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

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

(Stock Code: 6990)

ANNOUNCEMENT OF ANNUAL RESULTS FOR THE YEAR ENDED DECEMBER 31, 2023

The Board is pleased to announce the audited consolidated results of the Group for the year ended December 31, 2023, together with the audited comparative figures for the year ended December 31, 2022. Unless otherwise defined herein, capitalized terms used in this announcement shall have the same meanings as those defined in the prospectus of the Company dated June 29, 2023.

FINANCIAL HIGHLIGHTS

	Year ended December 31,		
	2023	2022	Year to year
	RMB'000	*RMB'000*	change
	(Audited)	(Audited)	
Revenue	**1,540,493**	803,933	91.6%
Gross profit	**759,185**	527,105	44.0%
Research and development expenses	**(1,030,966)**	(845,984)	21.9%
Loss for the year	**(574,134)**	(616,099)	-6.8%
Adjusted loss for the year[1]	**(450,788)**	(596,288)	-24.4%
Net cash generated from/(used in) operating activities	**59,559**	(270,847)	

	As at December 31, 2023	As at December 31, 2022
Cash and financial assets[2]	**2,528,342**	119,221
Bank loans and other borrowings	**–**	2,890,787

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

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

BUSINESS HIGHLIGHTS

Since the beginning of 2023, we have made encouraging progress in our business:

- **Key developments of our Core Product SKB264/MK-2870:**

  - **TNBC.** We completed patient enrollment for a pivotal phase 3 trial for advanced TNBC in China. In August 2023, we announced that the phase 3 clinical trial of SKB264 (MK-2870) in patients with unresectable locally advanced, recurrent or metastatic TNBC who have failed second-line or above prior standard of care met the primary endpoint.

    In December 2023, the NDA for SKB264 (MK-2870) 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) 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.

    The updated efficacy and safety results from a phase 2 expansion cohort in patients with previously treated metastatic TNBC for SKB264 (MK-2870) was presented on December 6, 2023 at the 2023 SABCS. SKB264 demonstrated an ORR of 42.4% and DCR of 76.3%. The median PFS was 5.7 months. Median OS was 16.8 months.

    In March 2024, SKB264 (MK-2870) was granted Breakthrough Therapy Designation by the NMPA for first-line treatment of unresectable locally advanced, recurrent or metastatic PD-L1 negative TNBC. We have initiated a phase 3 pivotal trial for 1L advanced TNBC accordingly.

  - **HR+/HER2- BC.** In June 2023, SKB264 (MK-2870) was granted Breakthrough Therapy Designation by the NMPA for locally advanced or metastatic HR+/HER2- BC who have previously received at least 2L systematic chemotherapy. We initiated a registrational phase 3 study for 2L+ HR+/HER2- metastatic BC.

    In September 2023, the CDE of the NMPA approved the IND application for SKB264 (MK-2870) with or without KL-A167 (anti-PD-L1 inhibitor) in patients with unresectable locally advanced, recurrent or metastatic HR+/HER2- BC.

    Data was presented on October 22, 2023 at the 2023 ESMO Congress from a phase 1/2 clinical trial for SKB264 (MK-2870) for previously-treated patients with metastatic HR+/HER2- BC. Results showed that SKB264 (MK-2870) had a manageable safety profile and showed promising anti-tumor activity. SKB264 demonstrated an ORR of 36.8%, DCR of 89.5% and median PFS of 11.1 months.

- o **EGFR-mutant NSCLC.** In January 2023, SKB264 (MK-2870) was granted Breakthrough Therapy Designation by the NMPA for EGFR-TKI failed EGFR-mutant locally advanced or metastatic NSCLC.

  In July 2023, we achieved first-patient-in for a pivotal phase 3 trial of SKB264 (MK-2870) for EGFR-mutant locally advanced or metastatic non-squamous NSCLC (following TKI failure) in China.

  Data presented on June 4, 2023 at the 2023 ASCO Annual Meeting from a phase 2 study of SKB264 (MK-2870) in patients with treated locally advanced or metastatic NSCLC showed that the SKB264 (MK-2870) demonstrated promising efficacy and manageable safety profile. For the subgroup with TKI-resistant EGFR-mutant NSCLC (among which 50% also failed at least one line of chemotherapy), SKB264 (MK-2870) demonstrated an ORR of 60.0%, DCR of 100% and median PFS of 11.1 months.

- o **EGFR-wild type NSCLC.** We are conducting a phase 2 trial for SKB264 (MK-2870) in combination with A167 with or without chemotherapy for EGFR-wild type advanced NSCLC in China.

  2023 ASCO data for the subgroup of patients with EGFR wild-type (who previously received median 2 lines of therapy including anti-PD-(L)1 therapy) showed that SKB264 (MK-2870) demonstrated an ORR of 26%, DCR of 89% and median PFS of 5.3 months.

- **Key developments of our Core Product A166 (Trastuzumab botidotin for Injection):**

  - o 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.

  - o We are conducting a confirmatory phase 3 trial in China for 2L+ advanced HER2+ BC which we initiated in June 2023.

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

  - o **SKB315/MK-1200.** We are carrying 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. A global phase 1/2 clinical study is in progress.

  - o **SKB410/MK-3120.** In February 2023, we received IND approval from the NMPA for SKB410 which targets advanced solid tumors. The phase 1a clinical study is currently in progress.

  - o **SKB501.** An IND application was accepted in the first quarter of 2024.

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

  - **A167 (Tagitanlimab Injection).** We have completed patient enrollment of the phase 3 trial of A167 in combination with chemotherapy as a 1L treatment for RM-NPC.

  - **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.

  - **A400.** We commenced pivotal trials for advanced RET+ NSCLC in July 2023 and patient enrollment is in progress.

    On June 5, 2023, data from the phase 1 clinical study of our second-generation selective RET inhibitor A400 was shared in the form of an oral presentation at a session of the 2023 ASCO Annual Meeting. A400 demonstrated ORR of 80.8% and 69.7% for 1L and 2L+ advanced RET+ NSCLC, respectively, and DCR of over 96% in both cases.

    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.

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

  - **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.

  - **A277.** We are conducting a phase 2 trial in patients with chronic kidney disease-associated pruritus (CKD-aP) in China.

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

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

  - **A296.** We initiated a phase 1 trial in China and the trial is making steady progress.

- **Commercialization.** 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.

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

  - We have entered into three license and collaboration agreements with MSD to develop multiple ADC assets for cancer treatment. Under the agreements, we have granted MSD (1) an exclusive, royalty-bearing and sub-licensable license to develop, use, manufacture and commercialize SKB264 (MK-2870) outside Greater China, (2) an exclusive, royalty-bearing, sub-licensable license to develop, use, manufacture and commercialize SKB315 globally, and (3) exclusive global licenses to research, develop, manufacture and commercialize multiple investigational preclinical ADC therapies and exclusive options to obtain additional licenses to ADC candidates. We retain the right to research, develop, manufacture and commercialize certain licensed and option ADCs for mainland China, Hong Kong and Macau.

    During the Reporting Period, MSD made several payments to us, including (1) a non-refundable upfront payment of US$175.0 million (equivalent to approximately RMB1,205.5 million[3]) in March 2023 pursuant to an exclusive license and collaboration agreement we entered into with MSD to develop multiple preclinical ADC assets, (2) payments totaling US$30.0 million (equivalent to approximately RMB215.3 million[4]) made upon achieving certain milestones in October 2023 pursuant to our license and collaboration agreement with MSD to develop, use, manufacture and commercialize SKB264 (MK-2870), as well as (3) reimbursements for routine R&D expenses incurred for our license and collaboration projects.

    MSD initiated three pivotal global phase 3 clinical trials in 2023, evaluating SKB264 (MK-2870) as a monotherapy for the treatment of previously treated advanced or metastatic NSCLC with EGFR mutations or other genomic alterations, as a monotherapy for the treatment of EC who have received prior platinum-based chemotherapy and immunotherapy, and in combination with pembrolizumab for metastatic NSCLC expressing PD-L1 greater than or equal to 50 percent. Such clinical trials for NSCLC and EC have triggered payment of the relevant clinical milestones in the aggregate amount of US$75.0 million (equivalent to approximately RMB532.9 million[5]) and the Company has received the payment from MSD in the first quarter of 2024.

    In January 2023, MSD subscribed for the Shares in our Company at a consideration of US$100.0 million (equivalent to approximately RMB677.0 million[6]) as part of the Series B Financing.

[3] Based on the exchange rate of US$1: RMB6.8886 published by the State Administration of Foreign Exchange of the PRC on March 30, 2023 for illustration purpose.

[4] Based on the exchange rate of US$1: RMB7.1779 published by the State Administration of Foreign Exchange of the PRC on October 31, 2023 for illustration purpose.

[5] Based on the exchange rate of US$1: RMB7.1059 published by the State Administration of Foreign Exchange of the PRC on March 1, 2024 for illustration purpose.

