sac-TMT from a phase 2 study of patients with previously treated advanced gastric or gastroesophageal junction (GEJ) cancer (among which 50% had received one prior line of therapy (2L), 50% had received ≥ 2 prior lines of therapy (3L+) and 83.3% had received prior anti-PD-1/L1 inhibitors) presented at the 2024 AACR Annual Meeting showed an ORR of 22.0% and DCR of 80.5%.

Global collaboration with MSD

In May 2022, we granted MSD exclusive development and commercialization rights for sac-TMT outside Greater China. As of June 30, 2024, MSD has initiated ten ongoing phase 3 global clinical studies of sac-TMT as a monotherapy or in combination with pembrolizumab or other agents for NSCLC, BC, GC, EC and CC. 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.

SACITUZUMAB TIRUMOTECAN (SAC-TMT) MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

A166 (Trastuzumab Botidotin)

A166, 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 and GI cancers, with the potential to be one of the first domestically developed ADCs for HER2+ BC in China.

A166 is armed with a highly cytotoxic payload that can exert potent tumor cell killing at a low drug-to-antibody ratio (DAR). Coupled with a uniformly low DAR, achieved via our site-specific conjugation technology, this design potentially ensures the safety of A166 by enhancing ADC stability and reducing premature payload release in blood circulation, while maintaining robust anti-tumor potency.

Configured with a potent cytotoxic payload, clinically proven mAb and site-specific conjugation technology, A166 demonstrated promising efficacy in heavily pretreated advanced HER2+ BC patients with an ORR of 73.9% at recommended phase 2 dose (RP2D) and in advanced HER2+ GC patients with an ORR of 31.3%, based on results from our phase 1 dose expansion study and preliminary results from our ongoing phase 1b trial in China. A166 also showed a differentiated safety profile from that of Kadcyla®, Enhertu® and Aidixi®, the only three United States Food and Drug Administration (FDA) and/or NMPA-approved HER2 ADCs as at June 30, 2024, with lower incidence of haematological, GI and lung toxicities in non-head-to-head, cross-trial comparisons. Although A166 demonstrated higher incidences of ocular and peripheral nerve-related toxicities, they were reversible and generally manageable[1]. This suggests the potential of A166 to widen the treatment options available to advanced HER2+ solid tumor patients with different susceptibility to adverse drug reactions.

We have designed a multi-indication clinical development plan to advance A166 in China. A166 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 addition, we are exploring the therapeutic potential of A166 compared with T-DM1 in an ongoing phase 3 trial in China for 2L+ advanced HER2+ BC which we initiated in June 2023, as well as in multiple ongoing phase 1b clinical trials in China for other advanced HER2+ solid tumors which are making steady progress.

A166 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

SKB315

SKB315 is a novel CLDN18.2 ADC designed for treating advanced solid tumors. Configured with a proprietary, in-house developed humanized CLDN18.2 mAb and a differentiated payload-linker design, SKB315 is among the tier of fastest-advancing ADCs globally with the same target.

CLDN18.2 is highly expressed in prevalent and lethal cancers with limited effective treatments such as GC and pancreatic cancer, while its normal expression is restricted to gastric mucosa. This selective expression makes CLDN18.2 a promising drug target, highlighted by the positive clinical results of zolbetuximab, a CLDN18.2 mAb which has received marketing approval in Japan in March 2024 and is in NDA-filing stage in China. Compared with mAbs, targeting CLDN18.2 ADC is potentially a more efficacious therapeutic strategy as ADCs exert anti-tumor effects primarily via cytotoxic payloads and bystander effect, which may overcome low or heterogeneous CLDN18.2 expression in tumors that traditionally limits the efficacy of mAbs. SKB315 demonstrated encouraging preclinical efficacy and safety in various vivo tumor models with heterogeneous CLDN18.2 expression, indicating its promising therapeutic potential.

We have carried out certain activities in support of MSD's global clinical development, including a phase 1a clinical trial of SKB315 in patients with advanced solid tumors in China.

[1] *Based on common drug adverse reactions and laboratory abnormalities (≥10% all grades or ≥2% grades 3 or 4) for A166, Kadcyla®, Enhertu®, or Aidixi®. Sources: Kadcyla®: Kadcyla®'s drug label; Enhertu®: Enhertu®'s drug label; Aidixi®: Aidixi®'s drug label.*

SKB315 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

SKB410/MK-3120

SKB410 is a novel Nectin-4 ADC targeting advanced solid tumors. Utilizing a differentiated payload-linker strategy, SKB410 is equipped with a moderately toxic payload that potentially reduces toxicities, and in particular, a hydrophilic linker with balanced stability to improve pharmacokinetics (PK) profile and accelerate payload release in the tumor site for better efficacy. In preclinical studies, SKB410 has shown improved therapeutic window and safety profile compared to the published data of an FDA approved ADC targeting the same antigen.

