Akeso, Inc.
康方生物科技（開曼）有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 9926)

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

The Board of Akeso, Inc. hereby announces the unaudited condensed consolidated results of the Group for the six months ended June 30, 2023.

In this announcement, "we", "us" and "our" refer to the Company or where the context otherwise requires, the Group.

FINANCIAL HIGHLIGHTS

1. Revenue

The Group's revenue increased by 2,154.4% from RMB163.1 million for the six months ended June 30, 2022 to RMB3,676.9 million for the six months ended June 30, 2023. Such revenue was mainly attributable to drug sales and license income.

2. Gross Profit

The Group's gross profit increased by 2,566.4% from RMB135.0 million for the six months ended June 30, 2022 to RMB3,599.7 million for the six months ended June 30, 2023. It was mainly attributable to the strong increase in the license income recognized by the Company.

3. Profit for the Period

The Group's profit for the period increased by 459.8% from loss of RMB691.9 million for the six months ended June 30, 2022 to profit of RMB2,489.5 million for the six months ended June 30, 2023.

MANAGEMENT DISCUSSION AND ANALYSIS

We are a biopharmaceutical company committed to researching, developing, manufacturing and commercialising affordable and high-quality innovative drugs for patients worldwide. Adhering to the clinical value-oriented innovation approach, we focus on oncology, autoimmune and other disease areas with significant global unmet medical need, and continue to develop next-generation innovative new drugs with global first-in-class and best-in-class potential.

During the Reporting Period, the Company recorded a profit of approximately RMB2,489.5 million, as compared to a loss of approximately RMB691.9 million for the six months ended June 30, 2022. This is the first time for the Company to achieve half-year profits, which was mainly attributable to the license income of RMB2,915.2 million from licensing ivonescimab (AK112, PD-1/VEGF). In addition, the product sales of 開坦尼® (cadonilimab, PD-1/CTLA-4) and ANNIKO® (penpulimab, PD-1) recorded significant increase, which reflects the excellent clinical value of two marketed products and contributed to the growth in the Company's product sales revenue during the Reporting Period. During the Reporting Period, the product sales of the Company is RMB794.7 million.

As of the date of this announcement, the Company has six* in-house developed innovative drugs which have received NDA approval or submitted NDA application.

開坦尼® (cadonilimab injection, PD-1/CTLA-4)

With its outstanding clinical value, 開坦尼® has recorded significant increase of patients as well as product sales. During the Reporting Period, the product sales attributable to 開坦尼® amounted to RMB605.8 million.

開坦尼® has also been included in a number of authoritative clinical guidelines, including the *Gynecologic Tumor Immune Checkpoint Inhibitor Clinical Practice (2023), the Chinese Expert Consensus on Multidisciplinary Combination Therapy of Hepatocellular Carcinoma (2023), Chinese Experts Concensus on the Diagnosis and Treatment of Gastric-type Endocervical (2023) and Chinese Gynecologic Tumor Clinical Practice 7th Edition (2023)*, reflecting the increasingly high recognition of 開坦尼® among doctors and patients in the clinical application. 開坦尼® has been included in the Chinese Medicare list of more than 10 provinces and 40 cities, including Beijing, Shanghai, Hangzhou, Chengdu, Shenyang, Wuhan, Tianjin and Chongqing, aiming to benefit more patients.

*: includes 普佑恒™ (pucotenlimab, PD-1), which was licensed out by the Group and developed by Lepu Biopharma Co., Ltd (stock code: 2157.HK).

開坦尼® has covered 13 indications with combination therapy, including lung cancer, liver cancer, gastric cancer, cervical cancer, kidney cancer, esophageal cancer and colorectal cancer, to build a higher marketing entry barrier. We have completed the patient enrollment of the Phase III trials of 開坦尼® as the first-line treatment of cervical cancer and G/GEJ adenocarcinoma. The Phase III trial for HCC adjuvant treatment is undergoing efficiently. We have also initiated the Phase III trial for the first line treatment of NSCLC patients with PD-L1 negative expression in July 2023.