[6] Based on the exchange rate of US$1: RMB6.7702 published by the State Administration of Foreign Exchange of the PRC on January 20, 2023 for illustration purpose.

- o During the Reporting Period, we have received a milestone payment from Ellipses pursuant to a collaboration and license agreement we entered into with Ellipses, under which we granted Ellipses an exclusive, revenue sharing, royalty-bearing, sub-licensable license to develop, manufacture and commercialize A400. A400 is known as EP0031 by Ellipses.

  Clinical trial applications of A400/EP0031 were approved by the Spanish agency, French agency and UK agency in February, August and September 2023, respectively. As of December 31, 2023, a total of 17 clinical sites in the United States and Europe were set up for A400/EP0031. 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.

- o In September 2023, we entered into an exclusive license agreement with the Affiliated Hospital of SMU for TBM-001, under which the Company was granted an exclusive license to research, develop and commercialize TBM-001 globally.

- **Listing on the Stock Exchange.** On July 11, 2023, the Company was successfully listed on the Main Board of the Stock Exchange. The net proceeds arising from the Listing amounted to approximately HK$1,258.9 million (equivalent to approximately RMB1,155.7 million[7]). On August 8, 2023, the Company also received net proceeds of additional HK$196 million (equivalent to approximately RMB179.7 million[8]) from the full exercise of the Over-Allotment Option.

[7] Based on the exchange rate of HK$1: RMB0.91803 published by the State Administration of Foreign Exchange of the PRC on July 11, 2023 for illustration purpose.

[8] Based on the exchange rate of HK$1:RMB0.91663 published by the State Administration of Foreign Exchange of the PRC on August 8, 2023 for illustration purpose.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS

FOR THE YEAR ENDED DECEMBER 31, 2023

	Note	**2023**	2022
		RMB'000	*RMB'000*
Revenue	*4*	**1,540,493**	803,933
Cost of sales		**(781,308)**	(276,828)
Gross profit		**759,185**	527,105
Other net income/(expense)	*5*	**89,809**	(4,368)
Selling and distribution expenses		**(19,534)**	–
Administrative expenses		**(181,877)**	(95,303)
Research and development expenses		**(1,030,966)**	(845,984)
Loss from operations		**(383,383)**	(418,550)
Finance costs		**(84,309)**	(148,814)
Loss before taxation		**(467,692)**	(567,364)
Income tax	*6*	**(106,442)**	(48,735)
Loss for the year attributable to equity shareholders of the Company		**(574,134)**	(616,099)
Loss per share	*7*		
Basic and diluted		**(2.84)**	(5.74)

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

FOR THE YEAR ENDED DECEMBER 31, 2023

	Note	**2023**	2022
		RMB'000	*RMB'000*
Loss for the year		**(574,134)**	(616,099)
Other comprehensive income for the year (after tax)			
Item that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of financial statements of an overseas subsidiary		**4,793**	13,988
Other comprehensive income for the year		**4,793**	13,988
Total comprehensive income for the year attributable to equity shareholders of the Company		**(569,341)**	(602,111)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Note	As at December 31, 2023 RMB'000	2022 RMB'000
Non-current assets			
Property, plant and equipment		**607,783**	530,349
Right-of-use assets		**84,950**	117,475
Intangible assets		**1,336**	3,179
Other non-current assets		**8,199**	9,826
		702,268	660,829
Current assets			
Inventories	*8*	**63,032**	52,636
Trade and other receivables	*9*	**214,761**	98,659
Amounts due from related parties		**1,352**	61,800
Financial assets measured at fair value through profit or loss ("**FVPL**")		**633,705**	–
Financial assets measured at amortized cost		**325,870**	–
Restricted deposits	*10*	**39,993**	26,261
Cash and cash equivalents	*10*	**1,528,774**	92,960
		2,807,487	332,316
Current liabilities			
Trade and other payables	*11*	**523,477**	243,405
Amounts due to related parties		**21,429**	206,908
Financial instruments issued to investors		**–**	580,021
Contract liabilities	*12*	**510,692**	163,976
Bank loans and other borrowings	*13*	**–**	2,890,787
Lease liabilities		**54,406**	82,264
		1,110,004	4,167,361
Net current assets/(liabilities)		**1,697,483**	(3,835,045)
Total assets less current liabilities		**2,399,751**	(3,174,216)

	Note	As at December 31, 2023 RMB'000	2022 RMB'000
Non-current liabilities			
Lease liabilities		**5,513**	41,292
Deferred income		**64,741**	10,678
		70,254	51,970
NET ASSETS/(LIABILITIES)		**2,329,497**	(3,226,186)
CAPITAL AND RESERVES	*14*		
Share capital		**219,196**	107,370
Reserves		**2,110,301**	(3,333,556)
TOTAL EQUITY/(DEFICIT)		**2,329,497**	(3,226,186)

CONSOLIDATED CASH FLOW STATEMENT

FOR THE YEAR ENDED DECEMBER 31, 2023

	2023	2022
	RMB'000	*RMB'000*
Operating activities		
Net cash generated from/(used in) operating activities	**59,559**	(270,847)
Investing activities		
Payment for the purchase of property, plant and equipment	**(80,982)**	(33,659)
Proceeds from disposal of property, plant and equipment	**5**	6,329
Payment for intangible assets	**(1,268)**	(5,333)
Payment for investment in financial assets measured at fair value through profit or loss	**(2,060,000)**	(370,000)
Proceeds from redemption of financial assets measured at fair value through profit or loss	**1,436,828**	370,513
Payment for investment in financial assets measured at amortized cost	**(320,000)**	–
Net cash used in investing activities	**(1,025,417)**	(32,150)
Financing activities		
Proceeds from new bank loans	**–**	115,000
Repayment of bank loans	**(100,000)**	(45,000)
Proceeds from other borrowings from Sichuan Kelun Pharmaceutical Co., Ltd. ("**Kelun Pharmaceutical**")	**–**	248,000
Repayment of other borrowings from Kelun Pharmaceutical	**(294,040)**	–
Proceeds from issuance of new shares	**158,681**	–
Proceeds from issuance of shares with preferential rights	**1,323,475**	–
Proceeds from issuance of ordinary shares by initial public offering and over-allotment, net of issuing costs	**1,370,939**	–
Interest paid	**(563)**	(2,893)
Capital element of lease rentals paid	**(66,762)**	(1,621)
Interest element of lease rentals paid	**(9,449)**	(34)
Net cash generated from financing activities	**2,382,281**	313,452
Net increase in cash and cash equivalents	**1,416,423**	10,455
Cash and cash equivalents at January 1	**92,960**	81,793
Effect of foreign exchange rate changes	**19,391**	712
Cash and cash equivalents at December 31	**1,528,774**	92,960

1 STATEMENT OF COMPLIANCE

These financial statements have been prepared in accordance with all applicable IFRS Accounting Standards which collective term includes all applicable individual International Financial Reporting Standards, International Accounting Standards ("**IASs**") and Interpretations issued by the International Accounting Standards Board ("**IASB**") and the disclosure requirements of the Hong Kong Companies Ordinance. These financial statements also comply with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited.

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

2 BASIS OF PREPARATION OF THE FINANCIAL STATEMENTS

The consolidated financial statements for the year ended December 31, 2023 comprise the Group.

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

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

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

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

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

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

3 CHANGES IN ACCOUNTING POLICIES

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

4 REVENUE

The principal activities of the Group are the 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 is as follows:

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Revenue from contracts with customers within the scope of IFRS 15		
Revenue from license and collaboration agreements	**1,531,699**	785,902
Revenue from provision of research and development service	**8,794**	18,031
	1,540,493	803,933

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

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Disaggregated by timing of revenue recognition		
Point in time	**814,568**	420,919
Over time	**725,925**	383,014
	1,540,493	803,933

5 OTHER NET INCOME/(EXPENSE)

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Interest income from bank deposits	**39,316**	1,417
Interest income on financial assets measured at amortised cost	**5,870**	–
Net foreign exchange gains/(losses)	**16,085**	(31,944)
Government grants	**20,578**	20,254
Net (loss)/gain on disposal of property, plant and equipment	**(1,488)**	5,418
Net realized and unrealized gain on financial assets measured at FVPL	**10,533**	513
Others	**(1,085)**	(26)
	89,809	(4,368)

6 INCOME TAX

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Current tax		
Provision for the year		
– The PRC Corporate Income Tax	**–**	–
– United States Withholding Tax	**106,442**	48,735
	106,442	48,735

(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 2023 is calculated at 16.5% (2022: not applicable) of the estimated assessable profits for the year. There were no assessable profits generating from the subsidiary incorporated in Hong Kong of the Group during the year ended December 31, 2023.

(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.