We are carrying out certain activities in support of MSD's global clinical development, including a phase 1a clinical trial of SKB410 in patients with advanced solid tumors in China.

SKB410 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

SKB518

SKB518 is a novel ADC drug with proprietary intellectual property rights developed by the Company based on the biological characteristics of the target and using the technology of the "OptiDC™" platform, which has demonstrated promising efficacy and safety window in preclinical studies and is intended to be used for the treatment of advanced solid tumors.

In June 2024, we received a clinical trial notice approving the IND application for SKB518 for advanced solid tumors from the CDE of the NMPA. Patient enrollment of a phase 1 study is ongoing.

SKB518 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

A167 (tagitanlimab)

A167 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 A167 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.

Building on its robust efficacy and safety results in multiple monotherapy trials for advanced solid tumors such as recurrent or metastatic nasopharyngeal carcinoma (RM-NPC), A167 in combination with sac-TMT demonstrated encouraging preliminary efficacy in an ongoing phase 2 trial conducted in China. A167's promising clinical results underscore its therapeutic potential as monotherapy and combination therapies.

A167 is our first innovative project to enter NDA filing stage. We filed an NDA with the NMPA in November 2021 to market A167 as a 3L+ treatment for RM-NPC. We have also completed patient enrollment of a phase 3 trial of A167 in combination with chemotherapy as a 1L treatment for RM-NPC. In May 2024, an NDA for the phase 3 registrational study of A167 as a 1L treatment of NPC was accepted by the NMPA. Moreover, we are actively exploring A167's potential as an early-line treatment in combination with our ADC assets to maximize the clinical value of our oncology franchise.

A167 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

A140

A140 is a biosimilar of EGFR mAb cetuximab providing increased accessibility and affordability to an underserved patient population for a widely used therapeutic targeting a key pathway in many cancers, starting with rat sarcoma virus (RAS) wild-type metastatic colorectal cancer (mCRC), recurrent and/or metastatic head and neck squamous cell carcinoma (RM-HNSCC) and locally advanced head and neck squamous cell carcinoma (LA-HNSCC).

We filed an NDA for the use of A140 for the treatment of RAS wild-type mCRC and HNSCC which was accepted by the NMPA in September 2023, the first NDA filed for a cetuximab biosimilar candidate in China.

A140 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

A400

A400, a next-generation selective rearranged during transfection (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 medullary thyroid cancer (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 June 30, 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.

We are rapidly progressing the clinical development of A400 in China and globally through our collaboration with Ellipses Pharma.

Within Greater China

For RET+ NSCLC, based on the promising preliminary results of A400 in both 1L and 2L+ advanced RET+ NSCLC patients, we completed CDE clinical consultation and received approval to commence pivotal trials. We are currently conducting pivotal clinical study and patient enrollment is in progress.

Data from the phase 1 clinical study of A400 was shared in the form of an oral presentation at a session of the 2023 ASCO Annual Meeting on June 5, 2023. Building upon its strong potency against diverse RET alterations and central nervous system penetration demonstrated in preclinical studies, A400 showed promising anti-tumor efficacy in patients with advanced RET+ solid tumors, highlighted by ORR of 80.8% and 69.7% for 1L and 2L+ advanced RET+ NSCLC, respectively, based on results from its ongoing phase 1/2 trial. In both cases, DCR of over 96% were reported.

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.

An IND application for A400 was approved by FDA in June 2022. In November 2023, A400 was granted Orphan Drug Designation by the FDA for the treatment of RET fusion-positive solid tumors. In March 2024, A400 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

A296 is a novel second-generation small molecule stimulator of interferon genes (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.

We received IND approval from the NMPA for phase 1 trial to evaluate A296 in advanced solid tumor patients. The phase 1 trial is in dose escalation phase and making steady progress.

A296 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

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 rheumatoid arthritis (RA) and alopecia areata (AA), as well as other indications ranging from chronic kidney disease (CKD)-associated pruritus (CKD-aP), moderate-to-severe asthma and thromboembolic disorders.

A223

Our non-oncology franchise is headlined by A223, potentially one of the first domestically developed small molecule Janus kinase 1 or 2 (JAK1/2) inhibitors for multiple autoimmune diseases with large patient populations in China, such as AA and RA.

Configured with a structural design that retains target selectivity with optimized pharmacological properties, A223 has demonstrated an encouraging safety profile in three completed trials and two ongoing trials, where most treatment-emergent adverse events were mild or moderate with no incidence of black box warning-related safety issues commonly reported by approved JAK inhibitors. Based on preliminary clinical data from its phase 2 trial, A223 demonstrated promising anti-rheumatic efficacy in moderate-to-severe RA patients, with A223 2 mg achieving substantial and statistically significant American College of Rheumatology 20 response criteria (ACR20) difference of 35.1% (63.6% vs. 28.6%) and American College of Rheumatology 50 response criteria (ACR50) difference of 33.7% (39.4% vs. 5.7%) at week 12 compared with placebo.

