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# Abbisko Cayman Limited 和譽開曼有限責任公司

(Incorporated in the Cayman Islands with limited liability)
(Stock Code: 2256)

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

The board of directors (the "Board") of Abbisko Cayman Limited (the "Company") is pleased to announce the unaudited condensed consolidated interim results of the Company and its subsidiaries (the "Group", "we", "our" or "us") for the six months ended June 30, 2024 (the "Reporting Period"), together with comparative figures for the corresponding period in 2023.

### **BUSINESS HIGHLIGHTS**

We have made significant progresses in every aspect during 2024 year-to-date:

#### FURTHER ADVANCED OUR CLINICAL-STAGE ASSETS

#### Pimicotinib (ABSK021)

- We completed patient enrollment for a global multicenter Phase III clinical trial of pimicotinib for tenosynovial giant cell tumor ("TGCT") in China, Canada, the U.S. and Europe. Pimicotinib was granted the breakthrough therapy designation ("BTD") from both National Medical Products Administration of the People's Republic of China ("NMPA") and the U.S. Food and Drug Administration ("FDA") and the Priority Medicine ("PRIME") designation by the European Medicines Agency ("EMA") for the treatment of TGCT patients who are not amenable to surgery. It was also granted the fast track designation ("FTD") by the FDA and orphan drug designation ("ODD") by the EMA for the treatment of TGCT patients.
- We are also concurrently conducting a Phase II clinical study in patients with chronic graftversus-host disease ("cGvHD") and a Phase II clinical study in combination with chemotherapy with or without toripalimab in patients with advanced pancreatic cancer in China. The first patients for those two trials were dosed in June 2023 and November 2023, respectively.
- In early December 2023, we entered into a license agreement with Merck Healthcare KGaA ("Merck"). Under the terms of the agreement, we have granted Merck an exclusive license to commercialize products comprising or containing pimicotinib in the Chinese mainland, Hong Kong, Macau and Taiwan, and an exclusive option for global commercial rights of pimicotinib. We had received the upfront payment of US\$70 million from Merck in February 2024.

- In January 2024, pimicotinib was granted ODD by the EMA for the treatment of inoperable TGCT.
- In March 2024, we completed patient enrollment for the global Phase III trial of pimicotinib, MANEUVER (ABSK021-301) study, to evaluate the efficacy and safety of treatment for patients with TGCT. A total of 94 patients were enrolled, exceeding the original target of 90 patients. The study is being conducted across more than 30 investigational sites worldwide, with European and North American patients accounting for more than half of the total enrollment.

### Irpagratinib (ABSK011)

- In China, we are conducting a Phase Ib trial of irpagratinib (monotherapy) in more patients with advanced hepatocellular carcinoma ("HCC") with FGF19 overexpression.
- We are also conducting a Phase II trial of irpagratinib in combination with the anti-PD-L1 antibody atezolizumab from F. Hoffmann-La Roche Ltd. and Roche China Holding Ltd. ("Roche") in late stage HCC patients with FGF19 overexpression in the Chinese mainland.
- In October 2023, the updated Phase Ib data of irpagratinib was presented at the European Society for Medical Oncology ("ESMO"). The results demonstrated that irpagratinib was well tolerated in HCC patients and the BID cohorts demonstrated a promising antitumor activity with an objective response rate ("ORR") of 40.7% in FGF19+HCC patients with prior therapies.
- In April 2024, irpagratinib was granted ODD by U.S. FDA for the treatment of HCC.
- In June 2024, our updated Phase II clinical trial data of irpagratinib in combination with atezolizumab for the treatment of advanced HCC was presented at the 2024 European Society for Medical Oncology Gastrointestinal Cancers Congress ("ESMO-GI Congress"). The presentation highlights that 220mg BID of irpagratinib in combination with atezolizumab demonstrated promising efficacy with an ORR of 50% in FGF19+ HCC patients. The study is still ongoing, and the efficacy of BID cohorts warrants further investigation.

## Fexagratinib (ABSK091, AZD4547)

- We are conducting a Phase II trial in the Chinese mainland for fexagratinib in patients with locally advanced or metastatic urothelial carcinoma with FGFR2/3 genetic alterations.
- The preliminary Phase II efficacy and safety results of fexagratinib were announced in patients with urothelial carcinoma harboring FGFR2 or FGFR3 alterations in the Chinese mainland in 2022.
- The preliminary efficacy results showed an ORR confirmed by Independent Review Committee ("IRC") of 30.7% (4/13) in mUC patients with FGFR3 alteration (including mutations and/ or fusions) and an IRC confirmed ORR of 44% (4/9) in patients with FGFR3 mutations, which is consistent with results from the prior BISCAY trial of fexagratinib in similar patient groups outside of China. The preliminary safety results showed that 80mg BID of fexagratinib was well-tolerated in Chinese patients, and no drug related grade 4 or above adverse effects were reported.
- These results support further development of fexagratinib in the ongoing Phase II trial.

#### ABSK043

- We expect to complete the Phase I trial in Australia soon, which is aimed to assess the safety, tolerability and PK/PD profile of ABSK043 in patients with solid tumors.
- We are also conducting a Phase Ib trial in China for patients with solid tumors.
- In October 2023, the clinical results of first-in-human dose-escalating of ABSK043 with advanced solid tumors were presented at the 2023 ESMO Annual Meeting. The results demonstrated that ABSK043 was well tolerated up to 1,000 mg BID. Among 11 evaluable patients (BID dosing), ABSK043 demonstrated an ORR of 27.3% with no Dose-Limiting Toxicity ("DLT") reported and has a safety profile consistent with monoclonal antibody immune checkpoint inhibitors.
- In May 2024, we announced that ABSK043 will be evaluated in a clinical study in combination with Furmonertinib Mesilate Tablets (IVESA®, "Furmonertinib"), independently developed by Shanghai Allist Pharmaceuticals Co., Ltd. ("Allist", SSE code: 688578), for the treatment of patients with advanced Non-Small Cell Lung Cancer ("NSCLC"). Details of the research collaboration includes an IND/CTA filing pertaining to the exploration of ABSK043 in combination with Furmonertinib in a multicenter, open-label Phase II dose-escalation or dose-expansion clinical trial.

#### ABSK061

- We are conducting Phase I clinical trials for ABSK061 in patients with solid tumors in both China and the U.S.
- In February 2024, the preliminary results of the first-in-human trial of the ABSK061 in patients with advanced solid tumors were presented orally at the 2024 European Society for Medical Oncology Targeted Anticancer Therapies Congress ("ESMO TAT"). The ABSK061 75mg BID and 150mg QD cohorts demonstrated a promising antitumor activity with an ORR of 37.5% among 8 patients with solid tumors carrying FGFR-activating alterations.
- We are also conducting ABSK061's IND-enabling study for Achondroplasia ("ACH"). We received the IND approval from NMPA for a Phase II combination clinical trial for solid tumors in July 2024.

#### ABSK121

- We are conducting Phase I clinical trials for ABSK121 in China and the U.S. concurrently.
- The dosing of first patient was completed in the treatment of patients with advanced solid tumors in China in June 2023.

#### ABSK112

- Next-generation EGFR Exon20ins inhibitor ABSK112 received clinical study approval from NMPA in October 2023 and the FDA in July 2023, and the Phase I studies are being conducted simultaneously in the U.S. and China.
- In February 2024, the first patient dosing was completed for the treatment of NSCLC.

#### ABSK051

- We are conducting a Phase I trial in China to assess the safety, tolerability and PK/PD profile of and preliminary antitumor activity of ABSK051 in patients with advanced solid tumors.
- In January 2024, we completed dosing of the first patient in China.

#### ABSK012

- ABSK012 was granted ODD by the FDA for the treatment of soft tissue sarcomas in April 2023.
- In November 2023, we obtained IND approval for ABSK012 of a first-in-human Phase I clinical study in patients with advanced solid tumors from the FDA.

#### CONTINUED TO MOVE FORWARD PRECLINICAL CANDIDATES

- **ABK3376** (AST2303) a highly potent, selective, and brain-penetrating new-generation EGFR inhibitor, was discovered by our proprietary drug discovery platform. ASK3376 can efficiently inhibit the EGFR-C797S mutation occurring after third-generation EGFR-TKI treatment. Its Greater China right has been licensed out to Allist and its IND preparation has been completed.
- ABSK131 a potent and selective a next generation and brain-penetrant MTA-cooperative PRMT5 inhibitor. It was discovered by us through leveraging advanced computation-aided structural analysis and medicinal chemistry design. Development of selective PRMT5\*MTA inhibitors may improve not only safety but also therapeutic efficacy. The preclinical result of ABSK131 was published at the 35th International Molecular Targets and Cancer Treatment Conference ("EORTC") in Boston, U.S. We are currently conducting IND-enabling studies for ABSK131.