7 LOSS PER SHARE

(a) Basic loss per share

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

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

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Loss for the year attributable to ordinary equity shareholders	**(574,134)**	(616,099)
Allocation of loss for the year attributable to financial instruments issued to investors	**51,925**	68,000
Loss for the year attributable to ordinary equity shareholders of the Company for the purpose of basic loss per share	**(522,209)**	(548,099)

(ii) Weighted average number of shares

	Year ended December 31,	
	2023	2022
Issued ordinary shares at January 1	**107,369,609**	107,369,609
Effect of issuance of new shares	**94,518,344**	–
Effect of the financial instruments issued to investors	**(18,258,773)**	(11,850,609)
Weighted average number of ordinary shares at December 31	**183,629,180**	95,519,000

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 loss per share

As the Group incurred losses for the years ended December 31, 2023 and 2022, the potential ordinary shares were not included in the calculation of diluted loss per share as their inclusion would be anti-dilutive. Accordingly, diluted loss per share for the years ended December 31, 2023 and 2022 were the same as basic loss per share.

8 INVENTORIES

	As at December 31,	
	2023	2022
	RMB'000	*RMB'000*
Raw materials	**57,922**	48,643
Low-value consumables	**5,110**	3,993
	63,032	52,636

9 TRADE AND OTHER RECEIVABLES

	As at December 31,	
	2023	2022
	RMB'000	*RMB'000*
Other receivables	**16,294**	1,846
Value Added Tax ("**VAT**") recoverable	**106,802**	40,785
Prepayments	**56,017**	56,028
Prepaid tax	**35,648**	–
	214,761	98,659

All of the trade and other receivables are expected to be recovered or recognized as expense within one year.

10 CASH AND CASH EQUIVALENTS

	As at December 31,	
	2023	2022
	RMB'000	*RMB'000*
Cash at bank	**1,568,767**	119,221
Less: restricted bank deposits	**(39,993)**	(26,261)
Cash and cash equivalents in the consolidated statement of financial position	**1,528,774**	92,960

Restricted bank deposits are pledged deposits for issuance of bills payable with the maturity date within six months. The pledged deposits will be released upon the settlement of relevant bills payable.

11 TRADE AND OTHER PAYABLES

	As at December 31,	
	2023	2022
	RMB'000	*RMB'000*
Trade payables	**315,501**	123,259
Other payables	**3,029**	3,059
Bills payable	**67,449**	27,777
Accrued payroll and benefits	**133,773**	86,608
Other taxes payable	**3,725**	2,702
	523,477	243,405

As of the end of the 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 December 31,	
	2023	2022
	RMB'000	*RMB'000*
Within 1 year	**365,199**	149,663
1 to 2 years	**16,798**	642
2 to 3 years	**349**	307
More than 3 years	**604**	424
	382,950	151,036

12 CONTRACT LIABILITIES

	As at December 31,	
	2023	2022
	RMB'000	*RMB'000*
Receipts in advance	**510,692**	163,976

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

Movements in contract liabilities

	2023	2022
	RMB'000	*RMB'000*
Balance at January 1	**163,976**	109,038
Decrease in contract liabilities as a result of recognising revenue during the year that was included in the contract liabilities at the beginning of the year	**(163,578)**	(109,038)
Increase in contract liabilities as a result of receipts in advance	**510,294**	163,976
Balance at December 31	**510,692**	163,976

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

13 BANK LOANS AND OTHER BORROWINGS

	As at December 31,	
	2023	2022
	RMB'000	*RMB'000*
Current		
Guaranteed bank loans	**–**	100,000
Other borrowings from Kelun Pharmaceutical	**–**	2,790,787
	–	2,890,787

Pursuant to a share subscription and debt-to-equity swap agreement between the Company, Kelun Pharmaceutical and the other then shareholders on January 3, 2023, the Company settled RMB2,500,000,000 of the outstanding balance of other borrowings by issuing equity to Kelun Pharmaceutical. The remaining balance of the other borrowings from Kelun Pharmaceutical had been repaid in full by cash in February 2023.

14 CAPITAL AND RESERVES

(a) On January 3, 2023, the Company, Kelun Pharmaceutical and the other then shareholders of the Company entered into a share subscription and debt-to-equity swap agreement, pursuant to which Kelun Pharmaceutical agreed to subscribe for an aggregate of 51,255,685 shares at a total subscription price of RMB2,650,000,000, among which RMB2,500,000,000 was settled through debt-to-equity swap and RMB150,000,000 was settled by cash on January 16, 2023. Accordingly, the Company recorded RMB51,256,000 in share capital and the remaining RMB2,598,744,000 in capital reserves.

(b) On January 3, 2023, a series of share subscription agreements ("**Series B Share Subscription Agreements**") were entered into among the Company, Kelun Pharmaceutical, the other then shareholders and other investors. Pursuant to the Series B Share Subscription Agreements, the investors agreed to subscribe for an aggregate of 26,076,205 shares at a total subscription price of RMB409,850,000 and USD135,000,000 (approximately RMB913,625,000) which was completed in February 2023. Accordingly, the Company recorded RMB26,076,000 in share capital and the remaining RMB1,297,399,000 in capital reserves, totaling RMB1,323,475,000 in equity. As the Company could not control all the triggering events of its redemption obligation, the Company reclassified RMB1,323,475,000 from capital reserves to financial liabilities as "financial instruments issued to investors". Following the Company's H shares were listed on the Stock Exchange on July 11, 2023, the contingent payment obligation lapsed and so the Company reclassified all of the financial liabilities amounted to RMB1,980,323,000 recognized for the preferential rights into was reclassified back to the equity.

(c) During the year ended December 31, 2023, the share-based payment vehicles had paid RMB8,681,000 to the Company in respect of 8,681,000 registered but unpaid shares of the Company. Accordingly, the Company recorded RMB8,681,000 in share capital.

(d) On July 11, 2023, the Company's H Shares were listed on the Stock Exchange, where 22,446,100 H Shares were issued and subscribed at an offer price of HKD60.6 per H Share by way of initial public offering to Hong Kong and overseas investors. On August 8, 2023, pursuant to the exercise in full of the over-allotment option by the joint international underwriters of the initial public offering, the Company issued an additional 3,366,900 H Shares at the offer price of HKD60.6 per H Share.

The gross proceeds raised from the Global Offering were HKD1,564,268,000 (equivalent to approximately RMB1,436,972,000). Net proceeds from the Global Offering were RMB1,362,674,000 (after offsetting costs directly attributable to the issue of shares of RMB74,298,000), of which RMB25,813,000 was recorded in share capital and the remaining RMB1,336,861,000 was recorded in capital reserves.