Ivonescimab (AK112, PD-1/VEGF)

The Company entered into a licence agreement with Summit Therapeutics Inc. (NASDAQ: SMMT) (the "**SUMMIT**") in December 2022 to license out its independently-developed bi-specific antibody, ivonescimab (AK112, PD-1/VEGF) to SUMMIT. The Company has received an upfront payment equivalent to US$500 million in total in the first quarter of 2023, of which RMB2,915.2 million has been recognised as licence fee income during the Reporting Period, which has substantially strengthen the Company's cash on hand.

In August 2023, the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) has accepted the New Drug Application (NDA) of ivonescimab with the indication of ivonescimab in combination with chemotherapy for the treatment of locally advanced or metastatic non-squamous NSCLC patients with EGFR mutation who progressed after the treatment of EGFR TKI, which marked the second core bi-specific antibody independently developed by the Company is entering the commercialization stage. Ivonescimab has been granted "Priority Review" designation by CDE. In China, we are accelerating the preparation for commercialization and two other Phase III clinical trials for NSCLC of ivonescimab. In August 2023, the Company completed the patient enrollment of phase III clinical trial of ivonescimab monotherapy versus pembrolizumab as the first-line treatment for locally advanced or metastatic NSCLC with PD-L1 positive expression. The Company has treated the first patient of the Phase III trial of ivonescimab in combination with chemotherapy versus tislelizumab in combination with chemotherapy as the first-line treatment for locally advanced or metastatic squamous NSCLC in August 2023.

In overseas markets, leveraging on SUMMIT's and the Company's resources, capabilities and experience, we collaborate to advance the clinical development of ivonescimab. In May 2023, SUMMIT announced first United States-based patient treated in the Phase III multiregional HARMONi study, which is to evaluate the efficacy and safety of ivonescimab in combination with chemotherapy in patients with EGFR-mutated, locally advanced or metastatic non-squamous NSCLC who have progressed after treatment with a third-generation EGFR-TKI. SUMMIT also announced that it will initiate the Phase III HARMONi-3 trial of ivonescimab in combination with chemotherapy for first-line treatment of squamous NSCLC in the second half of 2023. The rapid advancement of such global clinical trials of ivonescimab will bring valuable next-generation innovative therapies to patients around the world.

ANNIKO® (penpulimab injection, PD-1)

In January 2023, the supplemental NDA (sNDA) of ANNIKO® in combination with chemotherapy as first-line treatment of locally advanced or metastatic squamous NSCLC was approved by NMPA. ANNIKO® has been recommended as Grade 1 first-line treatment of squamous NSCLC without actionable genomic alterations (AGA) in *Chinese Medical Association Guidelines for Clinical Diagnosis and Treatment of Lung Cancer (2023)*. Currently, ANNIKO® has been included in the Chinese Medicare lists in more than 50 provinces and cities. The Company also continues to actively explore and expand the overseas market potential of ANNIKO®. In April 2023, CTTQ-Akeso, a joint venture of the Company and Chia Tai Tianqing, entered into a licence agreement with Specialised Therapeutics Asia Pte Ltd (ST), and granted ST the exclusive right to sell ANNIKO® in Australia, New Zealand, Papua New Guinea and 11 Southeast Asian countries, including Singapore and Malaysia. Such collaboration will supplement and become a powerful extension of the Company's commercialization pathway in the overseas markets. We expect ANNIKO® to cover more markets and benefit more patients. ST achieved launch of access programs of ANNIKO® in Australia and Singapore in July 2023 and initiated commercialization successfully. Pursuant to the license agreement with ST, CTTQ-Akeso will receive double-digit percentage of royalties on net product sales of ANNIKO® in licensed territories and retain the development rights of ANNIKO® except the licensed territories.

Ebronucimab (AK102, PCSK9) and ebdarokimab (AK101, IL-12/IL-23)

The Company's non-oncology pipeline also entered into the pre-marketing stage. In the field of metabolism diseases, ebronucimab injection (AK102, PCSK9) achieved excellent clinical results. In June 2023, the CDE has accepted the NDA of ebronucimab for the treatment of two indications: (i) essential hypercholesterolemia and mixed hypercholesterolemia; and (ii) heterozygous familial hypercholesterolaemia (HeFH). In the field of autoimmune diseases, the NDA of ebdarokimab (AK101, IL-12/IL-23) has been accepted by CDE in August 2023 for the treatment of moderate-to-severe plaque psoriasis. The Company is also preparing for marketing and commercialization of these two products.