#### FINANCIAL HIGHLIGHTS

We recorded positive net profit for the first time. For the six months ended June 30, 2024, the Company has generated revenue of RMB497.3 million (US\$70 million, representing Merck's license out up-front payment revenue), with a profit of RMB206.8 million, and a positive cash flow from operations.

We repurchased and cancelled shares to enhance the value of the stocks. On March 13, 2024, the board of directors approved an amount of no more than HKD100 million to repurchase shares of the Company on-market to enhance shareholder returns. For the six months ended June 30, 2024, the Company has repurchased a total of 18,571,000 shares with a cumulative amount of HKD56.3 million. On July 3, 2024, the Company cancelled 15,833,000 shares repurchased, accounting for 2.25% of the total issued shares, reducing the total number of issued shares of the Company to 686,366,350 shares.

### INTERNATIONAL FINANCIAL REPORTING STANDARDS ("IFRS") MEASURES:

**Time deposits/Cash and bank balances.** Time deposits/Cash and bank balances increased to RMB2,122.5 million as at June 30, 2024, from RMB1,971.5 million as at December 31, 2023, by RMB151.0 million primarily attributable to the increase in revenue, partially offset by increase of spending on research and development activities, and shares repurchase.

**Revenue.** Revenue increased to RMB497.3 million for the six months ended June 30, 2024, from RMB19.1 million for the six months ended June 30, 2023, by RMB478.2 million primarily attributable to the upfront payment we received from Merck.

**Other income and gains.** Other income and gains increased to RMB48.5 million for the six months ended June 30, 2024, from RMB37.7 million for the six months ended June 30, 2023, by RMB10.8 million primarily attributable to the increase in bank interest income.

**Research and development expenses.** Research and development expenses increased to RMB215.1 million for the six months ended June 30, 2024, from RMB204.6 million for the six months ended June 30, 2023, by RMB10.5 million primarily attributable to advancement of our pipeline programs.

**Administrative expenses.** Administrative expenses decreased to RMB40.3 million for the six months ended June 30, 2024, from RMB45.7 million for the six months ended June 30, 2023, by RMB5.4 million primarily attributable to the decrease in share-based payment expenses.

**Finance costs.** Finance costs decreased to RMB0.9 million for the six months ended June 30, 2024, from RMB1.2 million for the six months ended June 30, 2023, mainly due to the decrease of interest expenses on lease liabilities.

**Other expenses.** Other expense decreased to RMB4.1 million for the six months ended June 30, 2024, from RMB13.8 million for the six months ended June 30, 2023, by RMB9.7 million primarily attributable to the decrease of the foreign exchange loss.

**Income tax expenses.** During the six months ended June 30, 2024, the Group is subject to a Germany withholding tax, amounting to RMB78.7 million.

**Profit/(loss) for the period.** The Company recorded a profit of RMB206.8 million for six months ended June 30, 2024, an increase of RMB415.4 million from RMB208.6 million loss for six months ended June 30, 2023, primarily attributable to the increase in revenue.

## NON-INTERNATIONAL FINANCIAL REPORTING STANDARDS ("NON-IFRS") MEASURES:

**Research and development expenses,** excluding share-based compensation cost, increased to RMB209.3 million for the six months ended June 30, 2024, from RMB189.0 million for six months ended June 30, 2023, by RMB20.3 million primarily attributable to advancement of our pipeline programs.

Administrative expenses, excluding share-based compensation cost, increased to RMB37.4 million for the six months ended June 30, 2024, from RMB35.7 million for the six months ended June 30, 2023, by RMB1.7 million primarily attributable to an increase in operating expenses.

**Profit/(loss) for the period,** excluding the effect of the share-based compensation cost, increased to RMB215.4 million profit for the six months ended June 30, 2024, from RMB182.9 million loss for the six months ended June 30, 2023, by RMB398.3 million primarily attributable to increases in revenue and other income and gains, partially offset by the increase of research and development expenses.

#### 1. FINANCIAL INFORMATION

The Board announces the unaudited condensed consolidated results of the Group for the six months ended June 30, 2024, with comparative figures for the corresponding period in the previous year as follows:

## INTERIM CONDENSED CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the six months ended 30 June 2024

		For the six months ended 30 June	
	Notes	2024 (Unaudited) <i>RMB'000</i>	2023 (Unaudited) <i>RMB'000</i>
Revenue Cost of sales	4	497,273	19,060
Gross profit		497,273	19,060
Other income and gains Research and development expenses Administrative expenses	5	48,524 (215,073) (40,294)	37,702 (204,649) (45,729)
Other expenses Finance costs	7 6	(4,057) (888)	(13,816) (1,160)
PROFIT/(LOSS) BEFORE TAX Income tax expenses	8 9	285,485 (78,694)	(208,592)
PROFIT/(LOSS) FOR THE PERIOD		206,791	(208,592)
OTHER COMPREHENSIVE INCOME Other comprehensive income that may be reclassified to profit or loss in subsequent periods: Exchange differences on translation of foreign operations Other comprehensive income that will not be reclassified		362	765
to profit or loss in subsequent periods: Exchange differences on translation of the Company		9,768	67,694
OTHER COMPREHENSIVE INCOME FOR THE PERIOD, NET OF TAX		10,130	68,459
TOTAL COMPREHENSIVE INCOME/ (LOSS) FOR THE PERIOD		216,921	(140,133)
Total comprehensive income/(loss) attributable to: Owners of the parent		216,921	(140,133)
EARNINGS/(LOSS) PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT Basic and diluted	11		
For profit/(loss) for the period		RMB 0.32	RMB (0.32)

## INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

As at 30 June 2024

	Notes	30 June 2024 (Unaudited) <i>RMB'000</i>	31 December 2023 (Audited) <i>RMB'000</i>
NON-CURRENT ASSETS Property, plant and equipment Right-of-use assets Intangible assets	12	32,723 30,332 4,906	34,264 35,082 4,634
Total non-current assets		67,961	73,980
CURRENT ASSETS Prepayments and other receivables Financial assets at fair value through profit or loss Time deposits Cash and bank balances	15 13	67,006 1,241 1,816,506 305,991	68,993 918 1,385,973 585,518
Total current assets		2,190,744	2,041,402
CURRENT LIABILITIES Other payables and accruals Derivative financial instruments Lease liabilities	16 14	85,506 3,870 11,333	98,119 437 10,610
Total current liabilities		100,709	109,166
NET CURRENT ASSETS		2,090,035	1,932,236
TOTAL ASSETS LESS CURRENT LIABILITIES		2,157,996	2,006,216
NON-CURRENT LIABILITIES Lease liabilities		19,454	25,114
Total non-current liabilities		19,454	25,114
Net assets		2,138,542	1,981,102
EQUITY Equity attributable to owners of the parent Share capital Treasury shares Other reserves		46 (5) 2,138,501	46 (4) 1,981,060
Total equity		2,138,542	1,981,102

#### NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

#### 1. GENERAL INFORMATION

The Company is a limited liability company incorporated in the Cayman Islands on 28 March 2018. The registered address of the Company is P.O. Box 309, Ugland House, Grand Cayman KY1-1104, Cayman Islands.

The Company is an investment holding company. During the period, the Company's subsidiaries were involved in the research and development of pharmaceutical products.

The shares of the Company have been listed on the Main Board of the Stock Exchange of Hong Kong Limited (the "Stock Exchange") effective from 13 October 2021.

#### 2.1 BASIS OF PREPARATION

The interim condensed consolidated financial information for the six months ended 30 June 2024 has been prepared in accordance with IAS 34 Interim Financial Reporting. The interim condensed consolidated financial information does not include all the information and disclosures required in the annual financial statements, and should be read in conjunction with the Group's annual consolidated financial statements for the year ended 31 December 2023.

This interim condensed consolidated financial information is presented in Renminbi ("RMB") and all values are rounded to the nearest thousand except when otherwise indicated.

#### 2.2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The accounting policies adopted in the preparation of the interim condensed consolidated financial information are consistent with those applied in the preparation of the Group's annual consolidated financial statements for the year ended 31 December 2023, except for the adoption of the following revised International Financial Reporting Standards ("**IFRSs**") for the first time for the current period's financial information.

Amendments to IFRS 16

Lease Liability in a Sale and Leaseback

Amendment to IAS 1

Classification of Liabilities as Current or

Non-current (the "2020 Amendments")

Amendments to IAS 1 Non-current Liabilities with Covenants (the "2022 Amendments")

Amendments to IAS 7 and IFRS 7 Supplier Finance Arrangements

The adoption of the revised standards has had no significant financial effect on the Group's interim condensed consolidated financial information.