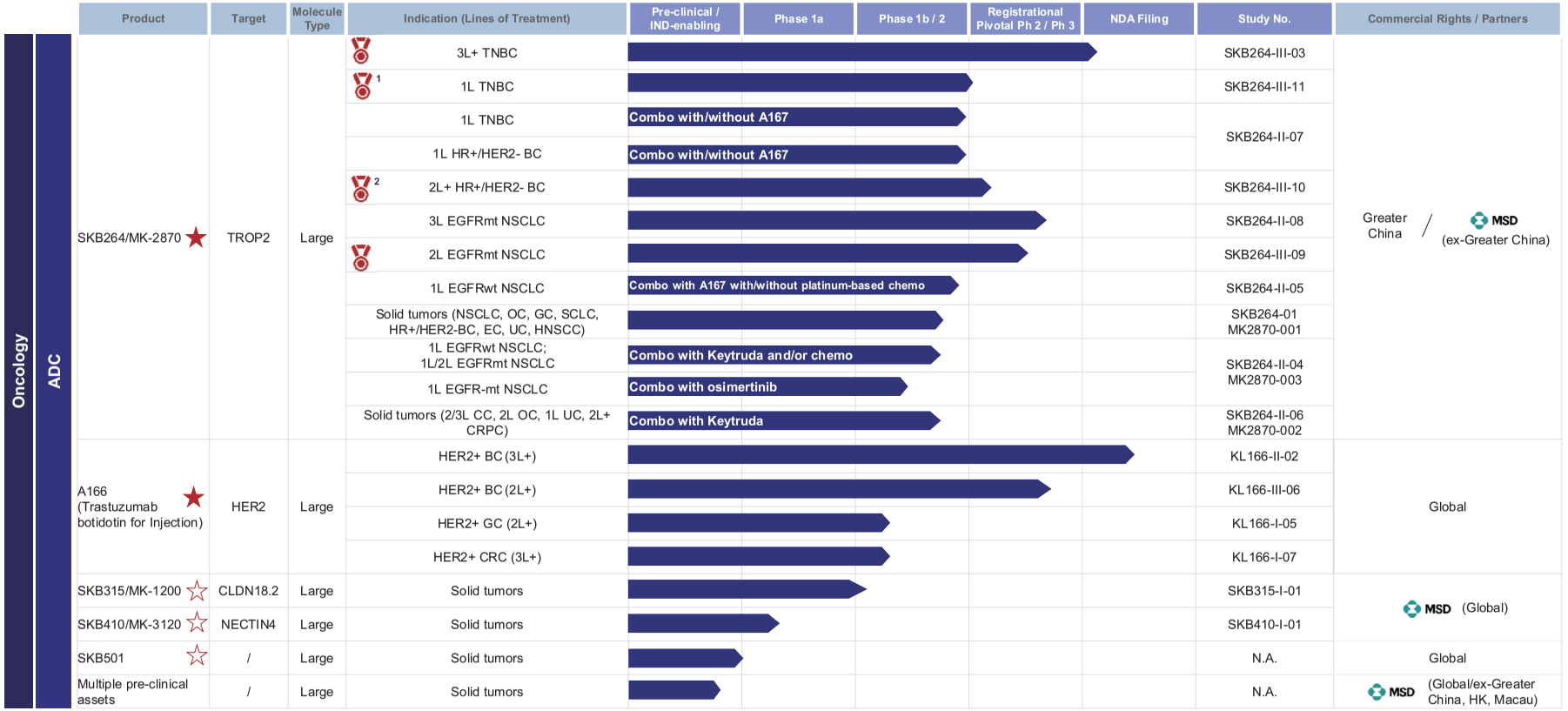
MANAGEMENT DISCUSSION AND ANALYSIS

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, SKB264 and A166. SKB264 is a novel NDA-stage TROP2 ADC positioned as a late-line monotherapy and part of early-line combination therapies for treating various advanced solid tumors. A166 is a differentiated NDA-stage HER2 ADC positioned as a late-line monotherapy to treat advanced HER2-positive (HER2+) solid tumors. As at the date of this announcement, we were also developing no less than 10 non-core clinical-stage assets in our pipeline.

The pipeline chart below summarizes the development status of our main clinical-stage drug candidates and selected preclinical 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.

★ Core Products ☆ Key Products Breakthrough Designation

	Product	Target	Molecule Type	Indication (Lines of Treatment)	Pre-clinical / IND-enabling	Phase 1a	Phase 1b / 2	Registrational Pivotal Ph 2 / Ph 3	NDA Filing	Study No.	Commercial Rights / Partners
Oncology – Other Modalities[1]	A167 (Tagitanlimab Injection) ☆	PD-L1	Large	NPC (3L+)						KL167-II-05-CTP	Greater China / HARBOUR BIOMED (ex-Greater China)
				NPC (1L)	Combo with chemotherapy					KL167-III-08	
	A140 ☆	EGFR (Biosimilar)	Large	CRC[2]						KL140-III-02	Global
	A400/EP0031 ☆	RET	Small	1L RET+ NSCLC						KL400-I/II-01	Greater China and part of Asia / ELLIPSES BIOMED (ex-Greater China and part of Asia)
				2L+ RET+ NSCLC							
				RET+ MTC and other RET+ solid tumors							
	A296	STING	Small	Solid tumors (intravenous injection)						KL296-I-01	Global
				Solid tumors (intratumoral injection)						KL296-I-02	
Non-oncology	A223	JAK 1/2	Small	Rheumatoid arthritis						KL223-II-03	Global
				Alopecia areata						KL223-II-05	
	A277	KOR	Small	CKD-aP						KL277-II-04	Global
	SKB378	TSLP	Large	Asthma						KL378	Global / HARBOUR BIOMED (Co-development)
	SKB336	FXI/FXIa	Large	Thromboembolic disorders						SKB336-I-01	Global

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; all approved indications of the original drug, including CRC and HNSCC, can be applied for by extrapolation of indications upon approval.

★ 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 SKB264 and key products SKB315 and 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, among others, Ellipses, Harbour BioMed and the Affiliated Hospital of Southwest Medical University. 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 10 clinical-stage drug candidates, including four in new drug application (NDA) filing-stage and one in pivotal trial. 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 assets:

- ***ADC:***
  - ***SKB264 (MK-2870)***, one of our Core Products, a novel TROP2 ADC targeting advanced solid tumors;
  - ***A166 (Trastuzumab botidotin for Injection)***, another Core Product, a differentiated HER2 ADC in NDA registration stage to treat advanced HER2+ solid tumors;
  - ***SKB315 (MK-1200)***, a novel CLDN18.2 ADC targeting advanced solid tumors;
  - ***SKB410 (MK-3120)***, a novel Nectin-4 ADC targeting advanced solid tumors; and
  - ***SKB501***, a novel ADC targeting advanced solid tumors with an IND application accepted in the first quarter of 2024.
- ***Other modalities (Immunotherapies and Targeted Therapies):***
  - ***A167 (Tagitanlimab Injection)***, 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 second-generation selective RET inhibitor, which is positioned to be the first domestically developed second-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.

SKB264 (MK-2870)

SKB264, one of our Core Products, is a novel human trophoblast cell-surface antigen 2 (TROP2) ADC targeting advanced solid tumors. 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 and the second TROP2 ADC globally to be commercialized, SKB264 utilizes a differentiated drug design to improve ADC stability and maintain ADC bioactivity, thus enhancing its targeting ability and reducing its off-target and on-target off-tumor toxicity, potentially leading to a broader therapeutic window.

SKB264 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. The hydrolytically linker permits both extracellular pH-sensitive cleavage and intracellular enzymatic cleavage to release the membrane permeable payload enabling the "bystander effect". The design was to achieve a more effective balance between stability in circulation and release of the ADC payload in tumor cells.

In May 2022, we granted MSD exclusive development and commercialization rights for SKB264 (MK-2870) outside Greater China. We retain the right to develop and commercialize SKB264 and other TROP2 ADCs within Greater China. Based on such retained rights, we will continue to advance our clinical development plan for SKB264 in Greater China.

We are actively advancing a multi-strategy clinical development plan to explore SKB264's potential as a monotherapy and combination therapies to treat various types of advanced solid tumors:

TNBC. SKB264 was granted Breakthrough Therapy Designation by the National Medical Products Administration (NMPA) for locally advanced or metastatic triple-negative breast cancer (TNBC) in July 2022. We achieved first-patient-in for a pivotal phase 3 trial for advanced TNBC in China in August 2022 and completed patient enrollment. In August 2023, we announced that the randomized, controlled, open-label, multi-center phase 3 clinical trial of SKB264 versus investigator selected regimens in patients with unresectable locally advanced, recurrent or metastatic 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 NDA for SKB264 to the Center for Drug Evaluation (CDE) of the 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. We expect to receive marketing approval for 3L+ advanced TNBC in 2024.

In March 2024, SKB264 was granted Breakthrough Therapy Designation by the NMPA for first-line treatment of unresectable locally advanced, recurrent or metastatic PD-1 ligand 1 (PD-L1) negative TNBC. We have initiated a phase 3 pivotal trial for 1L advanced TNBC accordingly.

Our updated efficacy and safety results from a phase 2 expansion cohort in patients with previously treated metastatic TNBC presented at the 2023 San Antonio Breast Cancer Symposium (SABCS) showed that SKB264 demonstrated an objective response rate (ORR) of 42.4% and disease control rate (DCR) of 76.3%. The median progression-free survival (mPFS) was 5.7 months. Median overall survival (OS) was 16.8 months. In the subset of patients with high TROP2 expression (H-score ≥200, n=32), ORR was 53.1%, median PFS was 5.8 months and median OS was not reached. The most common ≥ Grade 3 treatment-related adverse events (TRAEs) (≥10%) were neutrophil count decreased, white blood cell count decreased, anemia and platelet count decreased. TRAEs were mainly hematologic toxicity, which was clinically manageable; no interstitial lung disease or diarrhea of Grade 3 or higher was observed. No deaths occurred in this cohort due to TRAE.

HR+/HER2- BC. SKB264 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 systematic chemotherapy in June 2023. We initiated a registrational phase 3 study for 2L+ HR+/HER2- metastatic BC. We obtained the approval from the CDE of the NMPA in September 2023 for the IND application for SKB264 with or without KL-A167 (anti-PD-L1 inhibitor) in patients with unresectable locally advanced, recurrent or metastatic HR+/HER2- BC. We plan to initiate a pivotal trial for 1L HR+/HER2- BC after failure with endocrine therapy (ET) in 2024.

Data from a phase 1/2 clinical trial evaluating SKB264 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 SKB264 had an ORR of 36.8%, DCR of 89.5% and median PFS of 11.1 months. The most common ≥ Grade 3 TRAEs (≥5%) were neutrophil count decreased, white blood cell (WBC) count decreased, anemia, platelet count decreased and Gamma-glutamyl Transferase (GGT) increase. No neuropathy or drug-related interstitial lung disease/pneumonitis were reported. There were no TRAEs leading to treatment discontinuation or death in this cohort.

EGFR-mutant NSCLC. SKB264 was granted Breakthrough Therapy Designation by the NMPA for epidermal growth factor receptor (EGFR)- tyrosine kinase inhibitor (TKI) failed EGFR-mutant locally advanced or metastatic NSCLC in January 2023. We achieved first-patient-in for a pivotal phase 3 trial for EGFR-mutant locally advanced or metastatic non-squamous NSCLC (TKI failure) in China in July 2023. We commenced a registrational study for 3L EGFR-mutant locally advanced or metastatic NSCLC in the second half of 2023, and plan to submit an NDA in China in 2024.

