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KELUN-BIOTECH
科伦博泰

Sichuan Kelun-Biotech Biopharmaceutical Co., Ltd.

四川科倫博泰生物醫藥股份有限公司

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

(Stock Code: 6990)

**INTERIM RESULTS ANNOUNCEMENT FOR THE
SIX MONTHS ENDED JUNE 30, 2023**

The Board is pleased to announce the unaudited condensed consolidated interim results of the Group for the six months ended June 30, 2023, together with comparative figures for the six months ended June 30, 2022. The independent auditor of the Company has carried out a review of the interim financial information in accordance with the Hong Kong Standard on Review Engagements 2410 "Review of Interim Financial Information Performed by the Independent Auditor of the Entity". Unless otherwise defined herein, capitalized terms used in this announcement shall have the same meanings as those defined in the prospectus of the Company dated June 29, 2023.

FINANCIAL HIGHLIGHTS

	Six months ended June 30,		Period to period change
	2023	2022	
	RMB'000	RMB'000	
	(Unaudited)	(Unaudited)	
Revenue	1,046,226	344,988	203.3%
Gross profit	675,660	225,889	199.1%
Loss for the period	(31,130)	(270,864)	-88.5%
Research and development expenses	(490,347)	(343,787)	42.6%
	As at	As at	
	June 30,	December 31,	
	2023	2022	
	RMB'000	RMB'000	
	(Unaudited)	(Unaudited)	
Cash and cash equivalents	587,261	92,960	
Financial assets measured at fair value through profit or loss	731,870	—	
Financial assets measured at amortized cost	270,000	—	
Bank loans and other borrowings	—	2,890,787	

BUSINESS HIGHLIGHTS

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

- **Key developments of our Core Product SKB264:**

- **NSCLC.** In January 2023, SKB264 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 for EGFR-mutant locally advanced or metastatic non-squamous NSCLC (TKI failure) in China.

Data presented on June 4, 2023 at the 2023 ASCO Annual Meeting from a phase 2 study of SKB264 in patients with treated locally advanced or metastatic NSCLC showed that the SKB264 demonstrated promising efficacy and controlled safety.

- **BC.** On June 30, 2023, SKB264 was granted Breakthrough Therapy Designation by the NMPA locally advanced or metastatic HR+ /HER2- BC who have previously received at least 2L systematic chemotherapy.

We achieved first-patient-in for a pivotal phase 3 trial for advanced TNBC in China in August 2022 and had completed patient enrollment. On August 13, 2023, we announced that the phase 3 clinical trial of SKB264 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.

- **Key developments of our Core Product A166:**

- A166 has met the primary endpoints of its pivotal phase 2 trial for 3L+ advanced HER2+ BC based on results from the primary analysis, which we used to submit an NDA to the NMPA in May 2023.
- We are conducting a confirmatory phase 3 trial in China for 2L+ advanced HER2+ BC and multiple phase 1b clinical trials in China to explore the therapeutic potential of A166 for other advanced HER2+ solid tumors, including GC and CRC.

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

- **SKB315.** We are carrying out the phase 1a clinical trial of SKB315 in patients with advanced solid tumors in China and certain other activities in support of SKB315's clinical development.
- **SKB410.** On February 27, 2023, we received IND approval from the NMPA for SKB410 which targets advanced solid tumors. We achieved first-patient-in for phase 1a clinical trials on July 6, 2023.
- **A167.** We have completed patient enrollment of the phase 3 trial of A167 in combination with chemotherapy as a 1L treatment for RM-NPC.

- o **A140.** We have completed patient enrollment in November 2022 with an anticipated NDA filing with NMPA for RAS wild-type mCRC in the second half of 2023.
- o **A400.** On June 5, 2023, data from the phase 1 clinical study of our second-generation selective RET inhibitor A400 was shared at a session of the 2023 ASCO Annual Meeting.

We commenced pivotal trial for advanced RET+ NSCLC in July 2023.

In July 2023, we received IND approval from the NMPA for advanced RET+ MTC.

- **Commercialization.** We are setting 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 Commerce, 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.
- **Collaboration with MSD.** MSD paid us a non-refundable upfront payment of US\$175.0 million (equivalent to approximately RMB1,205.5 million⁽¹⁾) in March 2023 pursuant to an exclusive license and collaboration agreement we entered into with MSD to develop up to seven preclinical ADC assets for the treatment of cancer.

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⁽²⁾) as part of the Series B Financing.

- **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⁽³⁾). On August 8, 2023, the Company also received net proceeds of additional HK\$196 million (equivalent to approximately RMB179.7 million⁽⁴⁾) from the full exercise of the Over-Allotment Option.

Notes:

- (1) *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.*
- (2) *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.*
- (3) *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.*
- (4) *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.*

INTERIM RESULTS

Consolidated statement of profit or loss for the six months ended June 30, 2023 – unaudited (Expressed in Renminbi (“RMB”))

	Note	Six months ended June 30,	
		2023	2022
		RMB'000	RMB'000
Revenue	3	1,046,226	344,988
Cost of sales		<u>(370,566)</u>	<u>(119,099)</u>
Gross profit		675,660	225,889
Other net income/(expenses)		24,120	(13,261)
Administrative expenses		(89,424)	(42,608)
Research and development expenses		<u>(490,347)</u>	<u>(343,787)</u>
Profit/(loss) from operations		120,009	(173,767)
Finance costs		<u>(78,732)</u>	<u>(72,479)</u>
Profit/(loss) before taxation		41,277	(246,246)
Income tax	4	<u>(72,407)</u>	<u>(24,618)</u>
Loss for the period attributable to equity shareholders of the Company		<u>(31,130)</u>	<u>(270,864)</u>
Loss per share	5		
Basic and diluted		<u>(0.17)</u>	<u>(2.52)</u>

**Consolidated statement of profit or loss and other comprehensive income
for the six months ended June 30, 2023 – unaudited**
(Expressed in RMB)

	Note	Six months ended June 30,	
		2023	2022
		<i>RMB'000</i>	<i>RMB'000</i>
Loss for the period		<u>(31,130)</u>	<u>(270,864)</u>
Other comprehensive income for the period (after tax)			
<i>Item that may be reclassified subsequently to profit or loss:</i>			
<i>Exchange differences on translation of financial statements of an overseas subsidiary</i>		<u>9,277</u>	<u>8,421</u>
Other comprehensive income for the period		<u>9,277</u>	<u>8,421</u>
Total comprehensive income for the period attributable to equity shareholders of the Company		<u>(21,853)</u>	<u>(262,443)</u>

Consolidated statement of financial position
at June 30, 2023 – unaudited
(Expressed in RMB)

	Note	As at June 30, 2023 RMB'000	As at December 31, 2022 RMB'000
Non-current assets			
Property, plant and equipment		543,398	530,349
Right-of-use assets		100,631	117,475
Intangible assets		3,052	3,179
Other non-current assets		7,035	9,826
		<u>654,116</u>	<u>660,829</u>
Current assets			
Inventories		90,692	52,636
Trade and other receivables	6	205,696	98,659
Amounts due from related parties		2,390	61,800
Financial assets measured at fair value through profit or loss (“FVPL”)	7	731,870	–
Financial assets measured at amortized cost		270,000	–
Restricted deposits	8	19,600	26,261
Cash and cash equivalents	8	587,261	92,960
		<u>1,907,509</u>	<u>332,316</u>
Current liabilities			
Trade and other payables	9	353,618	243,405
Amounts due to related parties		36,963	206,908
Financial instruments issued to investors		1,976,773	580,021
Contract liabilities		623,078	163,976
Bank loans and other borrowings	10	–	2,890,787
Lease liabilities		41,206	82,264
		<u>3,031,638</u>	<u>4,167,361</u>
Net current liabilities		<u>(1,124,129)</u>	<u>(3,835,045)</u>
Total assets less current liabilities		<u>(470,013)</u>	<u>(3,174,216)</u>