#### 3. OPERATING SEGMENT INFORMATION

#### **Operating segment information**

For management purposes, the Group has only one reportable operating segment, which is the development of innovative medicines. Since this is the only reportable operating segment of the Group, no further operating segment analysis thereof is presented.

#### **Geographical information**

Since nearly all of the Group's non-current assets were located in Chinese mainland, no geographical information in accordance with IFRS 8 Operating Segments is presented.

#### 4. REVENUE

An analysis of revenue is as follows:

	For the six month 2024 <i>RMB'000</i> (Unaudited)	as ended 30 June 2023 <i>RMB'000</i> (Unaudited)
Revenue from contracts with customers	497,273	19,060
Disaggregated revenue information		
For the six months ended 30 June 2024		
		Licensing revenue <i>RMB'000</i>
Type of goods or services Licensing revenue		497,273
Geographical market European Union		497,273
Timing of revenue recognition Licensing revenue at a point in time		497,273

During the six months ended 30 June 2024, the Group recorded one-time licensing revenue of RMB497,273,000, which was generated from an exclusive licensing agreement with Merck Healthcare KGaA.

The revenue information above is based on the location of the customer.

## 5. OTHER INCOME AND GAINS

An analysis of other income and gains is as follows:

	For the six months ended 30 June		
	2024	2023	
	RMB'000	RMB'000	
	(Unaudited)	(Unaudited)	
Other income			
Bank interest income	45,747	27,016	
Other gains			
Government grants*	2,460	9,914	
Fair value gains on financial assets at fair value through profit or loss	317	772	
	2,777	10,686	
Total	48,524	37,702	

<sup>\*</sup> The government grants mainly represent subsidies received from the local governments for the purpose of supporting on research and clinical trial activities.

## 6. FINANCE COSTS

An analysis of finance costs is as follows:

	For the six month	For the six months ended 30 June		
	2024	2023		
	RMB'000	RMB'000		
	(Unaudited)	(Unaudited)		
Interest on lease liabilities	888	1,160		

## 7. OTHER EXPENSES

An analysis of other expenses is as follows:

	For the six months ended 30 June		
	2024	2023	
	RMB'000	RMB'000	
	(Unaudited)	(Unaudited)	
Fair value change of derivative financial instruments	3,433	_	
Foreign exchange loss, net	392	13,771	
Others	232	45	
Total	4,057	13,816	

#### 8. PROFIT/(LOSS) BEFORE TAX

The Group's profit/(loss) before tax is arrived at after charging/(crediting):

	For the six months ended 30 June		
	2024	2023	
	RMB'000	RMB'000	
	(Unaudited)	(Unaudited)	
Depreciation of items of property, plant and equipment	3,975	2,880	
Depreciation of right-of-use assets	4,750	4,850	
Amortisation of intangible assets	1,402	1,313	
Research and development expenses excluding depreciation and			
amortisation	206,539	198,023	
Auditor's remuneration	500	500	
Foreign exchange loss, net	392	13,771	
Fair value gains on financial assets at fair value through profit or loss	(317)	(772)	
Fair value change of derivative financial instruments	3,433	_	
Employee benefit expense:			
Wages and salaries	89,414	76,452	
Pension scheme contributions (defined contribution scheme)	14,849	11,869	
Share-based payments expense	8,640	25,709	

#### 9. INCOME TAX

The Group is subject to income tax on an entity basis on profits arising in or derived from the jurisdictions in which members of the Group are domiciled and operate.

#### **Cayman Islands**

Under the current laws of the Cayman Islands, the Company is not subject to tax on income or capital gains. In addition, upon payments of dividends by the Company to its shareholders, no Cayman Islands withholding tax is imposed.

#### **Hong Kong**

The subsidiary incorporated in Hong Kong are subject to income tax at the rate of 16.5% on the estimated assessable profits arising in Hong Kong during the period.

#### **Chinese Mainland**

Pursuant to the Corporate Income Tax Law of Chinese Mainland and the respective regulations (the "CIT Law"), the subsidiaries which operate in Chinese Mainland are subject to CIT at a rate of 25% on the taxable income. A subsidiary was accredited as a "High and New Technology Enterprise" ("HNTE") in October 2022 and therefore it was entitled to a preferential CIT rate of 15% from 1 January 2022 to 31 December 2024. This qualification is subject to review by the relevant tax authority in Chinese Mainland for every three years.

#### 9. INCOME TAX (continued)

#### Australia

No provision for Australia income tax has been made as the Group had no assessable profits derived from or earned in Australia during the period. The subsidiary incorporated in Australia is subject to income tax at the rate of 30% on the estimated assessable profits arising in Australia during the period.

Deferred taxation had not been recognized on the unused tax losses and deductible temporary differences since it is not probable that the taxable profits will be available against which the tax losses and deductible temporary differences can be utilized in the foreseeable future.

For the six months	ended 30 June
2024	2023
RMB'000	RMB'000
(Unaudited)	(Unaudited)
78,694	_

Current tax
Germany withholding tax

During the six months ended 30 June 2024, the Group is subject to a Germany withholding tax on licensing revenue received from a Germany-based customer, amounting to RMB78,694,000.

#### 10. DIVIDENDS

No dividend was paid or declared by the Company during the six months ended 30 June 2024 (30 June 2023: Nil).

## 11. EARNINGS/(LOSS) PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of the basic earnings/(loss) per share amount is based on the profit or loss for the period attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 639,220,610 (30 June 2023: 647,438,532) in issue during the period, as adjusted to reflect the rights issue during the period.

The calculation of the diluted earnings/(loss) per share amount is based on the profit or loss for the period attributable to ordinary equity holders of the parent. The weighted average number of ordinary shares used in the calculation is the number of ordinary shares in issue during the period, as used in the basic earnings per share calculation, and the weighted average number of ordinary shares assumed to have been issued at no consideration on the deemed conversion of all dilutive potential ordinary shares into ordinary shares. No adjustment has been made to the basic loss per share amounts presented for the six months ended 30 June 2023 in respect of a dilution as the impact of the share options outstanding had an anti-dilutive effect on the basic loss per share amounts presented.

The calculations of basic and diluted earnings/(loss) per share are based on:

	For the six months ended 30 June		
	2024	2023	
	RMB'000	RMB'000	
	(Unaudited)	(Unaudited)	
Earnings/(Loss)			
Profit/(loss) attributable to ordinary equity holders of the parent,			
used in the basic and diluted earnings/(loss) per share calculation	206,791	(208,592)	
	Numbers of		
	For the six months		
	2024	2023	
	(Unaudited)	(Unaudited)	
Shares			
Weighted average number of ordinary shares in issue during the			
period used in the basic earnings/(loss) per share calculation	639,220,610	647,438,532	
Effect of dilution – weighted average number of ordinary shares:			
Share options	12,695,217		
Weighted average number of ordinary shares in issue during the	<=4 04 = 0°=		
period used in the diluted earnings/(loss) per share calculation	651,915,827	647,438,532	

## 12. PROPERTY, PLANT AND EQUIPMENT

During the six months ended 30 June 2024, the Group acquired assets at a cost of RMB3,253,000 (30 June 2023: RMB4,861,000).

The Group disposed RMB83,000 of asset during the six months ended 30 June 2024 (30 June 2023: Nil).

No impairment losses were recognised during the six months ended 30 June 2024 and 2023.

As at 30 June 2024, there were no pledged property, plant and equipment (31 December 2023: Nil).

## 13. FINANCIAL ASSETS AT FAIR VALUE THROUGH PROFIT OR LOSS

30 June	31 December
2024	2023
RMB'000	RMB'000
(Unaudited)	(Audited)
1,241	918
	2024 <i>RMB'000</i> (Unaudited)

The above wealth management product was issued by a financial institution in Hong Kong. It was mandatorily classified as financial assets at fair value through profit or loss as their contractual cash flows are not solely payments of principal and interest.

#### 14. DERIVATIVE FINANCIAL INSTRUMENTS

	30 June 2024		
	Assets	Liabilities	
	RMB'000	RMB'000	
	(Unaudited)	(Unaudited)	
Forward currency contracts*		3,870	

<sup>\*</sup> Changes in the fair value of forward currency contracts are charged to the statement of profit or loss and other comprehensive income during the Reporting Period. The forward currency contracts incurred are pledged with one-year deposits of US\$1,050,000 (equivalent to RMB7,483,000) of the Group as collateral.