Data from SKB264's phase 2 expansion cohort of heavily pretreated advanced NSCLC patients presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting showed that for the subgroup of patients with TKI-resistant EGFR-mutant NSCLC (among which 50% also failed at least one line of chemotherapy), SKB264 demonstrated an ORR of 60.0%, DCR of 100% and median PFS of 11.1 months.

EGFR-wild type NSCLC. We received IND approval in March 2022 from the NMPA. We are conducting a phase 2 trial in combination with A167 with or without chemotherapy for EGFR-wild type advanced NSCLC in China. We expect to initiate a pivotal trial for 1L EGFR-wild type NSCLC in 2024.

2023 ASCO data for the subgroup of patients with EGFR wild-type (who previously received median 2 lines of therapy including anti-PD-(L)1 therapy) showed that SKB264 demonstrated an ORR of 26%, DCR of 89% and a median PFS of 5.3 months.

For NSCLC, the most common Grade ≥3 TRAEs (≥5%) were neutrophil count decreased, anemia, WBC decreased, stomatitis, rash, and lymphocyte count decreased. No discontinuation or death due to TRAEs occurred. No neurotoxicity or drug-related interstitial lung disease/pneumonitis was observed.

Multiple tumors. We are collaborating with MSD on a global phase 2 basket study for SKB264 (MK-2870) as monotherapy or in combination for multiple indications and have obtained interim efficacy and safety data. Patient enrollment is ongoing.

SKB264 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

A166 (Trastuzumab botidotin for Injection)

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 December 31, 2023, 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.

[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.

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, which we used to submit an NDA to the NMPA in May 2023. In addition to 3L+ advanced HER2+ BC, we are exploring the therapeutic potential of A166 compared with T-DM1 in an ongoing confirmatory 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, including GC and CRC. We expect to receive marketing approval for 3L advanced HER2+ BC in the second half of 2024 or the first half of 2025.

A166 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

SKB315 (MK-1200)

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 in phase 3 stage as of 2023. 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.

In June 2022, we entered into a license and collaboration agreement with MSD, under which we granted MSD exclusive global development and commercialization rights for SKB315. Pursuant to this agreement, we are carrying out certain activities in support of SKB315's clinical development, including an ongoing phase 1a clinical trial of SKB315 in patients with advanced solid tumors in China. A global phase 1/2 clinical study is in progress.

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.

In December 2022, we entered into an exclusive license and collaboration agreement with MSD to develop certain preclinical ADC assets including SKB410. We are working in collaboration with MSD on the early clinical development of SKB410.

We received IND approval from the NMPA for SKB410 in February 2023, and initiated the phase 1a clinical trials.

SKB410 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

A167 (Tagitanlimab Injection)

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 SKB264 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.

We filed an NDA with the NMPA in November 2021 and expect to receive approval in the second half of 2024 to market A167 as a 3L+ treatment for RM-NPC. We have also completed patient enrollment for a phase 3 trial of A167 in combination with chemotherapy as a 1L treatment for RM-NPC. 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, beginning with two ongoing phase 2 trials – a phase 2 trial of SKB264 in combination with A167 with or without chemotherapy, as a 1L treatment for EGFR-wild type advanced NSCLC and a phase 2 trial of SKB264 with or without A167 as a 1L treatment for advanced TNBC and in patients with unresectable locally advanced, recurrent or metastatic HR+/HER2- BC.

In August 2018, we granted Harbour BioMed an exclusive, royalty-bearing, sub-licensable license to develop, manufacture and commercialize A167 outside Greater China.

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 second-generation selective rearranged during transfection (RET) inhibitor, is positioned to be the first domestically developed second-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 December 31, 2023, 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.

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

We are rapidly progressing the clinical development of A400 in China and globally. 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. Patient enrollment is in progress and we plan to submit an NDA for RET+ NSCLC in 2024. 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.

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.

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. We initiated the phase 1 trial in China and the trial is 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. 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 December 31, 2023. We are conducting a phase 2 trial in patients with severe AA in China.

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 December 31, 2023, there were no approved treatments specifically targeting CKD-aP 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 pruritus in China.

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 and are making steady progress.

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 December 31, 2023, 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 and are making steady progress.

SKB336 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

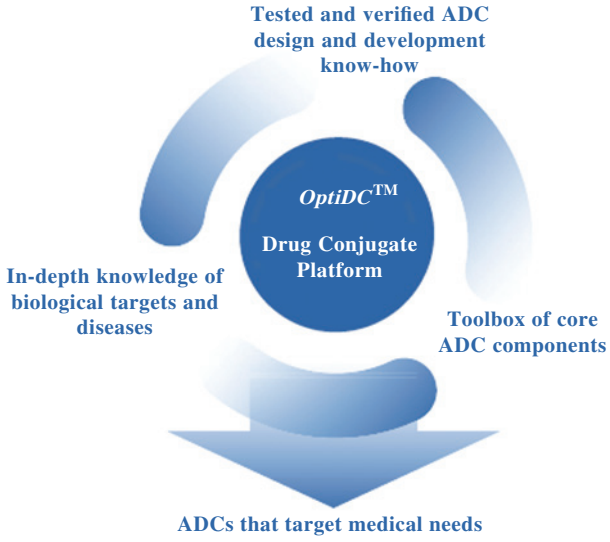
Apart from the above, we will continue to develop novel non-oncology drug candidates to address highly prevalent chronic diseases currently without effective treatments, including autoimmune and metabolic diseases.

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 more than 2,000 patients enrolled as at December 31, 2023.

  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, including (i) further optimizing our payload/linker technologies to solidify our ADC capabilities; (ii) developing novel ADC designs and structures such as bispecific ADCs, dual-payload ADCs, immunostimulatory ADCs, radionuclide drug conjugates (RDCs); and (iii) developing ADCs with non-cytotoxic payloads to target non-oncology diseases.



- ***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 three license and collaboration agreements with MSD to develop multiple ADC assets for cancer treatment. During the Reporting Period, MSD made several payments to us, including (1) a non-refundable upfront payment of US$175.0 million in March 2023 pursuant to an exclusive license and collaboration agreement we entered into with MSD to develop multiple preclinical ADC assets, (2) payments totaling US$30.0 million made upon achieving certain milestones in October 2023 pursuant to our license and collaboration agreement with MSD to develop, manufacture and commercialize SKB264 (MK-2870), as well as (3) reimbursements for routine R&D expenses incurred for our license and collaboration projects.

  In May 2022, we granted MSD an exclusive, royalty-bearing and sub-licensable license to develop, use, manufacture and commercialize SKB264 (also known as "MK2870" in MSD's portfolio). We retain the right to develop and commercialize SKB264 within Greater China. In 2023, MSD initiated three pivotal phase 3 clinical trials, evaluating SKB264 (MK-2870) as a monotherapy for the treatment of previously treated advanced or metastatic NSCLC with EGFR mutations or other genomic alterations, as a monotherapy for the treatment of endometrial carcinoma (EC) who have received prior platinum-based chemotherapy and immunotherapy, and in combination with pembrolizumab for metastatic NSCLC expressing programmed death ligand 1 (PD-L1) greater than or equal to 50 percent. Such clinical trials for NSCLC and EC have triggered payment of the relevant clinical milestones in the aggregate amount of US$75.0 million.

  In June 2022, we granted MSD an exclusive, royalty-bearing, sub-licensable license to develop, use, manufacture and commercialize SKB315 globally. We are carrying out certain activities in support of SKB315's clinical development, including an ongoing phase 1a clinical trial of SKB315 in patients with advanced solid tumors in China. A global phase 1/2 clinical study is in progress.

  In December 2022, we entered into an exclusive license and collaboration agreement with MSD to develop up to seven preclinical ADC assets. Under this agreement, we granted MSD exclusive global licenses to research, develop, manufacture and commercialize multiple ADC assets and exclusive options to obtain additional exclusive licenses to certain other ADC assets. We retain the right to research, develop, manufacture and commercialize certain licensed and option ADCs for China, Hong Kong and Macau. In October 2023, the Company received a formal notice from MSD that MSD made a decision (1) to terminate an exclusive license the Company granted to MSD to develop, manufacture and commercialize a preclinical ADC asset, and (2) not to exercise an exclusive option the Company granted to MSD to obtain an exclusive license to another preclinical ADC asset. The Group is not obliged to return any payments received or make any payments to MSD in respect of such termination of the collaboration on the aforementioned two ADC assets.

- ***Collaboration with Ellipses***. In March 2021, we entered into a collaboration and license agreement with Ellipses, under which we granted Ellipses an exclusive, revenue sharing, royalty-bearing, sub-licensable license to develop, manufacture and commercialize A400. A400 is known as EP0031 by Ellipses. The license includes all countries excluding Greater China, North Korea, South Korea, Singapore, Malaysia and Thailand.