We completed patient enrollment for phase 2 trials in patients with moderate-to-severe RA and the trials are making steady progress. We have also expanded A223's target indication to AA, a common autoimmune disease of the hair follicle, with Olumiant® and Litfulo® being the only two systemic treatments administered orally for severe AA approved by the FDA and the only two disease-specific treatment administered orally for the same indication approved in China as at June 30, 2024. We are conducting a phase 2 trial in patients with severe AA in China which is making steady progress.

A223 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

A277

A277 is potentially one of the first peripherally-restricted kappa-opioid receptor (KOR) agonists for treating CKD-aP in China, a distressing chronic itching condition with a large and underserved patient population. As of June 30, 2024, there were no peripheral KOR agonists approved for marketing in China.

A277 is a novel peripherally-restricted KOR agonist that selectively activates KORs, but not mu opioid receptors (MORs) or other opioid receptors. A277 is specifically designed to restrict its entry into the CNS and limit its action selectively to KORs on sensory nerves outside the brain and on certain immune cells, thereby potentially minimizing opioid-induced drug dependence, respiratory depression and constipation, as well as dysphoria and hallucination associated with centrally-acting KOR agonists. A277 demonstrated potential efficacy and good safety in a completed phase 1b clinical trial, where it exhibited potential in reducing the pruritus numerical rating scale, a widely adopted standard for evaluating itch intensity, in maintenance hemodialysis patients with moderate-to-severe CKD-aP, with no incidence of opioid-induced drug dependence, respiratory depression and constipation. These positive clinical results indicate the potential of A277 as a safe and effective therapeutic option for CKD-aP.

We have commenced a phase 2 trial in maintenance hemodialysis patients with moderate-to-severe CKD-aP in China and the trial is making steady progress.

A277 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

SKB378

SKB378 is potentially one of the first domestically developed thymic stromal lymphopoietin (TSLP) mAbs in China for treating patients with moderate-to-severe asthma. SKB378 targets TSLP, an important cytokine implicated in the pathophysiology of asthma as a key orchestrator of the underlying inflammation. Asthma can be broadly classified into two clinical inflammatory phenotypes, eosinophilic and noneosinophilic, which are respectively characterized by type 2 and non-type 2 inflammation with distinct immune response patterns. Given the major role of TSLP in both types of asthma based on recent published studies, targeting TSLP represents a promising strategy for treating asthma without phenotypic limitations.

Currently, the approved treatment options of moderate-to-severe asthma in China are mAbs that target type 2 inflammatory pathways and are thus ineffective for patients with noneosinophilic asthma, which account for approximately 50% of moderate-to-severe asthma cases. Tezepelumab, a TSLP mAb that achieved effective asthma control and exacerbation reduction regardless of patients' (non)eosinophilic phenotypes, is the only anti-TSLP treatment approved in the U.S. for severe asthma.

We received IND approval from the NMPA in February 2022. We have completed phase 1 clinical trial in healthy subjects in China.

SKB378 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

SKB336

SKB336 is a novel Factor XI (FXI)/Factor Xia (FXIa) mAb designed as an anticoagulant for preventing and treating thromboembolic disorders, starting with venous thromboembolism (VTE) after total knee arthroplasty (TKA). 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. As of June 30, 2024, there were no anti-FXI/FXIa drugs approved by the NMPA. According to Frost & Sullivan, SKB336 is the first domestically developed anti-FXI/FXIa drug to enter clinical stage in China.

FXI/FXIa have emerged as a promising anticoagulation target as these factors are not essential for initiating normal blood coagulation, but play a central role in promoting thrombosis, which refers to abnormal coagulation that leads to blood clots developing in a blood vessel. In published preclinical studies, FXI/FXIa deficiencies led to clot instability and prevented the occlusion of blood vessels, suggesting that targeting FXI/FXIa is potentially a safe and effective strategy for preventing and treating thromboembolic disorders, such as VTE after TKA.

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

SKB336 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

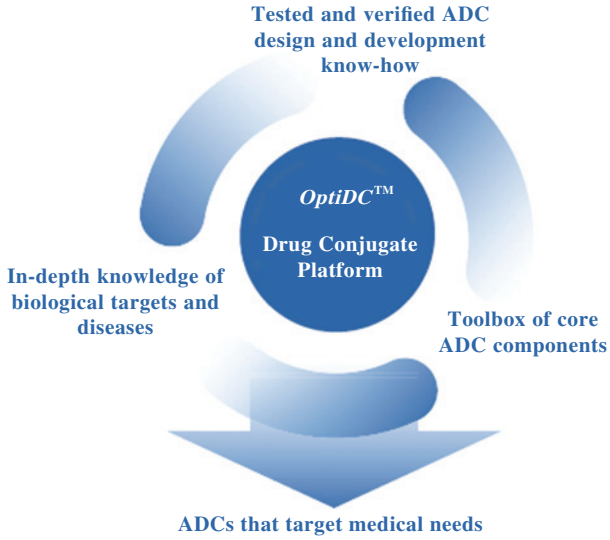
Apart from the above, we will continue to develop novel non-oncology drug candidates to address highly prevalent chronic diseases currently without effective treatments, including autoimmune and metabolic diseases.