**Consolidated statement of financial position
at June 30, 2023 – unaudited (continued)**
(Expressed in RMB)

	Note	As at June 30, 2023 <i>RMB'000</i>	As at December 31, 2022 <i>RMB'000</i>
Non-current liabilities			
Lease liabilities		44,520	41,292
Deferred income		10,678	10,678
		55,198	51,970
NET LIABILITIES		(525,211)	(3,226,186)
CAPITAL AND RESERVES			
Share capital	11	193,383	107,370
Reserves		(718,594)	(3,333,556)
TOTAL DEFICIT		(525,211)	(3,226,186)

Consolidated statement of changes in equity
for the six months ended June 30, 2023 – unaudited
(Expressed in RMB)

	Share capital <i>RMB'000</i>	Capital reserves <i>RMB'000</i>	Exchange reserves <i>RMB'000</i>	Accumulated losses <i>RMB'000</i>	Total <i>RMB'000</i>
Balance at January 1, 2022	107,370	128,066	(13,239)	(2,866,083)	(2,643,886)
Changes in equity for the six months ended June 30, 2022					
Loss for the period	–	–	–	(270,864)	(270,864)
Exchange differences on translation of financial statements of an overseas subsidiary	–	–	8,421	–	8,421
Total comprehensive income	–	–	8,421	(270,864)	(262,443)
Equity-settled share-based payment	–	9,797	–	–	9,797
Balance at June 30, 2022 and July 1, 2022	<u>107,370</u>	<u>137,863</u>	<u>(4,818)</u>	<u>(3,136,947)</u>	<u>(2,896,532)</u>
	Share capital <i>RMB'000</i>	Capital reserves <i>RMB'000</i>	Exchange reserves <i>RMB'000</i>	Accumulated losses <i>RMB'000</i>	Total <i>RMB'000</i>
Balance at July 1, 2022	107,370	137,863	(4,818)	(3,136,947)	(2,896,532)
Changes in equity for the six months ended December 31, 2022					
Loss for the period	–	–	–	(345,235)	(345,235)
Exchange differences on translation of financial statements of an overseas subsidiary	–	–	5,567	–	5,567
Total comprehensive income	–	–	5,567	(345,235)	(339,668)
Equity-settled share-based payment	–	10,014	–	–	10,014
Balance at December 31, 2022 and January 1, 2023	<u>107,370</u>	<u>147,877</u>	<u>749</u>	<u>(3,482,182)</u>	<u>(3,226,186)</u>

Consolidated statements of changes in equity
for the six months ended June 30, 2023 – unaudited (continued)
(Expressed in RMB)

	Share capital <i>RMB'000</i>	Capital reserves <i>RMB'000</i>	Exchange reserves <i>RMB'000</i>	Accumulated losses <i>RMB'000</i>	Total <i>RMB'000</i>
Balance at January 1, 2023	107,370	147,877	749	(3,482,182)	(3,226,186)
Changes in equity for the six months ended June 30, 2023					
Loss for the period	–	–	–	(31,130)	(31,130)
Exchange differences on translation of financial statements of an overseas subsidiary	–	–	9,277	–	9,277
Total comprehensive income	–	–	9,277	(31,130)	(21,853)
Issuance of new shares	59,937	2,598,744	–	–	2,658,681
Issuance of shares with preferential rights	26,076	1,297,399	–	–	1,323,475
Recognition of financial liabilities recognized for preferential rights issued to investors	–	(1,323,475)	–	–	(1,323,475)
Equity-settled share-based payment	–	64,147	–	–	64,147
Balance at June 30, 2023	<u>193,383</u>	<u>2,784,692</u>	<u>10,026</u>	<u>(3,513,312)</u>	<u>(525,211)</u>

**Condensed consolidated statement of cash flows
for the six months ended June 30, 2023 – unaudited**
(Expressed in RMB)

	Six months ended June 30,	
	2023	2022
	RMB'000	RMB'000
Operating activities		
Net cash generated from/(used in) operating activities	471,080	(155,038)
Investing activities		
Payment for the purchase of property, plant and equipment	(32,130)	(7,206)
Proceeds from disposal of property, plant and equipment	3	6,329
Payment for intangible assets	(1,137)	(1,837)
Payment for investment in financial assets measured at FVPL	(1,380,000)	–
Proceeds from redemption of financial assets measured at FVPL	651,635	–
Payment for investment in financial assets measured at amortized cost	(270,000)	–
Net cash used in investing activities	(1,031,629)	(2,714)
Financing activities		
Proceeds from new bank loans	–	115,000
Repayment of bank loans	(100,000)	(30,000)
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	–
Interest paid	(563)	(620)
Capital element of lease rentals paid	(37,663)	(498)
Interest element of lease rentals paid	(5,590)	(5)
Net cash generated from financing activities	1,044,300	331,877
Net increase in cash and cash equivalents	483,751	174,125
Cash and cash equivalents at January 1	92,960	81,793
Effect of foreign exchange rate changes	10,550	2,688
Cash and cash equivalents at June 30	587,261	258,606

Condensed consolidated statement of cash flows
for the six months ended June 30, 2023 – unaudited (continued)
(Expressed in RMB)

Significant financing activities not requiring the use of cash or cash equivalents:

	Note	Six months ended June 30,	
		2023	2022
		<i>RMB'000</i>	<i>RMB'000</i>
Settlement of other borrowings by issuing equity to Kelun Pharmaceutical	10	<u>2,500,000</u>	<u>–</u>

NOTES TO THE UNAUDITED INTERIM FINANCIAL REPORT

(Expressed in thousands of RMB, unless otherwise stated)

1 BASIS OF PREPARATION

This interim financial report has been prepared in accordance with the applicable disclosure provisions of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, including compliance with International Accounting Standard (IAS) 34, *Interim financial reporting*, issued by the International Accounting Standards Board (“IASB”). It was authorised for issue on August 28, 2023.

The interim financial report has been prepared in accordance with the same accounting policies adopted in the historical financial information for the years ended December 31, 2021 and 2022 (the “Historical Financial Information”) as disclosed in Appendix I to the prospectus of the Company dated June 29, 2023 (the “Prospectus”) in connection with the initial listing of shares of the Company (the “Listing”) on the Main Board of The Stock Exchange of Hong Kong Limited, as disclosed in the accountants’ report dated June 29, 2023, except for the accounting policy changes that are expected to be reflected in the 2023 annual financial statements. Details of any changes in accounting policies are set out in note 2.

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

This interim financial report contains condensed consolidated financial statements and selected explanatory notes. The notes include an explanation of events and transactions that are significant to an understanding of the changes in financial position and performance of the Company and its subsidiaries (together as “the Group”) since the Historical Financial Information as disclosed in Appendix I to the Prospectus. The condensed consolidated interim financial statements and notes thereon do not include all of the information required for a full set of financial statements prepared in accordance with the International Financial Reporting Standards (the “IFRSs”).

As at June 30, 2023, the Group had net current liabilities of RMB1,124,129,000 and net liabilities of RMB525,211,000, which was primarily because financial instruments issued to investors totalling RMB1,976,773,000 are classified as current liabilities. Such financial instruments issued to investors have been automatically and irrevocably converted into ordinary shares after the Listing on July 11, 2023 and turned the Group into net assets position since then.

Accordingly, the directors of the Company are of the opinion that no material uncertainties related to events or conditions which, individually or collectively, may cast significant doubt on the Group’s ability to continue as a going concern.

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

The financial information relating to the financial year ended 31 December 2022 that is included in the interim financial report as comparative information does not constitute the Company’s statutory annual consolidated financial statements for that financial year but is derived from the Historical Financial Information.