  An IND application for A400/EP0031 was approved by the FDA in June 2022. Clinical trial applications of A400/EP0031 were approved by the Spanish agency, French agency and UK agency in February, August and September 2023, respectively. As of December 31, 2023, a total of 17 clinical sites in the United States and Europe were set up for A400/EP0031. 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. We have received a milestone payment during the Reporting Period.

- ***License agreement with the Affiliated Hospital of SMU***. In September 2023, the Company entered into an exclusive license agreement with the Affiliated Hospital of SMU for TBM-001, an innovative RDC drug independently developed by the Department of Nuclear Medicine of the Affiliated Hospital of SMU and intended to be used for early diagnosis of bone tumor metastasis and precision targeted therapy. Under the license agreement, the Affiliated Hospital of SMU granted the Company an exclusive license to research, develop and commercialize TBM-001 globally and is in return entitled to receive certain economic interests such as upfront payment, milestone payments, commission on net sales after launch of the product and revenue sharing of third-party sub-licensing, including upfront payment and milestone payments in the aggregate amount of RMB38.5 million.

- ***License agreement with Multitude Therapeutics***. In October 2023, we entered into a license agreement with Multitude Therapeutics. Under the license agreement, the Company has granted Multitude Therapeutics an exclusive right to its payload-linker to research, develop and commercialize a first-in-class (FIC) target ADC and is in return entitled to receive certain economic interests such as milestone payments and running royalties on net sales after launch of the product. During the Reporting Period, we received certain payments. The Company has also agreed to supply the product to Multitude Therapeutics at an agreed price.

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 is 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 update 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. Furthermore, our quality expert team are actively involved in the discussion and promulgation of regulations and guidelines in China, such as the Chinese GMP regulatory guidelines and the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidelines, which attests to our recognized expertise in the respective fields. For example, we took an active role in the drafting of the "Biological Products (mAb)" section of the Chinese GMP Implementation Guide (Re-issued) (中國GMP實施指南(再版)《生物製品(單克隆抗體)》部分) in 2022. As a major participant, the Company took part in discussions on various domestic ADC technical guidelines and standards, such as the overview on ADCs in the Chinese Pharmacopoeia (《中國藥典》).

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, we expect to receive marketing approval from the NMPA for A167 (PD-L1 mAb) (3L+) in the second half of 2024. Subject to regulatory communications and marketing approval, we expect to launch our Core Products, SKB264 and A166, and A140 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 Commerce, 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 2023, the Hurun Research Institute released the 2023 Global Unicorn Index according to which there were 316 unicorn enterprises in China, ranking second in the world. The Company was one of the new unicorn enterprises to receive such recognition.

In September 2023, at the China International Fair for Trade in Services, the Company was recognised as the "Science and Technology Innovation Service Demonstration Case" and was selected for the "Ten Year Achievement Exhibition". The Company was also selected as a new economy demonstration enterprise in Sichuan Province for 2023.

In October 2023, the Company passed the national review for the renewal of its High and New Technology Enterprise accreditation.

In November 2023, it was announced that the initial public offering of the Company was awarded "Best IPO of the Year in Asia and Hong Kong SAR" at the FinanceAsia Achievement Awards 2023.

In December 2023, the Company was awarded the 2023 Most Innovative Value Award at the the 6th CLS Annual Investment Conference of 2023.

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

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Revenue from contracts with customers within the scope of IFRS 15		
Revenue from license and collaboration agreements	**1,531,699**	785,902
Revenue from provision of research and development service	**8,794**	18,031
	1,540,493	803,933

The Group's revenue for the year ended December 31, 2023 was RMB1,540.5 million, representing an increase of 91.6% compared to RMB803.9 million for the year ended December 31, 2022. The increase is mainly attributable to the revenue from the license and collaboration agreement we entered into with MSD to develop up to seven preclinical ADC assets for the treatment of cancer.

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) project cooperation expenses, being the expenses incurred in our license and collaboration arrangements, primarily payments to other third parties; (iii) employee salaries and benefits for R&D staff; (iv) tax and surcharge; (v) costs of raw materials and other consumables; (vi) depreciation and amortization expenses in connection with the machinery and equipment used; and (vii) 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.

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Staff costs	**107,778**	69,560
Trial and testing expenses	**469,846**	157,907
Project cooperation expenses	**92,726**	–
Raw materials	**38,477**	22,123
Depreciation and amortization expenses	**15,125**	9,603
Tax and surcharge	**32,078**	1,962
Others	**25,278**	15,673
Total	**781,308**	276,828

The Group's cost of sales for the year ended December 31, 2023 was RMB781.3 million, representing an increase of 182.2% compared to RMB276.8 million for the year ended December 31, 2022. The increase is mainly attributable to the license and collaboration agreements we entered into, pursuant to which we carried out more R&D activities with our collaboration partners.

Gross Profit and Gross Profit Margin

Gross profit represents revenue less cost of sales. Gross profit margin represents gross profit as a percentage of revenue. As a result of the aforementioned factors, the gross profit of the Group increased by 44.0% from RMB527.1 million for the year ended December 31, 2022 to RMB759.2 million for the year ended December 31, 2023.

Our gross profit margin is calculated as gross profit divided by revenue. Gross profit margin embedded in each license and collaboration agreement varies. The gross profit margin of the Group decreased from 65.6% for the year ended December 31, 2022 to 49.3% for the year ended December 31, 2023.

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 year ended December 31, 2023 was RMB89.8 million, representing an increase of RMB94.2 million compared to RMB-4.4 million for the year ended December 31, 2022, mainly due to an increase in the interest income from bank deposits and financial assets, and an increase in the 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) listing expenses incurred in connection with the Global Offering; (iii) depreciation and amortization expenses mainly associated with our office and equipment for administrative purposes; (iv) office and travel expenses in relation to our general operations; (v) consulting service fees paid to agents, independent financial advisor and other professional service providers in the ordinary course of our business; (vi) maintenance and repair expenses for office and equipment; and (vii) other miscellaneous expenses.

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

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Staff costs	**117,982**	62,436
Consulting service fee	**6,730**	6,139
Depreciation and amortization expenses	**9,904**	7,727
Office and travel expenses	**9,323**	3,617
Listing expenses	**27,346**	9,288
Maintenance and repair expenses	**2,413**	2,272
Others	**8,179**	3,824
Total	**181,877**	95,303

The Group's administrative expenses for the year ended December 31, 2023 was RMB181.88 million, representing an increase of 90.8% compared to RMB95.30 million for the year ended December 31, 2022. The increase was primarily attributable to (i) management and administrative personnel costs increased with the development of the Company's business, particularly the expenses related to the Pre-IPO Employee Incentive Scheme; and (ii) the listing expenses incurred in the key stages of the Global Offering.

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.

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Staff costs	**316,917**	267,288
Trial and testing expenses	**527,306**	401,614
Raw materials	**73,618**	80,857
Depreciation, amortization and short-term lease expenses	**44,854**	48,754
Others	**68,271**	47,471
Total	**1,030,966**	845,984

The Group's R&D expenses for the year ended December 31, 2023 was RMB1,030.97 million, representing an increase of 21.9% compared to RMB845.98 million for the year ended December 31, 2022, mainly due to (i) an increase in trial and testing expenses; (ii) an increase in staff costs; and (iii) an increase in other R&D expenses, such as travel expenses, utilities and transportation expenses in relation to our R&D activities. 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 financial instruments issued to investors, representing the Shares issued to Series A Investors and Series B Investors; (ii) interest expenses on our borrowings from Kelun Pharmaceutical; (iii) interest expenses on lease liabilities; and (iv) interest expenses on bank loans. We capitalized the interest expenses incurred for the construction in progress.

The Group's finance costs for the year ended December 31, 2023 was RMB84.3 million, representing a decrease of 43.3% compared to RMB148.8 million for the year ended December 31, 2022. The decrease in finance costs was primarily attributable to the significant decrease of interest expenses, which was due to (i) bank loans and other borrowings from Kelun Pharmaceutical were settled in early 2023; and (ii) financial instruments issued to investors had been transferred to equity when the Company was listed on the Stock Exchange on July 11, 2023.

Income Tax

During the Reporting Period, our income tax consisted of withholding tax. For the year ended December 31, 2022 and 2023, we recorded income tax of RMB48.7 million and RMB106.4 million, respectively.

PRC

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

According to the enterprise income tax laws and its relevant regulations, entities that qualified as High and New Technology Enterprise are entitled to a preferential income tax rate of 15%. We obtained our certificate of High and New Technology Enterprise on December 3, 2020 and October 16, 2023 respectively and are entitled to preferential income tax of 15% from 2020 to 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 2023 is calculated at 16.5% (2022: not applicable) of the estimated assessable profits for the year. There were no assessable profits generating from the subsidiary incorporated in Hong Kong of the Group during the year ended December 31, 2023.