The Group holds the following foreign exchange forward contracts:

		Maturity				
		Less than 3 months	3 to 6 months	6 to 9 months	9 to 12 months	Total
	As at 30 June 2024					
	Forward currency contracts					
	Nominal amount (RMB'000)	105,300	_	_	_	105,300
	Average forward rate (US\$/RMB)	7.0000-7.0600	N/A	N/A	N/A	
15.	PREPAYMENTS AND OTHER RECE	CIVABLES				
				30 J	une 3	l December
				2	024	2023
				RMB'	000	RMB'000
				(Unaudit	ed)	(Audited)
	Prepayments to suppliers			16,	688	21,292
	Loans to employees*				573	9,381
	Deposits and other receivables			44,		38,320
	Total			67,	006	68,993

<sup>\*</sup> The loans to employees were given by the Company for the purpose of enabling the employees to exercise share options of the Company.

The financial assets included in the above balances relate to receivables for which there was no recent history of default and past due amounts. As at 30 June 2024 and 31 December 2023, the loss allowance was assessed to be minimal.

## 16. OTHER PAYABLES AND ACCRUALS

	30 June 2024 <i>RMB'000</i>	31 December 2023 <i>RMB'000</i>
	(Unaudited)	(Audited)
Payables for research and development services	49,060	55,524
Payroll payable	20,459	25,740
Other tax payables	1,320	2,113
Amounts due to related parties	388	388
Payables of property, plant and equipment	48	132
Other payables	14,231	14,222
Total	85,506	98,119

Other payables and accruals are unsecured, non-interest-bearing and repayable on demand. The carrying amounts of financial liabilities included in other payables and accruals as at the end of each of the Reporting Period approximated to their fair values due to their short-term maturities.

#### MANAGEMENT DISCUSSION AND ANALYSIS

#### I BUSINESS REVIEW

#### Our vision

Our vision is to discover and develop novel, differentiated therapies in oncology and beyond to address critical unmet medical needs for patients in China and worldwide.

## Company overview

We are a clinical-stage biopharmaceutical company primarily dedicated to the discovery and development of innovative and differentiated small molecule oncology therapies. Since our inception in 2016, we have strategically designed and developed a pipeline of 16 candidates primarily focused on oncology, including 10 candidates at clinical stage. Our drug candidates are primarily small molecules that focus on small molecule precision oncology and small molecule immuno-oncology therapeutic areas.

## **Product pipeline**

We have a pipeline of 16 drug candidates ranging from pre-clinical stage to clinical stage programs. The following charts summarizes our pipeline and the development status of each candidate as of June 30, 2024.

## **Our Clinical Pipeline**



A Xolremdi™(mavorixafor) capsule is approved by FDA for use in patients 12 years of age and older with WHIM syndrome

## **Our Preclinical Pipeline**

Programs	Targets	Indication	Mono/Combo therapy	Lead optimization /PCC	IND-Enabling	IND	Commercial rights	Partner
<b>ABK3376</b> (AST2303)	EGFR-C797S	EGFRm NSCLC	Mono/Combo			Partner	Ex-Greater China	<b>◆◆</b> 艾力斯
ABSK131	PRMT5*MTA	Multiple tumors	Mono				Global	
ABSK132	PRMT5*MTA	Multiple tumors	Mono				Global	
ABSK141	KRas-G12D	Solid tumors	Mono				Global Global	
P011	undisclosed	NSCLC	Mono				Global Global	
P151	undisclosed	Non-oncology	Mono/Combo				Shared	Liley

Abbreviations: ALS = amyotrophic lateral sclerosis; cGvHD = chronic graft-versus-host disease; FGFRalt = FGFR altered; HCC = hepatocellular carcinoma; NSCLC = non-small cell lung cancer; RMS = rhabdomyosarcoma; TGCT = tenosynovial giant cell tumor; TNBC = triple-negative breast cancer; UC = urothelial cancer; WHIM = warts, hypogammaglobulinemia, infections and myelokathexis

#### Notes:

F. Hoffmann-La Roche Ltd. and Roche China Holding Ltd. ("Roche")

BeiGene, Ltd. ("BeiGene")

Shanghai Allist Pharmaceuticals Co., Ltd. ("Allist")

Shanghai Junshi Biomedical Technology Co., Ltd. ("Junshi")

#### **Clinical candidates**

## Pimicotinib (ABSK021)

Pimicotinib is an orally bioavailable, selective, potent small molecule CSF-1R inhibitor being developed for the treatment of multiple types of oncology and non-oncology indications. The overexpression of CSF-1 is observed in many tumors and at sites of inflammation. CSF-1R inhibitors have demonstrated promise as a potential treatment in adult patients with TGCT, pancreatic cancer, colorectal cancer, cGvHD and amyotrophic lateral sclerosis.

#### Current status

We completed patient enrollment for a global multicenter Phase III clinical trial of pimicotinib for TGCT in China, Canada, the U.S. and Europe. Pimicotinib was granted BTD from both NMPA and the FDA and the PRIME designation by the EMA for the treatment of TGCT patients who are not amenable to surgery. It was also granted FTD by the FDA and ODD by the EMA for the treatment of TGCT patients.

We are also conducting a Phase II clinical study in patients with cGvHD and a Phase II clinical study in combination with chemotherapy with or without toripalimab in patients with advanced pancreatic cancer in China for pimicotinib. The first patients for those two trials were dosed in June 2023 and November 2023, respectively.

In early December 2023, we entered into a license agreement with Merck. Under the terms of the agreement, we have granted Merck an exclusive license to commercialize products comprising or containing pimicotinib in the Chinese mainland, Hong Kong, Macau and Taiwan, and an exclusive option for global commercial rights of pimicotinib. In addition, Merck also has the option to co-develop pimicotinib in additional indications under certain conditions. We received the upfront payment of US\$70 million from Merck in February 2024.

In December 2023, pimicotinib was granted FTD by the FDA for the treatment of TGCT patients that are not amenable to surgery. Fast Track is a FDA process designed to facilitate the development and expedite the review of drugs in order to treat serious conditions and fulfill unmet medical needs. Its purpose is to get important new drugs to patients earlier. Moreover, the FTD enables the Company to maintain more frequent communications and meetings with the FDA. The drug also becomes eligible for accelerated approval and priority review by the FDA.

In January 2024, pimicotinib was granted ODD by the EMA for the treatment of inoperable TGCT. Following the successful ODD granted by the EMA, the product will benefit from incentives, including protocol assistance, fee reductions, procedural advantages for market authorization, market exclusivity, etc. In addition to the above-mentioned benefits within the European Union, member states may also offer specific stimuli for orphan drugs.

In March 2024, we completed patient enrollment for the global Phase III trial of pimicotinib, MANEUVER (ABSK021-301) study, to evaluate the efficacy and safety of treatment for patients with TGCT. A total of 94 patients were enrolled, exceeding the original target of 90 patients. The study is being conducted across more than 30 investigational sites worldwide, with European and North American patients accounting for more than half of the total enrollment. This is a Phase III, randomized, double-blind, placebo-controlled, multicenter trial, and it is the first global Phase III trial of TGCT conducted simultaneously in China, the U.S., Canada and Europe. Approval to conduct this Phase III trial was received from the China NMPA in October 2022, the FDA in March 2023, and the EMA in September 2023.

## WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ABSK021 SUCCESSFULLY.

### Irpagratinib (ABSK011)

Irpagratinib is a potent and highly selective small molecule inhibitor of FGFR4 that we are conducting clinical trials in China. Irpagratinib is being developed for the treatment of advanced HCC with hyperactivation of FGF19/FGFR4 signaling. The FGFR4 signaling pathway is a promising direction for the development of molecularly targeted therapies in HCC. The number of patients with an overexpression of FGF19/FGFR4 accounts for approximately 30% of total HCC patients worldwide, according to Frost & Sullivan. Currently, no FGFR4 inhibitor has been approved to the market yet.

#### Current status

In China, we are conducting a Phase Ib trial of irpagratinib (monotherapy) in more patients with advanced HCC with FGF19 overexpression.

We are also conducting a Phase II trial of irpagratinib in combination with the anti-PD-L1 antibody atezolizumab from Roche in late stage HCC patients with FGF19 overexpression in the Chinese mainland.

In October 2023, the updated Phase Ib data of irpagratinib was presented at the ESMO. The results demonstrated that irpagratinib was well tolerated in HCC patients and the BID cohorts demonstrated a promising antitumor activity with an ORR of 40.7% in FGF19+HCC patients with prior therapies.

In April 2024, irpagratinib was granted ODD by FDA for the treatment of HCC.