2 CHANGES IN ACCOUNTING POLICIES

The IASB has issued several new or amendments to IFRSs that are first effective for the current accounting period of the Group. None of these developments have had a material effect on how the Group’s results and financial position for the current or prior periods have been prepared or presented in this interim financial information.

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

3 REVENUE

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

Disaggregation of revenue

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

	Six months ended June 30,	
	2023	2022
	RMB'000	RMB'000
Revenue from contracts with customers within the scope of IFRS 15		
Revenue from license and collaboration agreements	1,040,171	335,976
Revenue from provision of research and development service	6,055	9,012
	<u>1,046,226</u>	<u>344,988</u>

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

	Six months ended June 30,	
	2023	2022
	RMB'000	RMB'000
Disaggregated by timing of revenue recognition		
Point in time	759,992	205,407
Over time	286,234	139,581
	<u>1,046,226</u>	<u>344,988</u>

4 INCOME TAX

	Six months ended June 30,	
	2023	2022
	RMB'000	RMB'000
Current tax		
Provision for the period		
– The PRC Corporate Income Tax	–	–
– Withholding Tax	72,407	24,618
	<u>72,407</u>	<u>24,618</u>

(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 is entitled to preferential income tax of 15% from 2020 to 2022.

(ii) Withholding Tax

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

5 LOSS PER SHARE

(a) Basic loss per share

The calculation of basic loss per share is based on loss attributable to ordinary equity shareholders of the Company of RMB31,130,000 (for the six months ended June 30, 2022: loss of RMB270,864,000), excluding allocation of loss for the period attributable to financial instruments issued to investors of RMB5,753,000 (for the six months ended June 30, 2022: loss of RMB29,896,000) and the weighted average of 152,240,000 ordinary shares in issue for the six months ended June 30, 2023 (for the six months ended June 30, 2022: 95,519,000 shares).

(b) Diluted loss per share

The calculation of diluted loss per share amounts for the six months ended June 30, 2022 and 2023 had not included financial instruments issued to investors by the Company, as they had an anti-dilutive effect on the diluted loss per share amounts.

Accordingly, diluted loss per share were the same as basic loss per share.

6 TRADE AND OTHER RECEIVABLES

	As at June 30, 2023 RMB'000	As at December 31, 2022 RMB'000
Trade receivables	1	–
Other receivables	3,193	1,846
Value Added Tax (“VAT”) recoverable	71,567	40,785
Prepayments	130,935	56,028
	<u>205,696</u>	<u>98,659</u>

(a) Ageing analysis

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

	As at June 30, 2023 RMB'000	As at December 31, 2022 RMB'000
Within 3 months (inclusive)	<u>1</u>	<u>–</u>

Trade debtors are due within 30 days from the date of billing.

7 FAIR VALUE MEASUREMENT OF FINANCIAL INSTRUMENTS

(a) Financial assets and liabilities measured at fair value

Fair value hierarchy

The following table presents the fair value of the Group's financial instruments measured at the end of the reporting period on a recurring basis, categorised into the three-level fair value hierarchy as defined in IFRS 13, *Fair value measurement*. The level into which a fair value measurement is classified is determined with reference to the observability and significance of the inputs used in the valuation technique as follows:

- Level 1 valuations: Fair value measured using only Level 1 inputs i.e. unadjusted quoted prices in active markets for identical assets or liabilities at the measurement date.
- Level 2 valuations: Fair value measured using Level 2 inputs i.e. observable inputs which fail to meet Level 1, and not using significant unobservable inputs. Unobservable inputs are inputs for which market data are not available.
- Level 3 valuations: Fair value measured using significant unobservable inputs.

The following table presents the Group's financial assets that are measured at fair value at the end of each reporting period:

The Group

	As at June 30, 2023 RMB'000	As at December 31, 2022 RMB'000
Level 3		
Financial assets measured at FVPL		
Wealth management products issued by banks	731,870	–

Information about Level 3 fair value measurements

	<i>Valuation techniques</i>	<i>Significant unobservable inputs</i>
Investment in wealth management products	Discount cash flow method	– Interest return rate

During the six months ended June 30, 2022 and 2023, there were no transfers between Level 1 and Level 2, or transfers into or out of Level 3. The Group's policy is to recognize transfers between levels of fair value hierarchy as at the end of the reporting period in which they occur.

The movements during the reporting periods in the balance of these Level 3 financial assets of the Group at fair value through profit or loss are as follows:

	2023 <i>RMB'000</i>	2022 <i>RMB'000</i>
Financial assets measured at FVPL		
At January 1	–	–
Payment for purchases	1,380,000	–
Changes in fair value recognized in profit or loss during the year/period	3,505	–
Redemption	(651,635)	–
	<u>731,870</u>	<u>–</u>
At June 30 / December 31	<u>731,870</u>	<u>–</u>

(b) Fair value of financial assets and liabilities carried at other than fair value

The carrying amounts of the Group's financial instruments carried at cost or amortized cost were not materially different from their fair values as at December 31, 2022 and June 30, 2023.

8 CASH AND CASH EQUIVALENTS

	As at June 30, 2023 <i>RMB'000</i>	As at December 31, 2022 <i>RMB'000</i>
Cash at bank	606,861	119,221
Less: restricted bank deposits	(19,600)	(26,261)
	<u>587,261</u>	<u>92,960</u>

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

9 TRADE AND OTHER PAYABLES

	As at June 30, 2023 <i>RMB'000</i>	As at December 31, 2022 <i>RMB'000</i>
Trade payables	251,988	123,259
Other payables	3,402	3,059
Bills payable	19,600	27,777
Accrued payroll and benefits	76,553	86,608
Other taxes payable	2,075	2,702
	<u>353,618</u>	<u>243,405</u>

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

	As at June 30, 2023 RMB'000	As at December 31, 2022 RMB'000
Within 1 year	270,507	149,663
1 to 2 years	296	642
2 to 3 years	80	307
More than 3 years	705	424
	<u>271,588</u>	<u>151,036</u>

10 BANK LOANS AND OTHER BORROWINGS

	As at June 30, 2023 RMB'000	As at December 31, 2022 RMB'000
Current		
Guaranteed bank loans	–	100,000
Other borrowings from Kelun Pharmaceutical (note)	–	2,790,787
	<u>–</u>	<u>2,890,787</u>

Note: 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.

11 CAPITAL, RESERVES AND DIVIDENDS

(a) Capital and reserves

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 further subscribe for an aggregate of 51,256,000 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.

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 26,076,000 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”.

During the six months ended June 30, 2023, the share-based payment vehicles paid RMB8,681,000 to the Company in exchange of 8,681,000 shares of the Company. Accordingly, the Company recorded RMB8,681,000 in share capital.

(b) Dividends

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

12 COMMITMENTS

Capital commitments outstanding at June 30, 2023 not provided for in the interim financial information were as follows:

	As at June 30, 2023 RMB'000	As at December 31, 2022 RMB'000
Contracted for construction in progress	<u>59,376</u>	<u>70,151</u>

13 SUBSEQUENT EVENTS

On July 11, 2023, the Company was listed on Hong Kong Stock Exchange. Upon completion of the initial public offering, the Company issued 22,446,100 shares, with a par value of RMB1.00 each and initial offer price of HK\$60.60 each and received the gross proceeds of approximately HK\$1,360 million.

On August 8, 2023, the Company issued 3,366,900 shares, with a par value of RMB1.00 each and initial offer price of HK\$60.60 each in connection with the full exercise of the over-allotment option. The Company received the additional gross proceeds of HK\$204 million from the exercise of over-allotment option.

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 since our incorporation in 2016. We have two antibody drug conjugate (ADC) drugs as our Core Products, namely, SKB264 and A166. SKB264 is a novel phase 3-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 new drug application (NDA) registration-stage HER2 ADC positioned as a late-line monotherapy to treat advanced HER2-positive (HER2+) solid tumors. As at June 30, 2023, we were also developing 12 non-core clinical-stage assets.