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 control, 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 TOPO1 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 radionuclide drug conjugates (RDCs), immunostimulatory ADCs (iADCs) and degrader-antibody conjugates (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 technology platform, while complementing our ADC platform, serves as the foundation of our immunotherapy and targeted therapy franchises. This platform is focused on mAbs and bsAbs 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 and computer-aided drug design (CADD) technologies, such as molecular docking, pharmacophore modeling, virtual screening and absorption, distribution, metabolism, elimination and toxicity (ADMET) prediction. These capabilities allow us to focus on 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 proteolysis targeting chimera (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 drug metabolism and pharmacokinetics, toxicology and biomarker development, to quantitative and clinical pharmacology. 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, quality criteria establishment, and technology transfer. 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.

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.

  - ***Sac-TMT***: We have granted MSD an exclusive, royalty-bearing and sub-licensable license to develop, use, manufacture and commercialize sac-TMT. We retain the right to develop and commercialize sac-TMT within Greater China. As of June 30, 2024, MSD has initiated ten ongoing phase 3 global clinical studies of sac-TMT as a monotherapy or with pembrolizumab or other agents for several indications:

    - *TNBC.* Sac-TMT plus pembrolizumab versus Treatment of Physician's Choice (TPC) in TNBC who received neoadjuvant therapy and did not achieve a pathological complete response (pCR) at surgery;

    - *HR+/HER2- BC*. 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 endocrine therapy (ET));

    - *NSCLC.*

      - 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 and 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;

§ *EC*. Sac-TMT monotherapy versus chemotherapy for the treatment of EC who have received prior platinum-based chemotherapy and immunotherapy;

§ *CC*. Sac-TMT monotherapy versus TPC as second-line treatment for participants with recurrent or metastatic CC; and

§ *GEA*. Sac-TMT in 3L+ advanced/metastatic gastroesophageal adenocarcinoma (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 ***Early-stage ADC assets:*** In addition to sac-TMT, we are also collaborating with MSD on certain early-stage clinical and preclinical ADC assets to continuously explore favorable ADC pipeline portfolios. On one hand, we aim to cover a wide range of tumor indications through our ADC pipelines with different targets, while on the other hand, we aim to apply differentiated payload-linker strategies for ADC assets with different targets to achieve better efficacy and/or differentiated safety profiles, and explore the combination of ADCs with different strategies. 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 licensed and option ADCs for mainland China, Hong Kong and Macau.

Based on the above strategy, we have been adjusting and optimizing our scope of collaboration with MSD regarding the early-stage pipelines from time to time, to gradually form a favorable early-stage licensing pipeline portfolio which complements sac-TMT and other late-stage ADC pipelines from the perspective of our partner's global commercialization in the future. We were informed recently by MSD with regard to an exclusive option exercise of SKB571. MSD shall pay US$37.5 million to the Company in connection with the option 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 if commercialized. The Company will retain the right to develop, use, manufacture and commercialize SKB571 in mainland China, Hong Kong and Macau. At the same time of exercising the option in respect of SKB571, MSD returned to the Company the global rights to develop, use, manufacture and commercialize SKB315, and the Company is not obliged to return any upfront and milestone payments received from MSD in respect of this asset. In addition, we plan to submit IND applications for other preclinical ADC assets already under licensed collaboration with MSD in the near future, and continue to explore new collaboration opportunities with MSD.

SKB571 is a novel bsAb ADC that primarily targets various solid tumors such as lung cancer and gastrointestinal tumors. Through a scientific selection of target combinations and a differentiated design of bsAb molecules, it is designed to enhance tumor targeting and help overcome tumor heterogeneity, thereby improving efficacy. By utilizing the high hydrophilicity drug-linker strategy of the OptiDC™ platform, this asset not only possesses a uniform DAR value but also exhibits good in vivo pharmacokinetic properties. Preclinical studies have demonstrated promising anti-tumor efficacy and a good safety profile of this asset in multiple patient-derived xenograft (PDX) models and cynomolgus monkeys, respectively. An IND application for this asset is expected to be submitted in the near future.

The early-stage clinical data of SKB315 demonstrates positive efficacy and acceptable safety profile in GC with high CLDN18.2 expression, and we expect to present relevant data at upcoming academic conferences. Given the significant population of GC patients in China, we have confidence in the market prospects of SKB315 in China. We will continue to expedite its development in China and explore suitable expansion into overseas markets.

The Company has received milestone payments totaling US$90.0 million from MSD with regard to multiple collaborated pipelines in the first half of 2024.