DEVELOPMENT OF PRODUCT PORTFOLIO

As of June 30, 2023, we have over 30 innovative programs covering the areas of oncology, autoimmune and metabolic diseases. 19 of these products are in the clinical trial stage (including 3[*1] marketed products, and four out-licensed products) and 6 of which are potential first-in-class or best-in-class bi-specific antibodies.

Oncology is one of the Company's focused therapeutic areas. We are conducting several clinical trials of 開坦尼® (cadonilimab, PD-1/CTLA-4) which has obtained marketing approval in June 2022, ivonescimab (AK112, PD-1/VEGF) which has entered into the NDA stage, ligufalimab (AK117, CD47), ANNIKO® (penpulimab, PD-1) which has obtained marketing approval in August 2021, drebuxelimab (AK119, CD73), pulocimab (AK109, VEGFR-2), AK127 (TIGIT), AK115 (NGF), AK129 (PD-1/LAG-3) and AK130 (TIGIT/TGF-β), and AK131 (PD-1/CD73) and AK132 (Claudin18.2/CD47), which will newly enter into clinical stage in 2023. Such drugs and drug candidates cover various indications including solid tumors and hematological tumors. Based on 開坦尼® and ivonescimab, as our two backbone drugs, we expect to target broader indication with huge market potential through combination strategy with high quality in-house developed products and external drugs.

We also have ebronucimab[*2] (AK102, PCSK9), an innovative product targeting metabolic diseases, of which the NDA was accepted by the CDE in June 2023. In autoimmune diseases, we also have a strong and broad pipeline. In particular, the NDA of ebdarokimab (AK101, IL-12/IL-23) has been accepted by CDE in August 2023. Meanwhile, we are also accelerating the clinical research and exploration of gumokimab (AK111, IL-17) and manfidokimab (AK120, IL-4R).

[*1] ANNIKO® (penpulimab, PD-1), 開坦尼® (cadonilimab, PD-1/CTLA-4) and 普佑恒™ (pucotenlimab, PD-1), which was licensed out by the Group and developed by Lepu Biopharma Co., Ltd (stock code: 2157.HK)

[*2] A product co-owned by the Company and Dawnrays Pharmaceutical.

The following chart highlighted the clinical development status of two commercialized products 開坦尼® (cadonilimab, PD-1/CTLA-4) and ANNIKO® (penpulimab, PD-1), and our other major clinical-stage products as of the date of this announcement:

Oncology – Core Products				Current Status			
Product (Target)	Areas	Mono/Combo Therapy	Indication	Phase Ia	Phase Ib/II	Pivotal/ Phase III	NDA Submitted/ Approved
Cadonilimab AK104 (PD-1/CTLA-4)	Cervical cancer	Mono	2L/3L cervical cancer				Approved on 2022.6.29
		+Chemo ±Bevacizumab	1L cervical cancer			Enrollment completed	
		Mono	Neoadjuvant cervical cancer				
	Gastric cancer	+XELOX	1L G/GEJ adenocarcinoma			Enrollment completed	
		+AK109+chemo	G/GEJ adenocarcinoma progressed after PD-(L)1 treatment				
		+AK117+chemo	1L G/GEJ adenocarcinoma				
		+AK117+chemo	Neoadjuvant G/GEJ adenocarcinoma				
	Hepatocellular carcinoma	Mono	HCC adjuvant therapy			Enrollment in process	
		+Lenvatinib	1L HCC		Completed		
		+Lenvatinib+TACE	HCC, intermediate stage		Enrollment completed		
		+AK109	HCC progressed after PD-(L)1 treatment				
	Lung cancer	+chemo	1L PD-L1(-) NSCLC			Initiated	
		+Chiauranib	≥2L SCLC				
		+Docetaxel	NSCLC progressed after platinum-based chemo and PD-(L)1 treatment				
		+AK109±Docetaxel	NSCLC progressed after PD-(L)1 treatment				
		+AK112±chemo	Advanced NSCLC				
	Esophageal cancer	±AK117+chemo	1L ESCC				
	Pancreatic cancer	+chemo	1L PDAC				
	Others	+AK117 (CD47)	Adv. solid tumors	Completed			
		+AK119 (CD73)	Adv. solid tumors				
		+AK127 (TIGIT)	Adv. solid tumors				
Ivonescimab AK112 (PD-1/VEGF)	Lung cancer	+Chemo	EGFRm NSCLC progressed after EGFR-TKI treatment				NDA accepted by CDE
		Mono	1L PD-L1(+) NSCLC				
		+Chemo	1L adv. sqNSCLC with driver gene negative				
		+Chemo	1L NSCLC with driver gene negative		Enrollment completed		
		+Docetaxel	IO-R NSCLC				
		±chemo	Neoadjuvant NSCLC		Enrollment completed		
		+AK119±chemo	EGFRm NSCLC progressed after EGFR-TKI treatment				
		+AK104±chemo	Advanced NSCLC				
	Gastrointestinal cancer	+chemo±AK117	1L G/GEJ adenocarcinoma, BTC, pancreatic cancer				
	Biliary tract cancer	+chemo±AK117	1L BTC				
	Pancreatic cancer	+chemo±AK117	1L pancreatic cancer				
	Breast cancer	+chemo±AK117	1L TNBC				
	Head and neck cancer	±AK117±chemo	HNSCC				
	Hepatocellular carcinoma	Mono	Unresectable HCC				
	Colorectal cancer	±AK117±chemo	1L CRC				
		+AK119±chemo	pMMR/MSS advanced CRC				
	Ovarian cancer	Mono	Platinum resistant OC				
	Others	Mono	Adv. solid tumors				
		+AK119	Adv. solid tumors				
		+AK127	Adv. solid tumors				
Ligufalimab AK117	Hematological tumor	+ azacitidine	1L MDS				
		+ azacitidine	1L AML				
	Solid tumor	+AK112+chemo	1L G/GEJ adenocarcinoma				
		+AK112+chemo	1L BTC				
		+AK112+chemo	1L pancreatic cancer				
		+AK112±chemo	HNSCC				
		+AK112+chemo	1L CRC				
		+Chemo±AK112	1L TNBC				
		+AK104+chemo	1L G/GEJ adenocarcinoma				
		+AK104+chemo	Neoadjuvant G/GEJ adenocarcinoma		In planning		
		+AK104+chemo	1L ESCC				
	Others	Mono	Adv solid tumors/lymphoma	Completed			
		+AK104	Adv solid tumors	Completed			

Global Large Indications NMPA approval Registrational Trials Breakthrough Therapy

Oncology – Other Products			Current Status			
Product (Target)	Mono/Combo Therapy	Indication	Phase Ia	Phase Ib/II	Pivotal/ Phase III	NDA Submitted/ Approved
Penpulimab AK105 (PD-1)	Mono	3L R/R cHL				Approved on 2021.8
	+Chemo	1L sq NSCLC ▲				Approved on 2023.1
	Mono	≥3L NPC				Submitted in China
	+Anlotinib	1L HCC ▲				
	+Chemo	1L NPC 🌐				
	+Anlotinib	dMMR				
	+Anlotinib	NSCLC, SCLC, HNC, thyroid cancer, mesothelioma and thymic cancer				
	+Anlotinib	ESCC, UC, GC/GEJ, cholangiocarcinoma, neuroendocrine tumor (NET)				
AK119 (CD73)	+AK112±chemo	EGFR-TKI failed EGFRm NSCLC				
	+AK112±chemo	Adv. solid tumors				
	+AK104	Adv. solid tumors				
	+AK112	Adv. solid tumors				
	Mono	Adv. solid tumors				
	+AK104	Adv. solid tumors 🌐	Completed			
AK109 (VEGFR-2)	±AK104+chemo	G/GEJ adenocarcinoma progressed after PD-(L)1 treatment				
	+AK104	HCC progressed after PD-(L)1 treatment				
	+AK104 ±Docetaxel	NSCLC progressed after PD-(L)1 treatment				
	Mono	Adv. solid tumors	Completed			
AK127 (TIGIT)	+AK104	Adv. solid tumors 🌐				
	±AK104	Adv. solid tumors				
	+AK112	Adv. solid tumors				
	Mono	Adv. solid tumors	Completed			
AK115(NGF)	Mono	Pain (including cancer pain)	Completed			
AK129 (PD-1/LAG-3)	Mono	Adv. solid tumors				
AK130 (TIGIT/TGF-β)	Mono	Adv. solid tumors				
AK131 (PD-1/CD73)	Mono	Adv. solid tumors				
AK130 (CLDN18.2/CD47)	Mono	Adv. solid tumors				