In June 2024, our updated Phase II clinical trial data of irpagratinib in combination with atezolizumab for the treatment of advanced HCC was presented at the 2024 ESMO-GI Congress. The presentation highlights that 220mg BID of irpagratinib in combination with atezolizumab demonstrated promising efficacy with an ORR of 50% in FGF19+HCC patients. The study is still ongoing, and the efficacy of BID cohorts warrants further investigation.

## WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ABSK011 SUCCESSFULLY.

## Fexagratinib (ABSK091, AZD4547)

Fexagratinib, previously known as AZD4547, is a highly potent and selective inhibitor of FGFR subtypes 1, 2 and 3. According to Frost & Sullivan, the cancers most commonly affected by FGFR aberration are urothelial cancer (32%), cholangiocarcinoma (25%), breast cancer (18%), endometrial carcinoma (11%) and gastric cancer (7%). Specific FGFR aberrations have been observed in a proportion of certain cancers. For example, FGFR1 amplification in squamous cell lung cancer, FGFR2 mutations in endometrial carcinoma and FGFR3 mutations in urothelial cancer.

Fexagratinib has a chemical structure different from other FGFR inhibitors with similar antitumor activities. Prior to the in-licensing of fexagratinib, AstraZeneca AB ("AstraZeneca") started conducting clinical trials on fexagratinib (AZD4547) in 2009. From 2009 to 2019, AstraZeneca sponsored and completed a total of four trials, including two Phase I trials and two Phase II trials. In November 2019, we entered into an exclusive license agreement with AstraZeneca and obtained the global rights for the development, manufacturing and commercialization of fexagratinib.

Among the clinical trials conducted by AstraZeneca, the BISCAY trial, a study in patients with advanced urothelial cancer who had progressed on prior treatments, achieved 31.3% response rate in the fexagratinib monotherapy arm, which is on par with the approved pan-FGFR inhibitor Erdafitinib in treatment of locally advanced or metastatic urothelial carcinoma with FGFR2/3 alteration (ORR 32.2%).

In another trial previously conducted by AstraZeneca in patients with previously treated advanced FGFR amplified cancer, 33% of the FGFR2-amplified gastro-oesophageal patients had confirmed responses to fexagratinib. This demonstrated that fexagratinib could potentially bring significant clinical benefits to the treatment of gastric cancer patients with FGFR alterations.

#### Current status

We are conducting a Phase II trial in the Chinese mainland for fexagratinib in patients with locally advanced or metastatic urothelial carcinoma with FGFR2/3 genetic alterations.

The preliminary Phase II efficacy and safety results of fexagratinib were announced in patients with urothelial carcinoma harboring FGFR2 or FGFR3 alterations in the Chinese mainland in 2022.

The preliminary efficacy results showed an ORR confirmed by IRC of 30.7% (4/13) in mUC patients with FGFR3 alteration (including mutations and/or fusions) and an IRC confirmed ORR of 44% (4/9) in patients with FGFR3 mutations, which is consistent with results from the prior BISCAY trial of fexagratinib in similar patient groups outside of China. The preliminary safety results showed that 80mg BID of fexagratinib was well-tolerated in Chinese patients, and no drug related grade 4 or above adverse effects were reported.

These results support further development of fexagratinib in the ongoing Phase II trial.

## WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ABSK091 SUCCESSFULLY.

#### ABSK043

ABSK043 is an orally bioavailable, highly selective small molecule PD-L1 inhibitor being developed for the treatment of various cancers and potentially non-oncology indications. While anti-PD-1/anti-PD-L1 antibodies have revolutionized cancer treatment, the antibody-based immunotherapies carry a number of disadvantages such as high cost, lack of oral bioavailability, and immunogenicity, which could likely be improved with small molecule inhibitors. Preclinical data have demonstrated strong inhibition of PD-1/PD-L1 interaction by ABSK043, and rescue of PD-L1-mediated inhibition of T-cell activation. ABSK043 has also demonstrated strong antitumor efficacy and excellent safety profile in several preclinical models.

#### Current status

We expect to complete the Phase I trial in Australia soon, which is aimed to assess the safety, tolerability and PK/PD profile of ABSK043 in patients with solid tumors.

We are also conducting a Phase Ib trial in China for patients with solid tumors.

In October 2023, the clinical results of first-in-human dose-escalating of ABSK043 with advanced solid tumors were presented at the 2023 ESMO Annual Meeting. The results demonstrated that ABSK043 was well tolerated up to 1,000 mg BID. Among 11 evaluable patients (BID dosing), ABSK043 demonstrated an ORR of 27.3% with no DLT reported and has a safety profile consistent with monoclonal antibody immune checkpoint inhibitors. Preliminary antitumor activity was observed, and further investigation is warranted to explore the efficacy in a larger number of patients.

In May 2024, we announced that ABSK043 will be evaluated in a clinical study in combination with Furmonertinib Mesilate Tablets (IVESA®, "Furmonertinib"), independently developed by Allist, for the treatment of patients with advanced NSCLC. Details of the research collaboration includes an IND/CTA filing pertaining to the exploration of ABSK043 in combination with Furmonertinib in a multicenter, open-label Phase II dose-escalation or dose-expansion clinical trial.

## WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ABSK043 SUCCESSFULLY.

## ABSK061

ABSK061 is a highly selective small molecule FGFR2/3 inhibitor. Preclinical research has shown that ABSK061 selectively inhibits FGFR2/3 over FGFR1 across various in vitro and cellular assays, with little activity against other kinases. Its high selectivity against FGFR2/3 and reduced FGFR1 activity could lead to an improved safety profile due to less off-target side effects, and potentially improved therapeutic window and efficacy as well as better opportunities for treating non-oncology indications.

Achondroplasia ("ACH") is a common form of human dwarfism with characteristically rhizomelic shortening of extremities and relative macrocephaly. It is transmitted as an autosomally dominant inheritance, and about 80% of affected individuals result from sporadic mutations without positive family histories. Majority of ACH are caused by the genetic point mutations in FGFR3, which enables abnormal cartilage growth-plate differentiation and insufficient bony development.

We believe that ABSK061 has the potential to be a next generation FGFR inhibitor with its improved selectivity over currently marketed FGFR inhibitors based on our preclinical data.

#### Current status

We are conducting Phase I clinical trials for ABSK061 in patients with solid tumors in both China and the U.S.

In February 2024, the preliminary results of the first-in-human trial of the ABSK061 in patients with advanced solid tumors were presented orally at the 2024 ESMO TAT. The ABSK061 75mg BID and 150mg QD cohorts demonstrated a promising antitumor activity with an ORR of 37.5% among 8 patients with solid tumors carrying FGFR-activating alterations.

We are also conducting ABSK061's IND-enabling study for ACH. We received the IND approval from NMPA for a Phase II combination clinical trial for solid tumors in July 2024.

## WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ABSK061 SUCCESSFULLY.

### ABSK121

ABSK121 is a highly selective, next-generation small molecule FGFR inhibitor that targets both wild-type and mutants of FGFR1-3 including those that are resistant to the currently approved or clinical FGFR inhibitors. It could potentially bring clinical benefits to patients who relapsed or progressed after initial treatment with first-generation FGFR inhibitors. In preclinical studies, ABSK121 has demonstrated strong potency against wild-type and various mutations of FGFR1-3, and showed excellence in vivo efficacy in FGFR dependent and FGFR-mutant dependent models.

#### Current status

We are conducting Phase I clinical trials in China and the U.S. concurrently. The dosing of first patient was completed in the treatment of patients with advanced solid tumors in China in June 2023.

## WE MAY NOT ABLE TO ULTIMATELY DEVELOP AND MARKET ABSK121 SUCCESSFULLY.

#### ABSK112

ABSK112 is a next-generation EGFR Exon20ins inhibitor with improved selectivity over wild-type EGFR and strong brain penetrating ability. EGFR-exon20 mutations occur in 3-5% of NSCLC patients, and are resistant to the currently available first, second and third generation EGFR inhibitors. Current clinical compounds targeting these mutations have limited therapeutic window due to limited selectivity against wild-type EGFR. Increased selectivity will likely lead to better target modulation and efficacy in clinical trials. ABSK112 demonstrated strong activity against EGFR-exon20 mutants and clear selectivity against wild-type EGFR in various cellular assays. It exhibited efficacy and PD effects in mouse xenograft models bearing EGFR-exon20 mutations.

#### Current status

ABSK112 received clinical study approval from NMPA in October 2023 and the FDA in July 2023, and the Phase I studies are being conducted simultaneously in the U.S. and China.

In February 2024, the first patient dosing was completed for the treatment of NSCLC.

## WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ABSK112 SUCCESSFULLY.

### ABSK081

ABSK081 (mavorixafor), also known as X4P-001, is a novel small molecule antagonist to CXCR4 and currently the only orally bioavailable CXCR4 modulator in clinical development globally, according to Frost & Sullivan. ABSK081 is a potential treatment option for various cancers in which CXCR4 and its ligand CXCL12 contribute to the tumor microenvironment (TME) that supports immune evasion, neoangiogenesis, and tumor metastasis. In July 2019, we entered into an exclusive license agreement with X4 Pharmaceuticals, Inc. ("X4") and obtained the rights for the development, manufacturing and commercialization of the licensed compound ABSK081 (mavorixafor) in the Chinese mainland, Taiwan, Hong Kong and Macau for any oncological indication and WHIM Syndrome in humans, excluding mozobil indications and any use for auto-HSCT treatment and allo-HSCT treatments.

## Current status

In Chinese mainland, we are conducting a Phase Ib/II clinical trial of ABSK081 (mavorixafor) in combination with toripalimab from Junshi in triple-negative breast cancer ("TNBC") patients in China. We dosed the first patient in July 2021. Patient enrollment has been completed.

## WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ABSK081 SUCCESSFULLY.

#### ABSK051

ABSK051 is a small molecule CD73 inhibitor being developed for the treatment of various tumor types including lung cancer, pancreatic cancer and other cancers. It has demonstrated strong potency in inhibiting the activities of soluble and surface-expressed CD73. It has also shown strong efficacy in vivo in various animal models.

#### Current status

We are conducting a Phase I trial in China to assess the safety, tolerability and PK/PD profile of and preliminary antitumor activity of ABSK051 in patients with advanced solid tumors. The IND approval for a Phase I trial of ABSK051 was obtained from NMPA for the treatment of patients with advanced solid tumors in China in November 2023.

In January 2024, we completed dosing of the first patient in China.

## WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ABSK051 SUCCESSFULLY.

#### ABSK012

ABSK012 is an orally bioavailable, highly selective, next-generation small molecule FGFR4 inhibitor with strong potency against both wild-type and mutant FGFR4. In preclinical studies, ABSK012 has demonstrated strong activities in vitro and in cells against both wild-type FGFR4 and various FGFR4 mutants that are resistant to current FGFR4 inhibitors in clinical development, and excellent in vivo efficacy in FGF19-driven and FGFR4-mutant models.

#### Current status

ABSK012 was granted ODD by the FDA for the treatment of soft tissue sarcomas in April 2023.

In November 2023, We obtained IND approval for ABSK012 of a first-in-human Phase I clinical study in patients with advanced solid tumors from the FDA.

## WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET ABSK012 SUCCESSFULLY.

## **IND-enabling candidates**

ABK3376 (AST2303) is a highly potent, selective, and brain-penetrating new-generation EGFR inhibitor, which was discovered by our proprietary drug discovery platform. ABK3376 can efficiently inhibit the EGFR-C797S mutation occurring after third-generation EGFR-TKI treatment. Its Greater China right has been licensed out to Allist and its IND preparation has been completed.

ABSK131 is a potent and selective a next generation and brain-penetrant MTA-cooperative PRMT5 inhibitor. It was discovered by us through leveraging advanced computation-aided structural analysis and medicinal chemistry design. Development of selective PRMT5\*MTA inhibitors may improve not only safety but also therapeutic efficacy. The preclinical result of ABSK131 was published at the 35th EORTC in Boston, U.S. We are currently conducting IND-enabling studies for ABSK131.

### **Business development activities**

At the forefront of our growth strategy lies a specialized team committed to cultivating new avenues for collaboration and expansion. This dedicated business development unit is tasked with identifying and assessing promising opportunities, ranging from licensing agreements to strategic partnerships. By actively engaging in these initiatives, our goal extends beyond mere commercial success; we aspire to unleash the full potential of our innovative drug pipeline while fostering synergistic relationships that drive progress.

In December 2023, we entered into a license agreement with Merck. Under the terms of the license agreement, we granted Merck an exclusive license to commercialize products comprising or containing pimicotinib for all indications in the Chinese mainland, Hong Kong, Macau and Taiwan, and an exclusive option for global commercial rights. In addition, Merck also has the option to co-develop pimicotinib in additional indications under certain conditions. The aggregate amounts of upfront payment, option exercising payment, and payments for development and commercialization milestones will total US\$605.5 million. We will also receive double-digit percentage (%) royalties on annual net sales.

In February 2024, we received the one-time, non-refundable upfront payment of US\$70 million pursuant to the terms of the license agreement with Merck. In the event that Merck exercises the global commercialization option, Merck will pay our Company an additional option exercising fee.

## Research and development

We believe R&D are critical to our future growth and our ability to remain competitive in the Chinese biopharmaceutical market. We are dedicated to enhancing our pipeline by leveraging our leading in-house R&D capabilities, which spans from early drug discovery to clinical development.

As at June 30, 2024, our R&D team consisted of approximately 221 employees and has extensive clinical development experience, with a particular focus on oncology. Among our R&D team members, 70% have obtained at least post-graduate degrees, and approximately 21% hold Ph.D. degrees. Among our preclinical R&D team members, approximately 81% have obtained at least postgraduate degrees, and approximately 29% hold Ph.D. degrees.

## Drug discovery and preclinical development

Our drug discovery effort is led by our co-founders, Dr. Xu Yao-Chang ("Dr. Xu"), Dr. Yu Hongping ("Dr. Yu") and Dr. Chen Zhui ("Dr. Chen"), who collectively have made contributions to dozens of discovery programs, a number of which led to successful commercialization, such as Ameile (almonertinib), Cymbalta (duloxetine), Balversa (erdafitinib), Reyvow (lasmiditan), Fu Laimei (PEG-loxenatide), Kisqali (ribociclib), Xinfu (flumatinib) and Venclexta (venetoclax).

We use various discovery and engineering technologies to discover and select our lead compounds with suitable pharmaceutical properties and market potential. Our drug discovery team collaborates with our Chemistry, Manufacturing and Controls ("CMC") team at an early stage to complement each team's needs and to ensure continued knowledge sharing, regulatory compliance and a streamlined transition from discovery to development. Our drug discovery team also includes a translational medicine function that conducts biomarker discovery and bioinformatics data processing and analysis to facilitate our clinical studies. We conduct translational research to assess the effectiveness of treatment, evaluate different ways to customize therapies, and improve personalized medicine guidelines using the new data generated. These insights help further guide us toward new directions in novel drug and biomarker discovery.

## Clinical development

Our clinical development team is led by Dr. Ji Jing, who received a M.D. degree from Fudan University and Shanghai Second Medical University, majoring in Gastrointestinal and liver disease. She has over 25 years of experience in early and late-stage clinical development in global pharmaceutical companies, serving as clinical development leader and head of therapy area. She has led and executed a wide range of functions, including medical, clinical operations, quality control, clinical research, clinical pharmacology and patient safety.

Our clinical development team manages all stages of our clinical trials, including clinical trial design, implementation, drug supply, and the collection and analysis of trial data. We have entered into agreements with hospitals and principal investigators located in China, the U.S. and other regions that can support our clinical trials of different indications at different stages. We believe our experience in executing clinical trials helps us accelerate our drug development.

With the vision to address unmet medical needs of global patients, we have always been aiming for the global markets. We believe such going-global approach will maximize the commercial value of our assets, for which we own global rights. We have received around 30 INDs or clinical trial approvals in multiple countries and regions as at June 30, 2024. Trials outside Chinese mainland include three Phase III trials ongoing in the U.S., Canada and Europe for pimicotinib, a Phase I trial ongoing in Australia for ABSK043, three Phase I trials ongoing in the U.S. for ABSK061, ABSK112 and ABSK121 respectively, a completed Phase Ib trial in Taiwan for irpagratinib and a completed Phase Ib/II trial in Taiwan for fexagratinib.

## **Events after the Reporting Period**

Subsequent to June 30, 2024, the significant events that took place are listed below:

From July 2, 2024 to July 4, 2024, the Company repurchased an aggregate of 700,000 shares on the Stock Exchange at the highest and lowest prices of HKD3.27 and HKD3.17 per share, respectively. The aggregate purchase consideration paid for the share repurchase was approximately HKD2,257,250.

On July 3, 2024, 15,833,000 shares of shares repurchased from March 13, 2024 to June 17, 2024 were cancelled, and upon the cancellation of 15,833,000 repurchased shares, the total issued shares of the Company decreased to 686,366,350 shares.

In July 2024, we received the IND approval from NMPA for a Phase II combination clinical trial for ABSK061 for solid tumors.