- ***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 November 2023, A400/EP0031 was granted Orphan Drug Designation by the FDA for the treatment of RET fusion-positive solid tumors. In March 2024, 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. Clinical trial applications of A400/EP0031 were approved by the UAE agency in April 2024. As of June 30, 2024, a total of 25 clinical sites in the United States and Europe were set up for A400/EP0031.

MANUFACTURING AND QUALITY CONTROL

We believe a well-established manufacturing and quality control system serves as the cornerstone of our future commercialization and underlies our ability to enhance our R&D capabilities and advance clinical development. Our manufacturing and quality control system is capable of supporting the production of antibodies, ADCs and their key drug substances. This system helps ensure the efficiency and cost-effectiveness of our clinical trials, and facilitates a smooth transition into commercial manufacturing.

- ***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 formulation center has now reached 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 formulation facilities are equipped with an annual production capacity to produce 60 batches (or 750,000 vials) of freeze-dried formulation or 100 batches (or 2.6 million vials) of injectable solutions.

- ***Quality Control***. We operate a comprehensive quality control 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. In October 2023, A166 became the first ADC project to have successfully passed the on-site combined GMP compliance inspection for its pharmaceutical development and production site, and notification of GMP compliance was issued by the local authority in November 2023. In January 2024, A140 became the first biosimilar drug to have passed the on-site registration inspection and GMP compliance inspection, and notification of GMP compliance was issued by the local authority in March 2024. In late February to early March 2024, sac-TMT became the second ADC project to have successfully passed the on-site combined GMP compliance inspection for its pharmaceutical development and production site, and notification of GMP compliance was issued by the local authority in May 2024.

COMMERCIALIZATION

We are well-positioned to develop our commercialization infrastructure and market access, leveraging our Controlling Shareholder Kelun Pharmaceutical's decades-long experience, industry connections and extensive network. Guided by Kelun Pharmaceutical's leading industry position, strong brand image and profound resources as one of China's largest and most established pharmaceutical companies, we have developed our own commercialization team and network, with an initial focus on Class III hospitals and leading physicians across China's extensive local markets. We will also 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.

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 our Core Products, sac-TMT (佳泰莱®) and A166 (舒泰莱®), and our Key Products, A167 (科泰莱®) and A140 (达泰莱®)[2] in the China market in the second half of 2024 or the first half of 2025, respectively. In anticipation of these upcoming milestones, we are actively recruiting talent with a strong background in oncology, especially in BC, NSCLC, GI cancers and NPC, our lead indications for these late-stage assets. We have established a departmental structure within the Company, consisting of various departments such as Marketing, Access and Distribution, Medical Affairs, Sales, and Strategic Planning and Commercial Excellence, for which we are actively recruiting. We have set up a fully-fledged commercialization team to prepare and complete the marketing and commercialization of our strategic products. The commercialization team is responsible for overseeing and coordinating pre-marketing preparation and commercialization, laying the groundwork for rapid commercial-scale distribution upon these anticipated NDA approvals by the NMPA. 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 June 2024, the Company was awarded "Excellence in ESG Governance Performance Award" by Ming Pao, a media brand under Media Chinese International Limited.

In July 2024, the initial public offering of the Company received the "2023 China Financing Best IPO Award" at the China Financial Market Awards.

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.

[2] *Trade name to be determined by NMPA approval.*

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); and (ii) revenue from research and development services. The following table sets forth the components of our revenue in absolute amounts for the period indicated:

	Six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
Revenue from contracts with customers within the scope of IFRS 15		
Revenue from license and collaboration agreements	**1,377,978**	1,040,171
Revenue from provision of research and development service	**4,813**	6,055
	1,382,791	1,046,226

The Group's revenue for the six months ended June 30, 2024 was RMB1,382.79 million, representing an increase of 32.2% compared to RMB1,046.23 million for the six months ended June 30, 2023. The increase was mainly attributable to our reinforced collaboration with MSD and receipt of a total of US$90.0 million in milestone payments for the first half of 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; (iii) tax and surcharge; (iv) costs of raw materials and other consumables; (v) depreciation and amortization expenses in connection with the machinery and equipment used; and (vi) others, including 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.

	Six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
Staff costs	**46,030**	45,195
Trial and testing expenses	**225,976**	170,637
Project cooperation expenses	**–**	92,896
Raw materials	**17,270**	11,567
Depreciation and amortization expenses	**4,618**	7,482
Tax and surcharge	**2,216**	29,168
Others	**9,991**	13,621
Total	**306,101**	370,566

The Group's cost of sales for the six months ended June 30, 2024 was RMB306.10 million, representing a decrease of 17.4% compared to RMB370.57 million for the six months ended June 30, 2023. The decrease was mainly because we did not incur project cooperation expenses in the first half of 2024.

Gross Profit and Gross Profit Margin

Gross profit represents revenue less cost of sales. As a result of the aforementioned factors, the gross profit of the Group increased by 59.4% from RMB675.66 million for the six months ended June 30, 2023 to RMB1,076.69 million for the six months ended June 30, 2024.