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

Product	Target	Molecule Type	Indication (Lines of Treatment)	Preclinical/IND-enabling	Phase Ia	Phase 1b/2	Registration Pivotal Ph. II/ Ph. III	NDA Filing	NCT/CTR No.	Commercial Rights/Partners
ADC			TNBC (3L+)	Combo with/without A167					NCT05371141; CTR20223474; NCT05445908; CTR20221755	Greater China /  (ex-Greater China)
			TNBC (1L)						NCT04152499; CTR20201069	
			HR+/HER2- BC (2L+)				(2H 2023)*		NCT05631523; CTR20222948	
			EGFR-mutant NSCLC (TKI failure)	Combo with Keytruda® and/or chemo						
			EGFR-wild type (1L) and EGFR-mutant (TKI failure) NSCLC	Combo with osimertinib						
	SKB264	TROP2	Large	EGFR-wild type NSCLC (1L)	Combo with A167 with/without platinum-based chemo				NCT05317881; CTR20220980	
				GC (2L+)						
				OC (platinum-resistant)						
				Solid tumors (SCLC, UC, HNSCC and EC)						
				NPC (PD-(L)- relapse or refractory)						
Other Modalities*			CC (2/3L)	Combo with Keytruda®						Global
			UC (1L)	Combo with Keytruda®						
			OC (2L maintenance)	Combo with Keytruda®						
			CRPC (2L+)	Combo with Keytruda®						
			HER2+ BC (3L+)							
	A166	HER2	Large	HER2+ BC (2L+)						
				HER2+ GC (2L+)						
				HER2+ CRC (3L+)						
				Solid tumors						
	SKB315	CLDN18.2	Large	Solid tumors						
Non-oncology*			Solid tumors							Greater China and part of Asia
			Solid tumors							
			Solid tumors							
	A167	PD-L1	Large	NPC (3L+)	Combo with chemotherapy					
	A140	EGFR (Biosimilar)	Large	NPC (1L)						
				CRC ³						
	A400	RET	Small	RET+ NSCLC						
				RET+ MTC and other RET+ solid tumors						
				RET+ inhibitor-resistant solid tumors						
	SKB337	PD-L1/ CTLA4	Large	Solid tumors						
A289†	LAG3	Large	Solid tumors						Global	
A296	STING	Small	Solid tumors (intravenous infusion)						Global	
			Solid tumors (intratumoral injection)						Global	
A223	JAK 1/2	Small	Rheumatoid arthritis						Global	
A277	KOR	Small	Alopecia areata						Global	
SKB378	TSLP	Large	CKD-aP						Global	
SKB336	FX/FXla	Large	Asthma						Global	
			Thromboembolic disorders						Global	

* Core Products † Key Products ‡ Breakthrough Designation

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

Notes: 1. Including immunotherapy and targeted therapies; 2. No phase II clinical trial is required for biosimilar drug candidates in China; 3. CDE consultation ongoing; 4. We completed a phase 1a study and are conducting a phase 1b study. Based on the NMPA's approval, we also commenced a pivotal phase 2 clinical trial. Upon meeting the primary endpoint in this trial, we filed NDA for conditional approval, which is under priority review. Although we completed the study per protocol, the trial is ongoing as certain patients responsive to the drug continue with treatment. We also initiated a confirmatory phase 3 trial of A166 as a 2L+ treatment in advanced HER2+ BC patients in June 2023; 5. CDE consultation ongoing; 6. A phase 1a and pivotal phase 2 clinical trial was completed. We commenced a confirmatory phase 3 trial upon consultation with the CDE; 7. Phase 1a/1b trial.

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. As at June 30, 2023, we have entered into nine out-license agreements, including three license and collaboration agreements with Merck Sharp & Dohme LLC (together with its affiliates, “MSD”) to develop up to nine ADC assets for cancer treatment with upfront and milestone payments totaling up to US\$11.8 billion. 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. Our collaboration with MSD to develop up to seven preclinical ADC assets is the largest biopharmaceutical out-license deal to date secured by a China-based company, according to Frost & Sullivan, and the world's largest biopharmaceutical partnership in terms of deal value in 2022, according to Nature Reviews Drug Discovery. We have also entered into collaboration and license agreements with Ellipses for A400, and with Harbour BioMed for A167 and SKB378. 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 June 30, 2023, we had established a pipeline of 14 clinical-stage drug candidates, including five in pivotal trial – or NDA registration-stage. We have also assembled a diverse portfolio of preclinical assets, including four in IND-enabling stage, 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:**
 - o **SKB264 (*sacituzumab tirumotecan*)**, one of our Core Products, a novel TROP2 ADC targeting advanced solid tumors;
 - o **A166 (*trastuzumab botidotin*)**, another Core Product, a differentiated HER2 ADC in NDA registration stage to treat advanced HER2+ solid tumors;
 - o **SKB315**, a novel CLDN18.2 ADC targeting advanced solid tumors; and
 - o **SKB410**, a novel ADC targeting advanced solid tumors.
- **Other modalities (*Immunotherapies and Targeted Therapies*):**
 - o **A167 (*tagitanlimab*)**, our PD-L1 mAb, which is expected to be our first commercialized product and the backbone of our immunotherapy franchise;
 - o **A140**, a pivotal phase 3 biosimilar of EGFR mAb cetuximab, which has the potential to be the first cetuximab biosimilar in China with an anticipated NDA filing in the second half of 2023; and
 - o **A400**, a 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.

We will also continue to accelerate the R&D of our preclinical oncology assets. For example, we are developing over ten preclinical ADC assets with their respective targets expressed across a broad spectrum of solid tumors.

SKB264

SKB264, one of our Core Products, is a novel 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, GC and OC. Positioned to be the first domestically developed TROP2 ADC in China, 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.

Our advanced triple-negative breast cancer (TNBC) data presented at the 2022 San Antonio Breast Cancer Symposium (SABCS) showed that SKB264 demonstrated an ORR of 43.6% and a DCR of 80% in TNBC patients. The median PFS was 5.7 months. Preliminary OS data were encouraging and 12-month OS rate was 66.4%. Preliminary clinical data from SKB264's global phase 1/2 trial presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting also showed that SKB264 demonstrated encouraging ORRs across heavily pretreated advanced NSCLC patients: for the subgroup with TKI-resistant EGFR-mutant NSCLC (among which 50% also failed at least one line of chemotherapy), the ORR was 60.0%, DCR was 100%, median PFS was 11.1 months, 9-month PFS rate was 66.7% and 12-month OS rate was 80.7%; for EGFR wild-type subgroup (previously received median 2 lines of therapy including anti-PD-(L)1 therapy), the ORR was 26.3%, DCR was 89.5%, median PFS was 5.3 months, 9-month OS rate was 80.4% and 12-month OS rate was 60.6%.

SKB264 also demonstrated a potentially favorable safety profile. Based on non-head-to-head cross-trial comparisons⁽¹⁾, SKB264 in patients with different types of advanced solid tumors (including TNBC) demonstrated lower incidences of decreased neutrophil count (54% vs 78% for all grades, 26% vs 49% for \geq grade 3) and diarrhea (4% vs 59% for all grades, 0% vs 11% for \geq grade 3) compared with Trodelvy®; and no incidence of treatment-related interstitial lung disease compared with that reported in DS-1062-treated patients (6% for all grades and 2% for \geq grade 3).⁽²⁾

Our data from SKB264's phase 1/2 clinical trial focusing on the treatment of previously-treated patients with metastatic hormone receptorpositive (HR+) and human epidermal growth factor receptor 2-negative (HER2-) BC will be presented in the form of an oral presentation at the 2023 European Society for Medical Oncology (ESMO) Congress in October 2023.