#### **Future and Outlook**

In the dynamic landscape of biotechnology, we still in the view that the future holds unprecedented promise and potential. We also firmly believe the breakthroughs and milestones we achieved have the potential to transform lives globally. Looking ahead, we'll keep exploring and try to seize any opportunity to redefine the realm of possibilities and endeavor to generate sustainable value for all stakeholders.

## Keeping advancing our pipeline

Our dedication to advancing our strong pipeline of promising candidates remains firm. We also continue to maximize the therapeutic value of our assets by expanding the number of indications and combinations for our drug candidates. As numerous candidates advance through late-stage clinical development and with significant regulatory milestones ahead, we stand ready to meet unmet medical needs and bring groundbreaking therapies to patients globally.

## Reinforcing strategic partnerships

We continue to prioritize strategic collaborations with leading biopharmaceutical companies, academic institutions, and research organizations. By forging alliances that harness complementary expertise and resources, we strive to accelerate innovation and extract maximum value from our partnerships, ultimately benefiting patients and shareholders of the Company ("Shareholder") alike.

## Investment in research and development

Our unwavering commitment to innovation drives our ongoing investments in research and development. We intend to continue to enhance our R&D capabilities and persist in pushing the boundaries of science to deliver breakthrough solutions that address pressing healthcare challenges and drive sustained long-term growth.

## Remunerating Shareholders

We appreciate and recognize our Shareholders' vital role and commit to rewarding their trust through initiatives including strategic resource allocation for optimizing returns and sustainable growth, and transparent communication. We are committed to creating long-term value for our Shareholders, ensuring their continued confidence in our mission and vision.

## II FINANCIAL REVIEW

	Six months ended 30 June		
	2024	2023	
	RMB'000	RMB'000	
	(Unaudited)	(Unaudited)	
Revenue	497,273	19,060	
Cost of sales			
Gross profit	497,273	19,060	
Other income and gains	48,524	37,702	
Research and development expenses	(215,073)	(204,649)	
Administrative expenses	(40,294)	(45,729)	
Other expenses	(4,057)	(13,816)	
Finance costs	(888)	(1,160)	
PROFIT/(LOSS) BEFORE TAX	285,485	(208,592)	
Income tax expenses	(78,694)		
PROFIT/(LOSS) FOR THE PERIOD	206,791	(208,592)	
OTHER COMPREHENSIVE INCOME  Other comprehensive income that may be reclassified to profit or loss in subsequent periods:  Exchange differences on translation of foreign operations Other comprehensive income that will not be reclassified	362	765	
to profit or loss in subsequent periods:  Exchange differences on translation of the Company	9,768	67,694	
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD, NET OF TAX	10,130	68,459	
,	·	<u> </u>	
TOTAL COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD	216,921	(140,133)	
Total comprehensive loss attributable to: Owners of the parent	216,921	(140,133)	
EARNINGS/(LOSS) PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT Basic and diluted	DMD 0.22	DIMD (0.22)	
For profit/(loss) for the period	RMB 0.32	RMB (0.32)	

**Revenue.** Revenue increased to RMB497.3 million for the six months ended June 30, 2024, from RMB19.1 million for the six months ended June 30, 2023, by RMB478.2 million primarily attributable to the upfront payment we received from Merck.

**Other income and gains.** Other income and gains increased to RMB48.5 million for the six months ended June 30, 2024, from RMB37.7 million for the six months ended June 30, 2023, by RMB10.8 million, primarily attributable to an increase in bank interest income of RMB18.7 million, partially offset by a decrease in government subsidies.

	Six months ended June 30		
	2024		
	(RMB'000)	(RMB '000)	
Bank interest income	45,747	27,016	
Government subsidies	2,460	9,914	
Fair value gains on financial assets at fair value through			
profit or loss	317	772	
	48,524	37,702	

**Research and development expenses.** Research and development expenses increased to RMB215.1 million for the six months ended June 30, 2024, from RMB204.6 million for the six months ended June 30, 2023, by RMB10.5 million, primarily attributable to an increase in third party contracting cost by RMB2.1 million as we advanced our clinical trials to later stage while expanding early discovery and research activities at the same time.

	Six months ended June 30		
	2024	2023	
	(RMB'000)	(RMB '000)	
Employee cost	85,292	81,918	
Third party contracting cost	109,079	106,962	
Others	20,702	15,769	
	215,073	204,649	

**Administrative expenses.** Administrative expenses decreased to RMB40.3 million for the six months ended June 30, 2024, from RMB45.7 million for the six months ended June 30, 2023, by RMB5.4 million, primarily attributable to a decrease in share-based payments.

	Six months ended June 30		
	2024		
	(RMB'000)	(RMB '000)	
Employee cost	27,611	32,112	
Third party advisory service cost	6,886	9,313	
Others	5,797	4,304	
	40,294	45,729	

**Finance costs.** Finance costs decreased to RMB0.9 million for the six months ended June 30, 2024, from RMB1.2 million for the six months ended June 30, 2023. Decrease in finance cost is mainly due to the decrease of interest on lease liabilities.

**Other expenses.** Other expense decreased to RMB4.1 million for the six months ended June 30, 2024, from RMB13.8 million for the six months ended June 30, 2023, by RMB9.7 million, primarily attributable to the decrease of the foreign exchange loss.

**Income tax expenses.** During the six months ended June 30, 2024, the Group is subject to a Germany withholding tax, amounting to RMB78.7 million.

## **NON-IFRS MEASURE**

To supplement the Group's Consolidated Financial Statements, which are presented in accordance with the IFRS, the Company also uses adjusted profit/(loss) for the year and other adjusted figures as additional financial measures, which are not required by, or presented in accordance with, the IFRS. The Company believes that these adjusted measures provide useful information to shareholders and potential investors in understanding and evaluating the Group's consolidated results of operations.

Adjusted profit/(loss) for the year represents the profit/(loss) for the year excluding the effect of certain non-cash items, namely share-based compensation cost. The term adjusted profit/(loss) for the year is not defined under the IFRS. The use of this non-IFRS measure has limitations as an analytical tool, and you should not consider it in isolation from, or as substitute for analysis of, the Group's results of operations or financial condition as reported under IFRS. The Company's presentation of such adjusted figure may not be comparable to a similarly titled measure presented by other companies. However, the Company believes that this and other non-IFRS measures are reflections of the Group's normal operating results by eliminating potential impacts of items that the management do not consider to be indicative of the Group's operating performance, and thus facilitate comparisons of operating performance from period to period and company to company to the extent applicable.

The table below sets forth a reconciliation of the profit/(loss) to adjusted profit/(loss) during the periods indicated:

	Six months ended June 30		
	2024		
	(RMB'000)	(RMB'000)	
Profit/(loss) for the period Added:	206,791	(208,592)	
Share-based compensation cost	8,640	25,709	
Adjusted profit/(loss) for the year	215,431	(182,883)	

The table below sets forth a reconciliation of the research and development expenses to adjusted research and development expenses during the periods indicated:

	Six months ended June 30		
	2024 (RMB'000)	2023 (RMB'000)	
Research and development expenses for the year Added:	(215,073)	(204,649)	
Share-based compensation cost	5,734	15,662	
Adjusted research and development expenses for the year	(209,339)	(188,987)	

The table below sets forth a reconciliation of the administrative expenses to adjusted administrative expenses during the periods indicated:

	Six months ended June 30		
	2024 (RMB'000)	2023 (RMB'000)	
Administrative expenses for the year Added:	(40,294)	(45,729)	
Share-based compensation cost	2,906	10,047	
Adjusted administrative expenses for the year	(37,388)	(35,682)	

## **Employee and Remuneration Policy**

The following table sets forth a breakdown of our employees as at June 30, 2024, by function:

Functions	Numbers	Percentage of total %
Research	87	31.6%
Pre-clinical Development	37	13.5%
Clinical Development	97	35.3%
Scientific Strategy and Operations	12	4.4%
Others	42	15.3%
Total	275	100.0%

As at June 30, 2024, the Group had 275 employees, where their salaries and allowances were determined based on their performance, experience and the then prevailing market rates. We have also invested in continuing education and training programs, including internal and external training, for our management staff and other employees to upgrade their skills and knowledge. We also provide competitive salaries, project and share incentive plans to our employees especially key employees.

## Liquidity and Financial Resources

The Group's time deposits/cash and bank balances as June 30, 2024, were RMB2,122.5 million, representing an increase of 7.7% compared to RMB1,971.5 million as at December 31, 2023, primarily attributable to the increase in revenue, partially offset by increase of spending on research and development activities, and shares repurchase.

As at June 30, 2024, the current assets of the Group were RMB2,190.7 million, including time deposits/cash and bank balances of RMB2,122.5 million and other current assets of RMB68.2 million. As at June 30, 2024, the current liabilities of the Group were RMB100.7 million, including other payables and accruals of RMB85.5 million and other current liabilities of RMB15.2 million.