Our gross profit margin is calculated as gross profit divided by revenue. The gross profit margin of the Group increased from 64.6% for the six months ended June 30, 2023 to 77.9% for the six months ended June 30, 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 for the six months ended June 30, 2024 was RMB94.40 million, representing an increase of RMB70.28 million compared to RMB24.12 million for the six months ended June 30, 2023, mainly due to an increase in government subsidies, an increase in interest income from bank deposits and financial assets, and an increase in net foreign exchange gains.

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) depreciation and amortization expenses mainly associated with our office and equipment for administrative purposes; (iii) office and travel expenses in relation to our general operations; (iv) consulting service fees paid to agents, independent financial advisor and other professional service providers in the ordinary course of our business; (v) maintenance and repair expenses for office and equipment; and (vi) other miscellaneous expenses.

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

	Six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
Staff costs	**50,638**	57,643
Consulting service fee	**2,043**	1,865
Depreciation and amortization expenses	**3,716**	4,243
Office and travel expenses	**3,189**	4,130
Listing expenses	**–**	17,322
Maintenance and repair expenses	**585**	1,060
Others	**5,668**	3,161
Total	**65,839**	89,424

The Group's administrative expenses for the six months ended June 30, 2024 was RMB65.84 million, representing a decrease of 26.4% compared to RMB89.42 million for the six months ended June 30, 2023. The decrease was primarily attributable to the absence of listing expenses in 2024.

Selling and Distribution Expenses

The Group's selling and distribution expenses for the six months ended June 30, 2024 was RMB41.15 million, compared to RMB0 for the six months ended June 30, 2023. Such expenses are primarily attributable to (i) the recruitment of staff into our commercialization team and (ii) pre-launch marketing activities for our products, as we are expanding our commercialization team and conducting pre-marketing preparation 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) depreciation, amortization and short-term lease expenses, primarily associated with machinery and equipment used in our research and development activities; (iv) raw materials costs in relation to research and development of our drug candidates; and (v) others, such as 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.

	Six months ended June 30,	
	2024	2023
	RMB'000	*RMB'000*
Staff costs	**200,857**	160,279
Trial and testing expenses	**298,119**	250,447
Raw materials	**85,278**	21,421
Depreciation, amortization and short-term lease expenses	**28,141**	22,930
Others	**39,942**	35,270
Total	**652,337**	490,347

The Group's R&D expenses for the six months ended June 30, 2024 was RMB652.34 million, representing an increase of 33.0% compared to RMB490.35 million for the six months ended June 30, 2023, mainly due to (i) an increase in staff costs; (ii) an increase in trial and testing expenses; and (iii) 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 six months ended June 30, 2024 was RMB2.51 million, representing a decrease of 96.8% compared to RMB78.73 million for the six months ended June 30, 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 the six months ended June 30, 2024.

Income Tax

During the Reporting Period, our income tax consisted of current tax and withholding tax. For the six months ended June 30, 2023 and 2024, we recorded income tax of RMB72.41 million and RMB99.03 million, respectively.

PRC

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

According to the enterprise income tax laws and its relevant regulations, entities that qualified as High and New Technology Enterprise are entitled to a preferential income tax rate of 15%. We obtained our certificate of High and New Technology Enterprise on December 3, 2020 and October 16, 2023 respectively and are entitled to preferential income tax of 15% from 2020 to 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税和防止偷漏税的協定》), 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 period. There were no assessable profits generating from the subsidiary incorporated in Hong Kong of the Group during the six months ended June 30, 2024.

Profit/Loss for the period

As a result of the foregoing, our profit for the Reporting Period increased by 1,096.6% from RMB-31.13 million for the six months ended June 30, 2023 to RMB310.23 million for the six months ended June 30, 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 (equivalent to approximately RMB492.72 million[3]).

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 estimated net proceeds from the Subscription is expected to be approximately RMB601.1 million, equivalent to approximately HK$661.9 million[4]. The independent Shareholders approved the subscription at the 2023 annual general meeting of the Company on June 20, 2024. As at the date of this announcement, the Company is in the process of obtaining the required regulatory approvals for the Subscription and completion of the Subscription has not taken place.

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 RMB1,528.77 million and RMB2,130.30 million as at December 31, 2023 and June 30, 2024, respectively. The increase in our cash and cash equivalents primarily reflected the net proceeds from the Placing and the milestone payments received from MSD pursuant to our collaboration.

As at December 31, 2023 and June 30, 2024, the balance of our financial assets measured at FVPL was RMB633.71 million and RMB371.54 million, respectively. As at December 31, 2023 and June 30, 2024, the balance of our financial assets measured at amortized cost was RMB325.87 million and RMB383.33 million, respectively. Such decrease was primarily because the wealth management products acquired by the Company had gradually reached maturity.