🌐 Global ▲ Large Indications NMPA approval Registrational Trials

Auto-immunity/Metabolism			Current Status			
Product (Target)	Mono/Combo Therapy	Indication	Phase Ia	Phase Ib/II	Pivotal/ Phase III	NDA Submitted
AK102 (PCSK9)	+Statin/Ezetimibe	Primary hypercholesterolemia and mixed hpyerlipidemia				NDA accepted by CDE
	+Statin/Ezetimibe	HeFH				NDA accepted by CDE
AK101 (IL-12/IL-23)	Mono	Moderate-to-severe psoriasis				NDA accepted by CDE
	Mono	Moderate-to-severe ulcerative colitis		Completed		
AK111 (IL-17)	Mono	Moderate-to-severe psoriasis				
	Mono	Ankylosing spondylitis		Completed		
AK120 (IL-4Rα)	Mono	Moderate-to-severe atopic dermatitis				

🌐 Global ▲ Large Indications Registrational Trials

Oncology

開坦尼® (cadonilimab, PD-1/CTLA-4)

1. Significant Clinical Progress in 2023H1

— In March, we completed patient enrollment of pivotal Phase III registration trial of cadonilimab in combination with chemotherapy as first line treatment of unresectable locally advanced or metastatic gastric/gastroesophageal junction (G/GEJ) adenocarcinoma.

— In March, we commenced R&D collaboration with Shanghai Pharmaceuticals Holding Co., Ltd. (Stock Code: 02607.HK; 601607.SH) to initiate combination therapies of cadonilimab in combination with SPH4336 (CDK4/6) for the treatment of well-differentiated liposarcomas (WDLS)/dedifferentiated liposarcoma (DDLS).

— In April, we obtained CDE approval to initiate Phase II clinical trial of cadonilimab in combination with AK117 as neoadjuvant treatment of G/GEJ.

— In May, we obtained CDE approval to initiate Phase II clinical trial of cadonilimab in combination with chemotherapy for the treatment of pancreatic cancer.

2. Publication in 2023H1

— In March, mechanism studies of cadonilimab was published at mAbs.

— In April, 開坦尼® was recommended in *Gynecologic Tumor Immune Checkpoint Inhibitor Clinial Practice (2023)*: (i) 開坦尼® in combination with chemotherapy as first line treatment of persistent, recurrent or metastatic cervical cancer (Category3); and (ii) 開坦尼® monotherapy for treatment of recurrent or metastatic cervical cancer failed to previous treatments (Category2A).

— In June, two-year updated data of Phase II trial of cadonolimab in combination with chemotherapy as first line treatment of G/GEJ was published at 2023 ASCO.

— In June, preliminary Phase II clinical data of cadonilimab in combination with AK117 and chemotherapy as first line treatment of advanced G/GEJ was published at 2023 ASCO.

— In June, 開坦尼® was recommended in *Chinese Experts Concensus on the Diagnosis and Treatment of Gastric-type Endocervical Adenocarcinomas (2023).*

3. Recent Development After the Reporting Period

— In July, the Phase Ia/Ib trial of cadonilimab in combination with AK127 for treatment of advanced solid tumor completed dosing first patient.

— In July, we obtained CDE approval to initiate Phase III clinical trial of cadonilimab in combination with chemotherapy, versus tislelizumab in combination with chemotherapy, as first line treatment of locally advanced or metastatic NSCLC patients with PD-L1 negative expression.

— In August, 開坦尼® was recommended in Chinese Gynecologic Tumor Clinical Practice 7th version (2023): (i) 開坦尼® in combination with chemotherapy as first line treatment of cervical cancer (Category3); and (ii) 開坦尼® as monotherapy as second line or subsequent treatment of cervical cancer.

Ivonescimab (AK112, PD-1/VEGF)

1. Significant Clinical Progress in 2023H1

— In March, we commenced collaboration with LaNova Medicines to initiate a series of clinical trials of AK112 in combination with LM-302 (Claudin18.2 ADC) for the treatment of solid tumors including gastrointestinal cancer.