We are also exploring SKB264's early-line potential in combination therapy. Based on preliminary results from a phase 2 trial conducted in China, SKB264 in combination with A167 demonstrated a promising ORR of 85.7% as a 1L therapy in advanced TNBC patients. We are actively advancing a multi-strategy clinical development plan to explore SKB264's potential as a monotherapy and combination therapies to treat various advanced solid tumors, including BC, NSCLC and other major cancers.

We achieved first-patient-in for a pivotal phase 3 trial for advanced TNBC in China in August 2022 and had completed patient enrollment. On August 13, 2023, we announced that the randomized, controlled, open-label, multi-center phase 3 clinical trial of SKB264 for injection 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 plans to communicate with the Center for Drug Evaluation (CDE) of the NMPA of China regarding the submission of an NDA of SKB264. We plan to advance to phase 3 trial for HR+/HER2-

Notes:

- (1) *Based on common drug adverse reactions (\geq 30% all grades or \geq 2% grades 3 or 4) for SKB264, Trodelvy®, or DS-1062.*
- (2) *Source: Trodelvy®: Trodelvy®'s drug label; DS-1062: WCLC 2021.*

BC in the second half of 2023. We also 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.

Supported by its promising proof-of-concept results, SKB264 was granted Breakthrough Therapy Designation by the NMPA for locally advanced or metastatic TNBC in July 2022, for EGFR-TKI failed EGFR-mutant locally advanced or metastatic NSCLC in January 2023 and locally advanced or metastatic HR+/HER2- BC who have previously received at least 2L systematic chemotherapy on June 30, 2023.

In May 2022, we granted MSD exclusive development and commercialization rights for SKB264 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.

SKB264 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

A166

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, with the potential to be one of the first domestically developed ADCs for HER2+ BC in China. HER2 overexpression is widely recognized as a major driver of prevalent cancers, including BC and GI cancers.

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 preliminary results from our ongoing phase 1 dose expansion study and ongoing phase 1b trial in China. A166 also showed a differentiated safety profile from that of Kadcyla[®], Enhertu[®] and Aidixi[®], the only three FDA and/or NMPA-approved HER2 ADCs as at June 30, 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⁽³⁾. This suggests the potential of A166 to widen the treatment options available to advanced HER2+ solid tumor patients with different susceptibility to adverse drug reactions.

We have designed a multi-indication clinical development plan to advance A166 in China. A166 has met the primary endpoints of its pivotal phase 2 trial for 3L+ advanced HER2+ BC based on results from the primary analysis, 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 for 2L+ advanced HER2+ BC in an ongoing confirmatory phase 3 trial in China and for other advanced HER2+ solid tumors, including GC and CRC, in ongoing phase 1b clinical trials in China.

Notes:

(3) *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.*

A166 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

SKB315

SKB315 is a novel CLDN18.2 ADC designed for treating advanced solid tumors. CLDN18.2 is highly expressed in prevalent and lethal cancers with limited effective treatments such as gastric cancer 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 reported at June 30, 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. With a differentiated payload-linker design and an independently developed humanized CLDN18.2 antibody, 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, which we initiated in February 2022.

SKB315 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

SKB410

SKB410 is a novel ADC targeting advanced solid tumors. Utilizing a differentiated payload-linker strategy, SKB410 is equipped with a moderately toxic payload that potentially reduces toxicities, with improved therapeutic window and safety profile demonstrated in preclinical studies compared to the latest non-head-to-head data publicly available for an FDA-approved ADC targeting the same tumor-associated antigen.

We received IND approval from the NMPA for SKB410 on February 27, 2023, and achieved first-patient-in for the phase 1a clinical trials on July 6, 2023.

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

SKB410 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

A167

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.

A167 is expected to be our first commercialized product and 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, highlighted by an ORR of 85.7% in 1L advanced TNBC patients. 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 conditional approval in the second half of 2023 or the first half of 2024 to market A167 as a 3L+ treatment for RM-NPC. This approval, if granted, will be conditional partly upon our commitment to complete a phase 3 trial of A167 in combination with chemotherapy as a 1L treatment for RM-NPC, for which we had completed patient enrollment as at June 30, 2023. 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.

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 pivotal phase 3 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 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 have completed patient enrollment in November 2022 and A140 has potential to be the first cetuximab biosimilar in China with an anticipated NDA filing in the second half of 2023. Notably, A140 is the first cetuximab biosimilar candidate in China to adopt a phase 3 head-to-head trial design that strictly follows the Guidelines for Design of Clinical Trials of Injectable Cetuximab Biosimilar (for Trial Implementation) of the CDE, which potentially translates into an accelerated review process.

A140 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

A400

A400, a second-generation selective 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 MTC. Although two first-generation selective RET inhibitors were approved in China for RET+ solid tumors as at June 30, 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.

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 74% and 66.7% at RP2D for 1L and 2L+ advanced RET+ NSCLC, respectively, based on preliminary results from its ongoing phase 1/2 trial. Notably, A400 also demonstrated therapeutic potential in selective RET inhibitor resistant patients with an ORR of 33% and disease control rate of 83% at RP2D, as well as a differentiated safety profile, with no incidence of grade 3 or above lymphopenia and thrombocytopenia and substantially lower incidence of grade 3 or above cardiovascular AEs (e.g., hypertension), hematological toxicity and electrolyte abnormalities, based on non-head-to-head cross-trial comparisons with approved selective RET inhibitors. These encouraging results support the potential of A400 to be an efficacious and safe second-generation selective RET inhibitor for NSCLC, MTC and other solid tumors with a high prevalence of RET alterations.

We are rapidly progressing the clinical development of A400 in China. We completed the dose escalation study of a phase 1/2 trial for advanced RET+ solid tumors with ongoing patient enrollment for the dose expansion study. On June 5, 2023, data from the phase 1 clinical study of A400 was shared at a session of the 2023 ASCO Annual Meeting. 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 for pivotal trial for advanced RET+ NSCLC, which we commenced in July 2023. In July 2023, we received IND approval from the NMPA for advanced RET+ MTC.

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.

A400 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

Other oncology assets

We are also advancing several early-stage oncology assets, including:

- **SKB337**, a differentiated PD-L1/cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) bsAb in phase 1 stage, with a potentially better safety and efficacy profile than monospecific PD-L1 and CTLA-4 mAbs demonstrated in preclinical studies.
- **A289**, a phase 1-stage mAb targeting lymphocyte-activation gene 3 (LAG-3), a new-generation immune checkpoint receptor, and has demonstrated its potential to synergize with PD-(L)1 mAbs and chemotherapy to promote anti-tumor response.
- **A296**, 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.

Meanwhile, we are exploring combination therapies between our other immunotherapy drugs, as well as with our ADC portfolio, to expand their clinical application in broad cancer types.

SKB337, A289 AND 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).

A223

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

RA is a prevalent autoimmune disease that requires long-term treatment. Inhibiting JAKs is a clinically validated approach for treating RA, with three JAK inhibitors, each with a different selectivity to the four JAKs, approved by the NMPA in China for treating RA. Among them, JAK1/2 inhibitor Olumiant® has been demonstrated to better improve the symptoms of RA patients based on cross-trial comparisons of clinical trials of the combination treatment with methotrexate (MTX) for treating RA. However, the approved JAK inhibitors have major safety issues, with black box warning issued by the FDA for increased risks of serious side effects including serious infection, death, malignancy, thrombosis, and major adverse cardiovascular events.

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.

Notably, based on non-head-to-head comparison, the ACR20 and ACR50 differences achieved by A223 2 mg are greater than those of Olumiant® 4 mg, the approved dosage of Olumiant® in China, in Chinese patients with moderate-to-severe RA (ACR20 difference vs. placebo: 30.8%; ACR50 difference vs. placebo: 20.7%). These promising clinical results indicate the potential of A223 to be an effective treatment option with improved efficacy and safety for RA.