Loss for the year

As a result of the foregoing, our loss for the Reporting Period decreased by 6.8% from RMB616.1 million for the year ended December 31, 2022 to RMB574.1 million for the year ended December 31, 2023.

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

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 RMB93.0 million and RMB1,528.8 million as at December 31, 2022 and December 31, 2023, respectively. The increase in our cash and cash equivalents primarily reflected the proceeds raised from Series B Financing, Global offering and the payment received from MSD pursuant to our collaboration.

As at December 31, 2022 and December 31, 2023, the balance of our financial assets measured at FVPL was nil and RMB633.7 million, respectively. As at December 31, 2022 and December 31, 2023, the balance of our financial assets measured at amortized cost was nil and RMB325.9 million, respectively. Such increase was primarily because we used idle own funds to purchase principal guaranteed bank deposit products.

Net Cash 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 generated net cash of RMB59.6 million in operating activities for the year ended December 31, 2023, compared to the net cash of RMB270.8 million used in operating activities for the year ended December 31, 2022. The increase in cash was primarily because MSD paid us an upfront payment of US$175.0 million in March 2023 pursuant to the license and collaboration agreement we entered into with MSD to develop up to seven preclinical ADC assets for the treatment of cancer. During the Reporting Period, we financed our operations primarily through payments received in accordance with our license and collaboration agreements and proceeds from our Series B Financing and Global Offering.

Borrowings and Gearing Ratio

As at December 31, 2023, our borrowings were fully repaid.

The gearing ratio is calculated by using interest-bearing borrowings and lease liabilities less cash and cash equivalents, divided by total equity and multiplied by 100%. As at December 31, 2022, the Group was in net deficit and thus, gearing ratio is not applicable. As at December 31, 2023, 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 December 31, 2023 were RMB1,697.5 million, meanwhile the Group's net current liabilities were RMB3,835.0 million as at December 31, 2022. The significant change of direction was due from the full settlement of bank loans and other borrowing, and the Pre-IPO Investments have been transferred from the Group's current liabilities to equity upon the Listing.

Currency Risk

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

Pledge of Shares

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

Significant Investments, Material Acquisitions and Disposals

As at December 31, 2023, we did not hold any significant investments. For the Reporting Period, we did not have material acquisitions or disposals of subsidiaries, associates and joint ventures.

Capital Expenditure

For the year ended December 31, 2023, the Group's total capital expenditure amounted to approximately RMB82.25 million, which was mainly used in purchasing R&D instruments and equipment.

Charge on Assets

As at December 31, 2023, there was no charge on assets of the Group.

Contingent Liabilities

As at December 31, 2023, we did not have any contingent liabilities.

Employees and Remuneration Policies

As at December 31, 2023, we had 1,415 employees in total.

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

Future Investment Plans and Expected Funding

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

Events after the Reporting Period

MSD initiated three pivotal phase 3 clinical trials in 2023, evaluating SKB264 (MK-2870) as a monotherapy for the treatment of previously treated advanced or metastatic NSCLC with EGFR mutations or other genomic alterations, as a monotherapy for the treatment of EC who have received prior platinum-based chemotherapy and immunotherapy, and in combination with pembrolizumab for metastatic NSCLC expressing PD-L1 greater than or equal to 50 percent. Such clinical trials for NSCLC and EC have triggered payment of the relevant clinical milestones in the aggregate amount of US$75.0 million and the Company has received the payment from MSD in the first quarter of 2024.

Save as disclosed above, the Company is not aware of any material subsequent events from December 31, 2023 to the date of this announcement.

III. PROSPECTS

We intend to capitalize on our competitive strengths by pursuing 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

We plan to advance the clinical development of our clinical-stage pipelines, with the goal to apply for regulatory approvals and initiate product launch at the earliest time practicable. We expect IND applications to be submitted for multiple pipelines in 2024, the majority of which are for ADC and ADC-derivative assets.

Guided by our indication-oriented approach, we will continue to advance our clinical-stage and preclinical oncology assets to target cancer indications with high prevalence and medical needs, notably BC, NSCLC, GI cancers and NPC. 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.

Full coverage of major breast cancer subtypes. We have strategically targeted BC, the most common cancer worldwide with significant underserved medical needs, as our lead oncology indication with coverage by three key assets, namely, SKB264, A166 and A167 (in combination with SKB264).

- *TNBC*. We have completed patient enrollment for SKB264's pivotal phase 3 trial in patients with advanced TNBC who have failed two or more lines of treatment in China, and the NDA was accepted by the NMPA in December 2023. For SKB264, we are also conducting a phase 2 trial with or without A167 as a 1L treatment for advanced TNBC. We expect to receive marketing approval in China for 3L advanced TNBC and to initiate pivotal trial for 1L advanced TNBC in 2024. The phase 2 trial results for SKB264 as a 1L treatment for TNBC and phase 3 trial results for SKB264 as a 3L treatment for TNBC are also expected to be released in 2024.

- *HER2+ BC*. 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 also initiated a confirmatory phase 3 trial of A166 compared with T-DM1 as a 2L+ treatment in advanced HER2+ BC patients in June 2023 and expect to complete patient enrollment in 2024. We expect to receive marketing approval for 3L advanced HER2+ BC in the second half of 2024 or the first half of 2025.

- *HR+/HER2- BC*. We initiated a registrational phase 3 study for 2L+ HR+/HER2- metastatic BC. We obtained approval from the CDE of the NMPA in September 2023 for the IND application for SKB264 with or without KL-A167 (anti-PD-L1 inhibitor) in patients with unresectable locally advanced, recurrent or metastatic HR+/HER2- BC. We plan to initiate a pivotal trial for 1L HR+/HER2- BC after failure with ET in 2024.

Robust development plan for NSCLC. We are developing multiple oncology assets engineered to target different subtypes of NSCLC, the second most common cancer worldwide, with an aim to benefit patients currently without effective treatment options. In particular:

- *EGFR-mutant NSCLC*. For SKB264, we achieved first-patient-in for a pivotal phase 3 trial in EGFR-mutant locally advanced or metastatic non-squamous NSCLC patients who have failed EGFR-TKI therapy in China in July 2023. We plan to submit an NDA for 3L EGFR-mutant NSCLC in China in 2024.

- *EGFR-wild type NSCLC*. For SKB264, we are conducting a phase 2 trial in combination with A167 with or without chemotherapy for EGFR-wild type advanced NSCLC in China. The ongoing dose expansion study of a global phase 1/2 trial for advanced NSCLC also includes EGFR-wild type NSCLC. We expect to initiate pivotal trial for 1L EGFR-wild type NSCLC in 2024.

- *RET+ NSCLC*. Based on the promising preliminary results of A400 in advanced RET+ NSCLC patients, we completed CDE clinical consultation and received approval for pivotal trials for advanced RET+ NSCLC, which we commenced in July 2023, and patient enrollment is in progress.

The phase 2 trial results for SKB264 as a 1L treatment for NSCLC is expected to be released in 2024.

Expanding clinical programs for GI cancers. We are targeting GC and CRC, the two most common GI cancers worldwide. GC is the second most common cancer in China, which had approximately 43.3% of the world's GC patients in 2022, and a leading cause of cancer death globally, while CRC is the third most common cancer and a leading cause of cancer death in China. To date, we have selected GC as a key indication for both of our Core Products, namely SKB264 and A166; and CRC as a key indication for A166 and A140. For GC, we are advancing the dose expansion study of SKB264's global phase 1/2 trial in advanced GC patients who have at least failed 1L treatment and a phase 1b trial of A166 for advanced HER2+ GC in China. Meanwhile, SKB315 targets CLDN18.2, which is highly expressed in GC. For CRC, an NDA of A140 for RAS wild-type mCRC was accepted by the NMPA in September 2023.

Advanced development for NPC. We are targeting NPC, a cancer with higher prevalence in China than in western countries. Patients with RM-NPC account for approximately 35% of total NPC cases and have a five-year survival rate of 10-20% in China. We expect to receive marketing approval for A167 for RM-NPC in 2024.

Building on non-oncology pipelines. For A223, our small molecule JAK1/2 inhibitor, we are conducting phase 2 trials in patients with moderate-to-severe RA and severe AA. Both phase 2 trials are making steady progress. For A277, our peripherally-restricted KOR agonist for CKD-aP, we are conducting a phase 2 proof-of-concept trial. We will also continue to advance the clinical development of our two early-stage drug candidates SKB378 and SKB336.

In addition, 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. These chronic diseases are often associated with aging and exacerbated by the complex interactions of numerous lifestyle and environmental factors. We are dedicated to designing novel drug candidates and promoting R&D innovations to address these and other medical needs.

(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 optimizing our payload-linker technologies to solidify our ADC capabilities. In addition to new Topoisomerase Inhibitors, we have developed DNA-damaging reagents and non-cytotoxic molecules to overcome drug resistance towards current ADCs via differentiated mechanism of action. To match the needs of constructing ADCs with appropriate drug load, we have developed site-specific conjugating technologies that allow precise control of DAR value (2/4), and this is realized via a practical and cost-effective chemistry, manufacturing and controls (CMC) process without complicated antibody engineering or modification.