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 RMB68.91 million in operating activities for the six months ended June 30, 2024, compared to the net cash of RMB471.08 million generated from operating activities for the six months ended June 30, 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.

[3] *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.*

[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 June 30, 2023, the Group was in net deficit and thus, gearing ratio is not applicable. As at June 30, 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/(Liabilities)

The Group's net current assets as at June 30, 2024 were RMB2,604.16 million, representing an increase of 53.4% compared to net current assets of RMB1,697.48 million as at December 31, 2023 primarily because of the net proceeds from the Placing 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 June 30, 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 six months ended June 30, 2024, the Group's total capital expenditure amounted to approximately RMB37.41 million, which was mainly used in purchasing R&D instruments and equipment.

Charge on Assets

As at June 30, 2024, there was no charge on assets of the Group.

Contingent Liabilities

As at June 30, 2024, we did not have any contingent liabilities.

Employees and Remuneration Policies

As at June 30, 2024, we had 1,542 employees in total.

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

III. PROSPECTS

In 2024, 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 and translational medicine to increase the efficacy and 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 ADC designs and structures, and expanded application to non-oncology diseases; (iii) enhancing our end-to-end drug development capabilities and advancing towards commercialization; (iv) expanding global footprints and strategic partnerships to maximize the value of our pipelines; and (v) optimizing our operation system to become a leading global biopharmaceutical company.

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

In the second half of 2024, 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, with the aim to apply for regulatory approvals and initiate product launch at the earliest time practicable. We expect to submit IND applications for multiple pre-clinical assets in the second half of 2024, continue to strengthen the establishment of our ADC pipeline, 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. 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 ADC designs and structures, and expanded application to non-oncology diseases

We are establishing novel ADC designs to further advance our ADC 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, nonoverlapping binding sites on a single antigen to improve efficacy by promoting cellular uptake of an ADC; (ii) bsAbs that target two different antigens co-expressed on the same cancer cells to improve binding specificity toward cancer cells and reduce off-tumor toxicity; and (iii) TAA-IO bsAbs to enhance anti-tumor effect by simultaneously targeting TAA on tumor cells and IO antigen.

- Expanding payloads beyond common cytotoxic agents. In addition to new topoisomerase and tubulin inhibitors with optimized drug-like properties, DNA-damaging reagents and other novel cytotoxic agents 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 chemistry, manufacturing and controls (CMC) process without complicated antibody engineering or modification.

Expansion into non-chemo-based cancer therapies.

- Developing ADC derivatives 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 introduce 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 Control. We will continue to expand our cGMP facilities to support the anticipated commercialization of our near-commercial assets. 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 control system, benchmarking against the highest international standards adopted by pharmaceutical multinational corporations, to ensure patient safety and regulatory compliance.

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 Products, sac-TMT (佳泰莱®) and A166 (舒泰莱®), and our Key Products, A167 (科泰莱®) and A140 (达泰莱®)[5] in the China market in the second half of 2024 or the first half of 2025. In anticipation of these upcoming milestones, we are actively recruiting talents with a strong background in oncology, especially in BC, NSCLC, GI cancers and NPC, our lead indications for these late-stage assets. We have set up a fully-fledged commercialization team, which we plan to expand to around 400 people by the end of 2024, to oversee and coordinate pre-marketing preparation and commercialization, laying the groundwork for rapid commercial-scale distribution upon these anticipated NDA approvals by the NMPA. Targeting major hospitals and cancer institutes in major cities in China, the commercial team will engage with physicians to conduct medical education programs for BC, LC, GI cancers and NPC to prepare for our product launches. Marketing and academic activities will also be conducted to further enhance the brand presence of our Company and our innovative products. 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.

[5] *Trade name to be determined by NMPA approval.*

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

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

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

PURCHASE, SALE OR REDEMPTION OF THE COMPANY'S SECURITIES

None of the Company or any of its subsidiaries has made any purchase, sale or redemption of the listed securities of the Company (including sale of treasury shares) during the six months ended June 30, 2024.

As at 30 June 2024, the Company did not hold any treasury shares.

CORPORATE GOVERNANCE

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

The Company has strictly complied with the CG Code during the six months ended June 30, 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 six months ended June 30, 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 six months ended June 30, 2024.

EVENTS AFTER THE REPORTING PERIOD

The Company is not aware of any material subsequent events from June 30, 2024 to the date of this announcement.

REVIEW OF INTERIM RESULTS

The Audit Committee comprises three independent non-executive Directors, namely Dr. LI Yuedong, Dr. TU Wenwei and Dr. 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 unaudited interim condensed consolidated financial information of the Group for the six months ended June 30, 2024 with the management and the auditor of the Company. The Audit Committee considered that the interim results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company and internal control with senior management of the Company.

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

INTERIM DIVIDEND

The Board does not recommend the payment of an interim dividend for the six months ended June 30, 2024 (June 30, 2023: nil).