In December 2020, we initiated a phase 2 trial in patients with moderate-to-severe RA. Based on the promising preliminary results from A223's ongoing phase 2 trial, we plan to commence a pivotal phase 3 trial in patients with moderate-to-severe RA in China in the second half of 2023. We have also expanded A223's target indication to AA, a common autoimmune disease of the hair follicle, with Olumiant® being the first and one of the only two systemic treatments administered orally for severe AA approved by the FDA and the only disease-specific treatment administered orally for the same indication approved in China as at June 30, 2023. We initiated a phase 2 trial for severe AA in China in August 2022 which we expect to complete patient enrollment in the second half of 2023.

A223 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

Other non-oncology assets

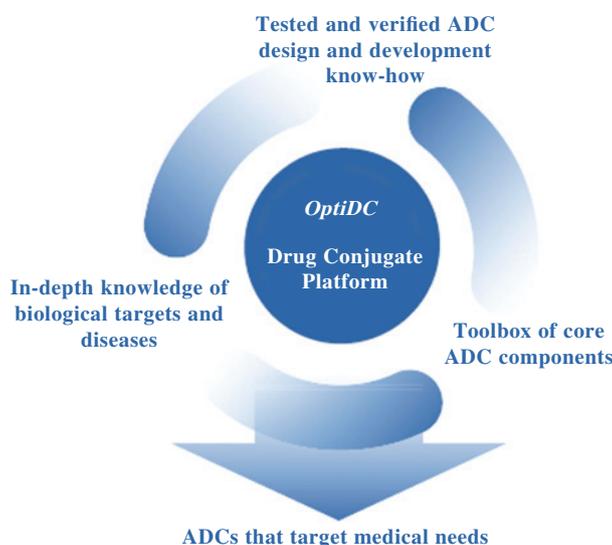
In addition to A223, we are also evaluating three other clinical-stage assets (A277, SKB378 and SKB336) and various preclinical assets to target indications ranging from chronic kidney disease (CKD)-associated pruritus (CKD-aP), moderate-to-severe asthma, thromboembolic disorders, to other diseases and conditions with large patient populations and medical needs. Apart from our existing assets, 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.

A277, SKB378 AND SKB336 MAY NOT ULTIMATELY BE SUCCESSFULLY DEVELOPED AND COMMERCIALIZED.

OUR TECHNOLOGY PLATFORMS

We have established three core platforms specializing in ADC, 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 over 1,200 patients as at June 30, 2023.



Our platform has been tested through extensive studies and trials, including validation from over ten clinical or preclinical ADC candidates. Our ADC design strategies are exemplified by Kthiol, our proprietary drug-linker strategy implemented in SKB264. An optimized balance between safety and efficacy is achieved in this strategy by incorporating a novel irreversible antibody conjugating technology, a pH-sensitive toxin release mechanism, and a moderately potent toxin homogeneously loaded with a drug-to-antibody ratio of 7.4. Our continued advancement in ADC research and development forms a feedback loop that strengthens our platform and enables our consistent and rapid delivery of highly competitive ADC candidates.

- **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. As at June 30, 2023, we had six clinical assets and various preclinical assets developed under our biologics platform. Our clinical assets include two mAbs at pivotal phase 3 or NDA registration-stage, A167 (PD-L1) and A140 (EGFR), as well as SKB337 (PD-L1/CTLA-4), A289 (LAG-3), SKB378 (TSLP) and SKB336 (factor XI/XIa). Our preclinical assets are mainly antibodies with novel targets and differentiated mechanisms of action that potentially enable broad clinical applications and reduced drug resistance.
- **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. Leveraging this platform, we have built an innovative pipeline of four clinical-stage small molecule drug candidates, including A400 (selective RET inhibitor), A223 (JAK1/2 inhibitor), A296 (STING agonist) and A277 (kappa-opioid receptor (KOR) agonist), and various preclinical assets. We are also exploring state-of-the-art technologies such as proteolysis targeting chimera (PROTAC) to navigate challenging protein targets, with one small-molecule PROTAC candidate currently at IND-enabling stage.

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. Our end-to-end capabilities 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.

- ***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 ten 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 pharmacology 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.*** To date, we have entered into three license and collaboration agreements with MSD to develop up to nine ADC assets (including SKB264, SKB315 and SKB410) for cancer treatment.

In May 2022, we granted MSD an exclusive, royalty-bearing and sub-licensable license to develop, use, manufacture and commercialize our TROP2 ADCs, including SKB264 (also known as “MK2870” in MSD’s portfolio) and any other TROP2 ADCs we may develop in the future, and products containing one or more such TROP2 ADCs 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. As at the date of this announcement, SKB264 was the only TROP2 ADC in our pipeline, and therefore the only TROP2 ADC specifically out-licensed to MSD to date, and we had no specific plans to develop other TROP2 ADCs in addition to SKB264.

In June 2022, we granted MSD an exclusive, royalty-bearing, sub-licensable license to develop, use, manufacture and commercialize SKB315 and products based on SKB315 globally.

In December 2022, we entered into an exclusive license and collaboration agreement with MSD to develop up to seven preclinical ADC assets (including SKB410, which had progressed to clinical trial stage as at the date of this announcement). 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. MSD paid us a non-refundable upfront payment of US\$175.0 million (equivalent to approximately RMB1,205.5 million⁽⁴⁾) in March 2023.

- ***Collaboration with Ellipses.*** In March 2021, we entered into a collaboration and license agreement with Ellipses, under which we granted Ellipses an exclusive, royalty-bearing, sublicensable license to develop, manufacture and commercialize A400 (the “**A400 Licensed Products**”) in all countries excluding Greater China, North Korea, South Korea, Singapore, Malaysia and Thailand.

An IND application for A400 was approved by FDA in June 2022. A clinical trial application of A400 was approved by the Spanish Agency of Medicines and Medical Devices (AEMPS) in February 2023. As of July 26, 2023, seven and four clinical research centers in the United States and Europe, respectively, were in use for A400. We have received certain milestone payments from Ellipses during the Reporting Period.

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.

Notes:

- (4) *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.*

- **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, antibody production, syntheses of payloads and linkers, ADC conjugation to formulation, fill and finish. In particular, our in-house cell culture and purification facilities enable us to secure quality supplies that match our specific production requirements at significantly reduced costs, supported by two 2,000 L single-use bioreactors. We are also equipped with one 300 L ADC conjugation tank with a maximum annual production capacity of 40 batches of ADC drug substance. Our new ADC formulation center is designed with an annual output of 45 batches (or 900,000 vials) of freeze-dried ADCs or 60 batches (or 1.2 million vials) of injectable ADCs.
- **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. Furthermore, our quality expert team are actively involved in the discussion and promulgation of regulations and guidelines in China, 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.

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 are planning to develop 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 conditional marketing approval from the NMPA for A167 (PD-L1 mAb), our first innovative drug in NDA registration stage, in the second half of 2023 or the first 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 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 plan to set up a fully-fledged commercialization team of around 100 people by the end of 2023 to prepare and complete the marketing and commercialization of our strategic products, and specifically in relation to SKB264, A166 and A167. The commercialization team will oversee and coordinate the sales and marketing of A167, as well as the pre-marketing preparation for SKB264 and A166, laying the groundwork for rapid commercial-scale distribution upon these ADCs' anticipated NDA approval by the NMPA. The commercialization team will also engage with major BC and LC hospitals and specialists, conduct academic activities and work to expand the brand presence of the Company. 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

On April 18, 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. Among them, 10 unicorn enterprises were in Chengdu, with an increase of five unicorn enterprises compared to 2022. The Company was one of the five new unicorn enterprises to receive such recognition.