- developing novel ADC designs and structures such as bispecific ADCs, dual-payload ADCs, immunostimulatory ADCs and RDCs. We are developing bsADCs equipped with dual-targeting antibodies to deliver enhanced clinical benefits, 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. We are also harnessing the synergy between IO and tumor targeting via iADCs, which are a novel form of ADCs to activate anti-tumor immune response on top of conventional tumor-directed cytotoxin delivery, with promising efficacy and safety results observed in preclinical studies. Moreover, we are developing RDCs that carry radioactive isotopes to cancer cells. By manipulating a distinct mechanism of action, RDCs represent a promising strategy to overcome drug resistance associated with traditional cytotoxin-based ADCs.

- developing ADCs with non-cytotoxic payloads to target non-oncology diseases. 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.

- other than developing new forms of drug conjugation, exploring PROTAC technology, a novel method to generate small molecules with the potential to induce the degradation of a target protein. We aim to improve the therapeutic value and drug-like properties of the resulting PROTAC molecules through in-depth target biology research, CADD, enhanced preclinical safety evaluation methods, and other techniques that help optimize the discovery process.

(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, we expect to receive conditional marketing approval from the NMPA for A167 (PD-L1 mAb) in the second half of 2024. Subject to regulatory communications and marketing approval, we expect to launch our Core Products, SKB264 and A166, and A140 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 500 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.

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

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

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

CORPORATE GOVERNANCE AND OTHER INFORMATION

Compliance with the Corporate Governance Code

The Board is committed to maintaining high corporate governance standards.

The Board believes that high corporate governance standards are essential in providing a framework for the Company to safeguard the interests of Shareholders, enhance corporate value, formulate its business strategies and policies, and enhance its transparency and accountability.

Since the Shares of the Company were listed on the Main Board of the Stock Exchange on July 11, 2023, the Company has adopted the principles and code provisions of the CG Code contained in Appendix C1 of the Listing Rules as the basis of the Company's corporate governance practices since the Listing Date.

In the opinion of the Directors, throughout the period from the Listing Date to December 31, 2023, the Company has complied with the applicable code provisions as set out in the CG Code, except for code provision C.5.1.

Code provision C.5.1 of the CG Code recommends that the board should meet regularly, and board meetings should be held at least four times a year at approximately quarterly intervals. Our Company was listed on the Stock Exchange during the Reporting Period, on July 11, 2023, from which date the CG Code applied to our Company. From the Listing Date to December 31, 2023, we held less than four Board meetings within less than a year. Nevertheless, our Board members have been in regular communication with one another and, going forward, will continue to meet regularly to update themselves on our Company's affairs.

The Company has also put in place certain recommended best practices as set out in the CG Code.

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.

Compliance with the Model Code

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.

The Model Code was only applicable to the Company for the Reporting Period from the Listing Date to December 31, 2023. Upon specific enquiry, all Directors and Supervisors confirmed that they have complied with the Model Code since the Listing Date and up to December 31, 2023. In addition, the Company is not aware of any non-compliance with the Model Code by the senior management of the Group since the Listing Date and up to December 31, 2023.

Purchase, Sale or Redemption of the Company's Securities

Disclosure on the particulars of purchase, sale or redemption by the Company or any of its subsidiaries of the listed securities of the Company is not applicable to the Company for the period before the Listing Date, as the Company was not listed on the Stock Exchange. Since the Listing Date and up to December 31, 2023, none of the Company or any of its subsidiaries has made any purchase, sale or redemption of the listed securities of the Company.

Completion of H Share Full Circulation

On November 24, 2023, the conversion of an aggregate of 62,567,234 domestic shares and unlisted foreign shares of the Company (the "**Converted H Shares**") was completed and the listing of the Converted H Shares on the Stock Exchange commenced on November 27, 2023.

For further details, please refer to the Company's announcements dated November 17 and November 24, 2023.

Audit Committee

The Audit Committee comprises three independent non-executive Directors, namely Dr. LI Yuedong, Dr. TU Wenwei and Dr. JIN Jinping. The chairman of the Audit Committee is Dr. LI Yuedong who holds the appropriate qualification as required under Rules 3.10(2) and 3.21 of the Listing Rules. The Audit Committee has reviewed the annual financial results for the year ended December 31, 2023 with the management and the auditor of the Company. The Audit Committee considered that the annual financial results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company and internal control with senior management of the Company.

Scope of Work of the Company's Auditors

The financial figures in respect of the Group's consolidated statement of profit or loss, consolidated statement of profit or loss and other comprehensive income, consolidated statement of financial position and the related notes thereto for the year ended December 31, 2023 as set out in the preliminary announcement have been compared by the Group's auditor, KPMG, Certified Public Accountants, to the amounts set out in the Group's consolidated financial statements for the year and the amounts were found to be in agreement. The work performed by KPMG in this respect did not constitute an assurance engagement and consequently, no opinion or assurance conclusion has been expressed by KPMG on the preliminary announcement.

Final Dividend

The Board has resolved not to recommend the payment of a final dividend for the year ended December 31, 2023 (2022: Nil).

2023 AGM

An announcement containing information in relation to the latest registration date and the period of closure of the share register of the Company for attending the 2023 AGM of the Company will be published separately when the date of the 2023 AGM of the Company is fixed.

Publication of Annual Results Announcement and Annual Report

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

The annual report of the Company for the year ended December 31, 2023 containing all the information required by the Listing Rules will be despatched to the Shareholders and published on the websites of the Stock Exchange and the Company in due course.

DEFINITIONS

"2023 AGM"	the 2023 annual general meeting of the Company
"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)
"Affiliated Hospital of SMU"	the Affiliated Hospital of Southwest Medical University (西南醫科大學附屬醫院)
"ASCO"	American Society of Clinical Oncology
"Audit Committee"	the audit committee of the Board
"associate(s)"	has the meaning ascribed thereto under the Listing Rules
"BC"	breast cancer
"Board of Directors" or "Board"	the board of Directors
"bsAbs"	bispecific antibodies
"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 annual 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 SKB264 and A166
"CRC"	colorectal cancer
"CRO"	contract research organization
"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"	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
"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
"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
"GC"	gastric cancer
"GI"	gastrointestinal
"Global Offering"	the Hong Kong Public Offering and the International Offering (each as defined in the Prospectus)
"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
"Harbour BioMed"	Harbour BioMed Therapeutics Limited, an indirect wholly owned subsidiary of HBM Holdings Limited (和鉑醫藥控股有限公司), a company listed on the Stock Exchange (stock code: 02142)
"HER2"	human epidermal growth factor receptor 2
"HK$" or "HKD"	Hong Kong dollars, the lawful currency of Hong Kong
"HNSCC"	head and neck squamous cell carcinoma
"Hong Kong"	the Hong Kong Special Administrative Region of the PRC
"HR"	hormone receptor
"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
"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
"LC"	lung cancer
"Listing"	the listing of our H Shares on the Stock Exchange on July 11, 2023
"Listing Date"	July 11, 2023
"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"	proportion of patients with a complete response or partial response to treatment
"OS" or "overall survival"	the length of time from either the date of diagnosis or the start of treatment for a disease that patients diagnosed with the disease are still alive, used in clinical trials as a measurement of a drug's effectiveness
"Over-Allotment Option"	the over-allotment option which had been granted by the Company to the relevant underwriters to allot and issue up to an aggregate of 3,366,900 additional H Shares, representing 15% of the offer shares initially available under the Global Offering
"PD-1"	programmed cell death protein 1
"PD-L1"	PD-1 ligand 1
"PD-(L)1"	PD-1 or PD-L1

"PFS"	the length of time during and after the treatment that a patient lives without the disease getting worse
"Pre-IPO Employee Incentive Scheme"	the pre-IPO employee incentive scheme of the Company approved and adopted by the Board in 2016, as amended from time to time
"Pre-IPO Investments"	the Series A Financing and Series B Financing as defined in the Prospectus
"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
"Reporting Period"	the year ended December 31, 2023
"RDC(s)"	radionuclide drug conjugate(s)
"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
"subsidiary(ies)"	has the meaning ascribed thereto under the Listing Rules
"Supervisor(s)"	member(s) of the supervisory committee of the Company
"TKI"	tyrosine kinase inhibitor
"TNBC"	triple-negative breast cancer
"TRAE"	treatment-related adverse event, which is an adverse event that in the investigator's opinion may have been caused by the study medication with reasonable possibility

"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
"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, March 25, 2024

As at the date of this announcement, the Board of Directors of the Company comprises Mr. LIU Gexin as the chairman of the Board and non-executive Director, Dr. GE Junyou and Dr. WANG Jingyi as executive Directors, Mr. LIU Sichuan, 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.