PUBLICATION OF INTERIM RESULTS ANNOUNCEMENT AND INTERIM REPORT

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

The 2024 interim report will be made available on the websites of the Company and the Stock Exchange in due course.

DEFINITIONS

"AA"	alopecia areata, a common, distressing autoimmune disease in which immune cells in the body attack hair follicles, causing hair loss
"ADC(s)"	antibody drug conjugate(s)
"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
"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
"China" or "PRC"	the People's Republic of China, which for the purpose of this interim results announcement and for geographical reference only, excludes Hong Kong, Macau and Taiwan
"CKD-aP"	chronic kidney disease (CKD)-associated pruritus, a common condition of intense and systemic itchy skin in patients with CKD, a slowly progressive (months to years) decline in the kidneys' ability to filter metabolic waste products from the blood
"CLDN18.2"	claudin 18.2, a member of the Claudin protein family
"CMC"	chemistry, manufacturing and controls, also commonly referred to as process development, which covers the various procedures used to assess the physical and chemical characteristics of drug products, and to ensure their quality and consistency during manufacturing
"Company", "our Company", "the Company", "we" or "us"	Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd. (四川科倫博泰生物醫藥股份有限公司), a joint stock company established in the PRC with limited liability on November 22, 2016 and the H Shares of which are listed on the Stock Exchange (stock code: 6990) and which includes its subsidiaries (from time to time) where the context so requires
"Controlling Shareholders"	has the meaning ascribed to it under the Listing Rules and unless the context otherwise requires, refers to Kelun Pharmaceutical, Kelun International Development Co., Limited, the Employee Incentive Platforms and Mr. LIU Gexin
"Core Products"	has the meaning ascribed thereto in Chapter 18A of the Listing Rules; for the purpose of this announcement, our Core Products refer to sac-TMT and A166
"CRC"	colorectal cancer

"CRO"	contract research organization
"CRPC"	castration-resistant prostate cancer
"DAC(s)"	degrader-antibody conjugate(s)
"DAR"	drug-to-antibody ratio, the average number of drugs conjugated to the antibodies
"DCR"	disease control rate, the total proportion of patients who demonstrate a response to treatment, equal to the sum of complete responses (CR), partial responses (PR) and stable disease (SD)
"Director(s)"	the director(s) of the Company
"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))
"ET"	endocrine therapy
"FDA"	the United States Food and Drug Administration
"first/second/third-line" or "1/2/3L"	the first/second/third line treatment
"Frost & Sullivan"	Frost & Sullivan (Beijing) Inc., Shanghai Branch Co., an independent market, research and consulting company
"FXI/FXIa"	factor XI, a type of blood protein playing a role in aiding the blood to clot. Factor XIa, one of the enzymes of the coagulation cascade. FXI is the zymogen form of FXIa
"GC"	gastric cancer
"GEA"	gastroesophageal adenocarcinoma

"GEJ"	gastroesophageal junction
"GI"	gastrointestinal
"GMP"	the Good Manufacturing Practice of Medical Devices (《醫療器械生產質量管理規範》)
"Greater China"	the PRC, Hong Kong, Macau and Taiwan
"Group", "our Group" or "the Group"	the Company and its subsidiaries
"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
"HER2"	human epidermal growth factor receptor 2
"HK$" or "HKD"	Hong Kong dollars, the lawful currency of Hong Kong
"HNSCC"	head and neck squamous cell carcinoma
"Hong Kong"	the Hong Kong Special Administrative Region of the PRC
"HR"	hormone receptor
"iADC(s)"	immunostimulatory ADC(s)
"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China or the U.S.
"JAK1/2"	Janus kinase 1 or Janus kinase 2
"Kelun Pharmaceutical"	Sichuan Kelun Pharmaceutical Co., Ltd. (四川科倫藥業股份有限公司), a company listed on the Shenzhen Stock Exchange (stock code: 002422), one of our Controlling Shareholders
"Key Products"	SKB315, SKB410/MK-3120, SKB518, A167, A140 and A400/EP0031
"KOR"	kappa-opioid receptor, one major type of opioid receptor, which are ubiquitously distributed in the central and peripheral nervous system, with a major role in the induction, transmission and perception of sensations such as pain and itch

"Listing Rules"	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
"mAb(s)"	monoclonal antibody(ies)
"Main Board"	the stock exchange (excluding the option market) operated by the Stock Exchange, which is independent from and operated in parallel with Growth Enterprise Market of the Stock Exchange
"mCRC"	metastatic colorectal cancer
"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"	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
"Prospectus"	the prospectus issued by the Company dated June 29, 2023
"PROTAC"	proteolysis targeting chimera, a heterobifunctional small molecule composed of two active domains and a linker, capable of removing specific unwanted proteins
"RDC(s)"	radionuclide drug conjugate(s)
"Reporting Period"	the six months ended June 30, 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
"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)"	member(s) of the supervisory committee 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
"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
"%"	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, August 19, 2024

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.