II. FINANCIAL REVIEW

Overview

The following discussion is based on, and should be read in conjunction with, the financial information 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:

	Six months ended June 30,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Revenue from contracts with customers		
within the scope of IFRS 15		
Revenue from license and collaboration agreements	1,040,171	335,976
Revenue from provision of research and development service	6,055	9,012
	<u>1,046,226</u>	<u>344,988</u>

The Group's revenue for the six months ended June 30, 2023 was RMB1,046.23 million, representing a significant increase of 203.3% compared to RMB344.99 million for the six months ended June 30, 2022. The increase is mainly attributable to the receipt of the upfront payment of US\$175.0 million (equivalent to approximately RMB1,205.5 million⁽⁵⁾) from MSD 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.

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.

Notes:

(5) 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.

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

	Six months ended June 30,	
	2023	2022
	RMB'000	RMB'000
Staff costs	45,195	34,010
Trial and testing expenses	170,637	56,060
Project cooperation expenses	92,896	–
Raw materials	11,567	18,518
Depreciation and amortization expenses	7,482	4,276
Tax and surcharge	29,168	448
Others	13,621	5,787
	<hr/>	<hr/>
Total	370,566	119,099
	<hr/> <hr/>	<hr/> <hr/>

The Group's cost of sales for the six months ended June 30, 2023 was RMB370.57 million, representing a significant increase of 211.1% compared to RMB119.10 million for the six months ended June 30, 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 199.1% from RMB225.89 million for the six months ended June 30, 2022 to RMB675.66 million for the six months ended June 30, 2023.

Our gross profit margin is calculated as gross profit divided by revenue. The gross profit margin of the Group decreased slightly from 65.5% for the six months ended June 30, 2022 to 64.6% for the six months ended June 30, 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 or expenses for the six months ended June 30, 2023 was RMB24.12 million, representing an increase of RMB37.38 million compared to RMB-13.26 million for the six months ended June 30, 2022, mainly due to an increase in the interest income from bank deposits 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.

	Six months ended June 30,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Staff costs	57,643	30,193
Consulting service fee	1,865	2,056
Depreciation and amortization expenses	4,243	3,469
Office and travel expenses	4,130	1,317
Listing expenses	17,322	2,692
Maintenance and repair expenses	1,060	1,235
Others	3,161	1,646
	<hr/>	<hr/>
Total	89,424	42,608
	<hr/> <hr/>	<hr/> <hr/>

The Group's administrative expenses for the six months ended June 30, 2023 was RMB89.42 million, representing an increase of 109.88% compared to RMB42.61 million for the six months ended June 30, 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.

	Six months ended June 30,	
	2023	2022
	<i>RMB'000</i>	<i>RMB'000</i>
Staff costs	160,279	135,090
Trial and testing expenses	250,447	121,050
Raw materials	21,421	43,487
Depreciation, amortization and short-term lease expenses	22,930	22,593
Others	35,270	21,567
	<hr/>	<hr/>
Total	490,347	343,787
	<hr/> <hr/>	<hr/> <hr/>

The Group's R&D expenses for the six months ended June 30, 2023 was RMB490.35 million, representing an increase of 42.6% compared to RMB343.79 million for the six months ended June 30, 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 utilities, maintenance and repair costs, and expenses incurred for the application and maintenance of intellectual property rights 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 six months ended June 30, 2023 was RMB78.73 million, representing an increase of 8.6% compared to RMB72.48 million for the six months ended June 30, 2022. The increase in finance costs was primarily attributable to an increase in the interest expenses on financial instruments issued to investors in the Pre-IPO Investments, partially offset by a decrease in the interest expenses on other borrowings from Kelun Pharmaceutical.

Income Tax

During the Reporting Period, our income tax consisted of current tax and withholding tax. For the six months ended June 30, 2022 and 2023, we recorded income tax of RMB24.62 and RMB72.41 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 are entitled to preferential income tax of 15% from 2020 to 2022.

United States

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

Loss for the period

As a result of the foregoing, our loss for the Reporting Period decreased by 88.5% from RMB270.86 million for the period ended June 30, 2022 to RMB31.13 million for the six months ended June 30, 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 cash 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 RMB587.26 million as at December 31, 2022 and June 30, 2023, respectively. The increase in our cash and cash equivalents primarily reflected the proceeds raised from Series B Financing and the payment received from MSD pursuant to our collaboration.

As at December 31, 2022 and June 30, 2023, the balance of our financial assets measured at FVPL was nil and RMB731.87 million, respectively. As at December 31, 2022 and June 30, 2023, the balance of our financial assets measured at amortized cost was nil and RMB270.0 million, respectively. Such increase was primarily because we used idle 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 RMB471.08 million in operating activities for the six months ended June 30, 2023, compared to the net cash of RMB155.04 million used in operating activities for the six months ended June 30, 2022. The increase in cash was primarily because MSD paid us an upfront payment of US\$175.0 million (equivalent to approximately RMB1,205.5 million⁽⁶⁾) 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.

Borrowings and Gearing Ratio

As at June 30, 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 June 30, 2022 and 2023, the Group was in net deficit and thus, gearing ratio is not applicable.

Notes:

(6) *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.*

Net Current Assets/(Liabilities)

The Group's net current liabilities, as at June 30, 2023 were RMB1,124.13 million, representing a decrease of 70.69% compared to net current liabilities of RMB3,835.0 million as at December 31, 2022 primarily because of the full settlement of bank loans and other borrowing. 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 relate. 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. We currently take certain foreign currency hedging measures and we did not experience any material impact on our operations resulting from fluctuation in exchange rates during the Reporting Period. However, our management monitors our foreign currency risk exposure and will review and adjust our hedging measures in accordance with our needs.

Pledge of Shares

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

Significant Investments, Material Acquisitions and Disposals

As at June 30, 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 six months ended June 30, 2023, the Group's total capital expenditure amounted to approximately RMB33.27 million, which was mainly used in purchasing R&D instruments and equipment.

Charge on Assets

As at June 30, 2023, there was no charge on assets of the Group.

Contingent Liabilities

As at June 30, 2023, we did not have any contingent liabilities.

Employees and Remuneration Policies

As at June 30, 2023, we had 1,309 employees in total.

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

III. PROSPECTS

We intend to capitalize on our competitive strengths by pursuing the following development strategies: (i) advance our indication-oriented oncology pipeline; (ii) advance and expand our differentiated non-oncology drug portfolio; (iii) enhance our drug development capabilities; (iv) continue to seek and deepen strategic partnerships to extend the potential of our technology platforms and maximize the value of our pipeline; and (v) optimize our operation system to become a leading global biopharmaceutical company.

(i) Advance our indication-oriented oncology pipeline

We plan to advance the clinical development of our oncology assets, with the goal to apply for regulatory approvals and initiate product launch at the earliest time practicable. 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 and GI cancers. At the same time, we will continue to explore indication expansion and combination therapies to maximize the clinical and commercial potential of our oncology pipeline.

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 advanced TNBC patients who have failed two or more lines of treatment, and plan to submit an NDA to the NMPA by the end of 2023. For SKB264, we are also conducting a phase 2 trial with or without A167 as a 1L treatment for advanced TNBC.
- ***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.
- ***HR+/HER2- BC.*** We are advancing the dose expansion study of SKB264's global phase 1/2 trial in advanced HR+/HER2- BC patients who have previously received at least one line of standard chemotherapy for metastatic disease. We expect to advance to phase 3 in the second half of 2023.

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, and expect to complete patient enrollment 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.
- ***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 trial for advanced RET+ NSCLC, which we commenced in July 2023, and expect to complete patient enrollment in the first half of 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 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, we are conducting a phase 1b trial of A166 in China for advanced HER2+ CRC and a pivotal phase 3 trial of A140 in combination with chemotherapy in patients with RAS wild-type mCRC in China, for which we completed patient enrollment in November 2022 and expect to file an NDA to the NMPA in the second half of 2023.