### Gearing ratio

Gearing ratio is calculated using total liabilities divided by total assets and multiplied by 100%. As at June 30, 2024, our gearing ratio was 5.32% (as at December 31, 2023: 6.35%).

## Material Acquisition and Disposal of Subsidiaries, Associates and Joint Ventures

The Group had no material acquisitions and disposals of subsidiaries, associates and joint ventures during the Reporting Period.

## Future Plans for Material Investments or Capital Assets

Save as disclosed in this announcement, we do not have any future plans for material investments or capital assets as at the date of this announcement.

## Foreign Exchange Risk

Our financial statements are expressed in RMB, but certain of our financial assets measured at fair value through profit or loss and other payables are denominated in foreign currencies, and are exposed to foreign currency risk. We currently do not have a foreign currency hedging policy. However, the management monitors foreign exchange exposure and will consider hedging significant foreign currency exposure should the need arise.

## Bank Loans and Other Borrowings

As at June 30, 2024, we did not have any bank loans or other forms of borrowings.

#### Contingent Liabilities

The Group had no material contingent liability as at June 30, 2024.

## Charges on Group Assets

As at June 30, 2024, we did not have any charges on our assets.

#### CORPORATE GOVERNANCE AND OTHER INFORMATION

## **Compliance with the Corporate Governance Code**

The Company is committed to maintain high standards of corporate governance to safeguard the interests of the Shareholders and to enhance corporate value and accountability. The Company has applied the principles and code provisions as set out in the Corporate Governance Code (the "CG Code") contained in Appendix C1 to Listing Rules. During the Reporting Period, the Board is of the opinion that the Company has complied with all the applicable code provisions apart from the deviation below.

Code provision C.2.1 of the CG Code provides that the roles of the chairman of the Board (the "Chairman") and chief executive officer (the "CEO") should be separated and should not be performed by the same individual. As at the date of this announcement, the roles of the Chairman and the CEO of the Company are held by Dr. Xu.

The Board believes that, in view of Dr. Xu's experience, personal profile and his roles in our Company, Dr. Xu is the Director best suited to identify strategic opportunities and focus of the Board due to his extensive understanding of our business as our CEO. The Board also believes that the combined role of Chairman and CEO can promote the effective execution of strategic initiatives and facilitate the flow of information between management and the Board.

Further, the decisions to be made by the Board require approval by at least a majority of our Directors and that the Board comprises one non-executive Director, three independent non-executive Directors, and three executive Directors, which we believe provides an adequate system of checks and balances within the Board. Dr. Xu and other Directors are aware of and undertake to fulfill their fiduciary duties as Directors, which require, among other things, that they shall act for the benefit and in the best interest of the Company and will make decisions for the Group accordingly.

The Board will continue to review and consider splitting the roles of the Chairman and the CEO at the time when it is appropriate by taking into account the circumstances of the Group as a whole. The Company will continue to regularly review and monitor its corporate governance practices to ensure compliance with the CG Code, and maintain a high standard of corporate governance practices of the Company.

## **Compliance with Model Code**

The Company has adopted a code of conduct regarding Directors' securities transactions on terms no less exacting than the required standard set out in the Model Code for Securities Transactions by Directors of Listed Issuers set out in Appendix C3 to the Listing Rules (the "Model Code"). Specific enquiries have been made to all the Directors and they have confirmed that they have complied with the Model Code during the Reporting Period.

## Use of Proceeds from the Global Offering

The shares of the Company were listed on the Stock Exchange on October 13, 2021 and the Company obtained net proceeds of approximately HKD1,674 million (after deducting the underwriting commissions and other estimated expenses in connection with the global offering and the exercise of the over-allotment option).

The net proceeds have been and will be utilized in accordance with the purposes set out in the prospectus of the Company dated September 30, 2021 under the section headed "Future Plans and Use of Proceeds". The table below sets out the planned allocations of the net proceeds and actual usage up to June 30, 2024:

Planned usage	Approximate percentage of use of proceeds	Net proceeds from the IPO	Amount of unutilized net proceeds as at January 1, 2024		Unutilized net proceeds as of June 30, 2024	Expected timeline for application of the unutilized net proceeds
2.11.11.00 10.000	Process		(HKD million)			Process
Fund the ongoing and future R&D including planned clinical trials, preparation of registration fillings, and future commercialization of our Core Product Candidate Irpagratinib (ABSK011)	19.7%	329.78	263.59	32.87	230.72	Expected to be fully utilized by December 31, 2024
Fund the ongoing and future R&D including planned clinical trials, preparation of registration filings and future commercialization of our Core Product candidate Fexagratinib (ABSK091, AZD4547)	32.6%	545.72	462.80	10.07	452.73	Expected to be fully utilized by December 31, 2024
Fund our other clinical stage products and product candidates in our pipeline	28.0%	468.72	170.78	119.62	51.16	Expected to be fully utilized by December 31, 2024
Fund our pre-clinical research and studies, including continued development of our R&D platform and R&D of new pre-clinical candidates	8.4%	140.62	0	0	0	Expected to be fully utilized by December 31, 2024
Fund the construction of manufacturing facility in Shanghai	6.3%	105.46	60.93	0	60.93	Expected to be fully utilized by December 31, 2024
Working capital and general corporate purposes	5.0%	83.70	0	0	0	Expected to be fully utilized by December 31, 2024
Total	100%	1,674.00	958.10	162.56	795.54	

Note:

Net IPO proceeds were received in HKD and translated to RMB for application planning.

### **Significant Investments Held**

During the Reporting Period, the Group did not hold any significant investments.

## Purchase, Sale or Redemption of Listed Securities

On March 12, 2024, the Board approved and the Company announced a no more than HKD100 million share repurchase plan (the "Share Repurchase Plan") of the shares listed on the Main Board of The Stock Exchange of Hong Kong Limited (the "Stock Exchange"). During the Reporting Period, the Company repurchased a total of 18,571,000 shares on-market for a total consideration of HKD56,318,840 pursuant to the Share Repurchase Plan.

Details of the share repurchases during the Reporting Period are as follows:

Month of repurchase	Number of shares and method of repurchased	Price per s Highest	hare paid Lowest	Total consideration paid
March 2024 April 2024 May 2024 June 2024	2,001,000 shares on the Stock Exchange 8,177,000 shares on the Stock Exchange 2,500,000 shares on the Stock Exchange 5,893,000 shares on the Stock Exchange	HKD3.03 HKD3.33 HKD3.41 HKD3.29	HKD2.72 HKD2.73 HKD3.18 HKD2.90	HKD5,783,060.00 HKD24,215,510.00 HKD8,265,120.00 HKD18,055,150.00
Total	18,571,000 shares on the Stock Exchange			HKD56,318,840.00

Save as disclosed above, neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the Company's listed securities (or sale of treasury shares<sup>(Note 1)</sup>, if any) during the Reporting Period. As at June 30, 2024, the Company did not hold any treasury shares<sup>(Note 1)</sup>.

Note 1: as defined under the Rules Governing the Listing of Securities on the Stock Exchange (the "Listing Rules")

#### INTERIM DIVIDEND

The Board has resolved not to declare the payment of an interim dividend for the six months ended June 30, 2024 (June 30, 2023: Nil).

#### REVIEW OF INTERIM RESULTS BY AUDIT COMMITTEE

The audit committee of the Company (the "Audit Committee") has considered and reviewed the unaudited interim results of the Group for the six months ended June 30, 2024 and the accounting principles and practices adopted by the Group, and has discussed with management on issues in relation to internal control, risk management and financial reporting. The Audit Committee is of the opinion that the unaudited interim results of the Group for the six months ended June 30, 2024 are in compliance with the relevant accounting standards, laws and regulations.

#### PUBLICATION OF INTERIM RESULTS AND INTERIM REPORT

This results announcement is published on the Company's website (www.abbisko.com) and the website of the Stock Exchange (www.hkexnews.hk).

The Company's interim report for the six months ended June 30, 2024 containing all relevant information required under the Listing Rules will be published on the aforementioned websites and dispatched to the shareholders of the Company in due course.

By order of the Board **Abbisko Cayman Limited Dr. Xu Yao-Chang**Chairman

Shanghai, August 12, 2024

As at the date of this announcement, the board of Directors of the Company comprises Dr. Xu Yao-Chang, Dr. Yu Hongping and Dr. Chen Zhui as executive Directors; Ms. Tang Yanmin as a non-executive Director; and Dr. Sun Piaoyang, Mr. Sun Hongbin and Mr. Wang Lei as independent non-executive Directors.