We strive to advance the clinical development of our ADCs and other drug candidates to solidify our comprehensive coverage of major tumor types and enhance our oncology portfolio.

Besides advancing our clinical-stage oncology assets, we also seek to explore the therapeutic potential of our preclinical oncology assets for a broad range of tumor types, targeting cancers with medical needs. We will continue to leverage our in-depth expertise in tumor biology and multiple drug modalities to expand our innovative oncology programs.

(ii) Advance and expand our differentiated non-oncology drug portfolio

We will continue to build and expand our differentiated non-oncology drug portfolio to target indications with significant disease burden and medical needs, leveraging our competitive ADC, biologics and small-molecule technology platforms. For A223, our small molecule JAK1/2 inhibitor, we are conducting a phase 2 trial in patients with moderate-to-severe RA and plan to initiate a pivotal phase 3 trial in the second half of 2023. We also expect to complete patient enrollment of A223's ongoing phase 2 trial for severe AA in the second half of 2023. For A277, our peripherally-restricted KOR agonist for CKD-aP, we have completed a phase 1b clinical trial with encouraging anti-pruritic effect observed in patients on maintenance hemodialysis with moderate-to-severe CKD-aP, and we commenced a phase 2 proof-of-concept trial in September 2022. 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.

(iii) Enhance our drug development capabilities

R&D. In addition to expanding our drug portfolio, we are dedicated to optimizing our R&D platforms and developing novel technologies to support the R&D of next-generation drugs. In particular, 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 bispecific ADCs equipped with dual-targeting antibodies to deliver enhanced clinical benefits; (iii) developing other novel ADC designs such as immunostimulatory ADCs, radionuclide drug conjugates (RDCs), dual-payload ADCs; and (iv) developing ADCs with non-cytotoxic payloads to target non-oncology diseases.

Besides developing new forms of drug conjugation, we are 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.

Manufacturing and Quality Control. We will continue to expand our cGMP facilities to support the anticipated commercialization of our near-commercial assets. For our cell culture and purification unit, we plan to install one additional 2,000 L single-use bioreactor, bringing our total in-house capacity to 6,000 L. Going forward, we will continue to enhance our manufacturing capabilities, both through expanding our in-house capacity and 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), our first innovative drug in NDA registration stage, in the second half of 2023 or the first 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 plan to set up a fully-fledged commercialization team by the end of 2023 to oversee and coordinate the sales and marketing of A167, as well as the pre-marketing preparation for SKB264 and A166, laying the groundwork for rapid commercial-scale distribution upon these two ADCs' anticipated NDA approval 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.

(iv) Continue to seek and deepen strategic partnerships to extend the potential of our technology platforms and maximize the value of our pipeline

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, such as PROTAC and RDCs, 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) Optimize our operation system to become a leading global biopharmaceutical company

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

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

PURCHASE, SALE OR REDEMPTION OF LISTED SECURITIES OF THE COMPANY

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 Reporting Period as the Company was not listed on the Stock Exchange during the Reporting Period. Since the Listing Date and up to the date of this announcement, none of the Company or any of its subsidiaries has made any purchase, sale or redemption of the listed securities of the Company.

CORPORATE GOVERNANCE

The Company recognises the importance of good corporate governance for enhancing the management of the Company as well as preserving the interests of the shareholders as a whole. The Company has adopted corporate governance practices based on the principles and code provisions as set out in the CG Code as contained in Appendix 14 to the Listing Rules as its own code of corporate governance practices.

The CG Code was not applicable to the Company for the Reporting Period, as the Company had not been listed on the Stock Exchange as at June 30, 2023. Since the Listing Date and up to the date of this announcement, the Company has strictly complied with 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.

MODEL CODE FOR SECURITIES TRANSACTIONS

The Company has adopted the Model Code as set out in Appendix 10 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 senior management 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 not applicable to the Company for the Reporting Period, as the Company had not been listed on the Stock Exchange as at June 30, 2023. Upon specific enquiry, all Directors and Supervisors confirmed that they have complied with the Model Code since the Listing Date and up to the date of this announcement. 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 the date of this announcement.

EVENTS AFTER THE REPORTING PERIOD

On July 11, 2023, the Company was successfully listed on the Main Board of the Stock Exchange following the completion of the issue of 22,446,100 H Shares at the price of HK\$60.60 per share. 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 3, 2023, the Over-Allotment Option was exercised in full, following which an additional 3,366,900 H Shares at the price of HK\$60.60 per share was issued on August 8, 2023. On August 8, 2023, the Company received additional net proceeds of approximately HK\$196 million (equivalent to approximately RMB179.7 million⁽⁸⁾) in connection with the full exercise of the Over-Allotment Option. The Group will utilize the net proceeds in accordance with the intended purposes as set out in the Prospectus. The Board is not aware of any material change to the planned use of the net proceeds as at the date of this announcement.

REVIEW OF INTERIM RESULTS

The Audit Committee comprises three independent non-executive Directors, namely Dr. LI Yuedong, Dr. TU Wenwei and Dr. JIN Jinping. The chairman of the Audit Committee is Dr. LI Yuedong who holds the appropriate qualification as required under Rules 3.10(2) and 3.21 of the Listing Rules. The Audit Committee has reviewed the unaudited interim condensed consolidated financial information of the Group for the six months ended June 30, 2023 with the management and the auditor of the Company. The Audit Committee considered that the interim results are in compliance with the applicable accounting standards, laws and regulations, and the Company has made appropriate disclosures thereof. The Audit Committee has also discussed matters with respect to the accounting policies and practices adopted by the Company and internal control with senior management of the Company.

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

INTERIM DIVIDEND

The Board does not recommend the distribution of any interim dividend for the Reporting Period.

PUBLICATION OF INTERIM RESULTS AND 2023 INTERIM REPORT

This announcement is published on the websites of the Company (<http://kelun-biotech.com>) and the Stock Exchange (<http://www.hkexnews.hk>). The 2023 interim report will be dispatched to the Shareholders and will be made available on the websites of the Company and the Stock Exchange as and when appropriate.

Notes:

(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.

DEFINITIONS

“ADC(s)”	antibody drug conjugate(s)
“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”	our board of Directors
“CDE”	Center for Drug Evaluation
“CG Code”	the “Corporate Governance Code” as contained in Appendix 14 to the Listing Rules
“China” or “PRC”	the People’s Republic of China, which for the purpose of this interim results announcement and for geographical reference only, excludes Hong Kong, Macau and Taiwan
“CLDN18.2”	claudin 18.2, a member of the Claudin protein family
“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
“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 or any one of them
“EGFR”	epidermal growth factor receptor
“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))
“FDA”	the United States Food and Drug Administration
“first/second/third-line” or “1/2/3L”	the first/second/third line treatment
“GC”	gastric cancer
“GI”	gastrointestinal
“Global Offering”	the Hong Kong Public Offering and the International Offering
“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 (和鉅醫藥控股有限公司), a company listed on the Stock Exchange (stock code: 02142)
“HER2”	human epidermal growth factor receptor 2
“HK\$”	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
“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
“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
“mAbs”	monoclonal antibodies
“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 10 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
“Reporting Period”	the six months ended June 30, 2023
“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)”	supervisor(s) of the Company
“TKI”	tyrosine kinase inhibitor

“TNBC”	triple-negative breast cancer
“TROP2”	human trophoblast cell-surface antigen 2, which is a transmembrane protein frequently over-expressed in many types of solid tumors
“TSLP”	thymic stromal lymphopietin
“US” or “U.S.” or “United States”	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
“US\$” or “USD”	United States dollars, the lawful currency of the United States
“%”	per cent

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

Hong Kong, August 28, 2023

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.