— In April, we obtained CDE approval to initiate Phase I clinical trial of AK112 in combination with AK127 for the treatment of advanced solid tumor.

— In May, our partner SUMMIT has first patient treated in the United States in the Phase III HARMONi trial. The HARMONi trial is ivonescimab in combination with chemotherapy for treatment of EGFR-mutated, locally advanced or metastatc non-squamous NSCLC patients who progressed after the third generation EGFR-TKI treatment.

— In May, we initiated Phase III clinical trial of ivonescimab in combination with chemotherapy, versus tislelizumab in combination with chemotherapy, as first line treatment of squamous NSCLC.

2. *Publication in 2023H1*

— In June, Phase II clinical data of ivonescimab in combination with chemotherapy as first line treatment advanced or metastatic NSCLC without actionable genomic alterations (AGA) in EGFR/ALK was published at 2023 ASCO.

3. *Recent Development After the Reporting Period*

— In August, we completed patient enrollment of Phase III trial of ivonescimab monotherapy versus pemprolizumab monotherapy as first line treatment of NSCLC with PD-L1 positive expression.

— In August, Phase III clinical trial of ivonescimab in combination with chemotherapy, versus tislelizumab in combination with chemotherapy, for the treatment of squamous NSCLC have first patient treated.

— In August, phase II clinical data of ivonescimab in combination with chemotherapy for the treatment of advanced NSCLC was published at *eclinical medicine*.

Ligufalimab (AK117, CD47)

1. *Significant Clinical Progress in 2023H1*

— In April, we obtained CDE approval to initiate Phase II clinical trial of cadonilimab in combination with AK117 as neoadjuvant treatment G/GEJ.

2. *Publication in 2023H1*

— In June, preliminary Phase II clinical data of AK117 in combination with cadonilimab and chemotherapy as first line treatment of advanced G/GEJ was published at 2023 ASCO.

Pulocimab (AK109, VEGFR2)

1. *Significant Clinical Progress in 2023H1*

— In March, Phase I clinical data of AK109 was published at *ESMO Open*.

NGF (AK115)

1. *Significant Clinical Progress in 2023H1*

— In March, we completed Phase I clinical trial of AK115 for alleviating pain (including cancer pain).

AK127 (TIGIT)

1. Significant Clinical Progress in 2023H1

— In April, we obtained CDE approval to initiate Phase I clinical trial of AK127 in combination with ivonescimab for the treatment of advanced solid tumor.

2. Recent Development After the Reporting Period

— In July, the Phase Ia/Ib trial of AK127 in combination with cadonilimab for the treatment of advanced solid tumor completed dosing first patient.

AK129 (PD-1/LAG3)

1. Significant Clinical Progress in 2023H1

— In March, Phase I clinical trial of AK129 for the treatment of advance solid tumor completed dosing first patient.

AK130 (TIGIT/TGF-β)

1. Significant Clinical Progress in 2023H1

— In February, Phase I clinical trial of AK130 for the treatment of advanced solid tumor completed dosing first patient.

After the Reporting Period, IND application of two of our pre-clinical oncology drug candidates have been accepted by CDE.

AK131 (PD-1/CD73)

1. Recent Development After the Reporting Period

— In July, CDE accepted the IND application of AK131.

AK132 (Claudin18.2/CD47)

1. Recent Development After the Reporting Period

— In July, CDE accepted the IND application of AK132.

Autoimmune and Other Therapeutic Areas

Ebronucimab (AK102, PCSK9)

1. Significant Clinical Progress in 2023H1

— In May, results of a pivotal Phase III trial of AK102 for the treatment of primary hypercholesterolemia and mixed hyperlipidemia was published at 2023 European Atherosclerosis Society (EAS).

Ebdarokimab (AK101, IL-12/IL-23)

1. Significant Clinical Progress in 2023H1

— In February, Phase III clinical trial of AK101 for the treatment of moderate-to-severe psoriasis reached its primary endpoint.

2. Publication in 2023H1

— In June, results of Phase I clinical trial of AK101 for the treatment of moderate-to-severe active ulcerative colitis was published at 2023 Federation of Clinical Immunology Societies (FOCIS).

Gumokimab (AK111, IL-17)

1. Publication in 2023H1

— In February, results of Phase Ib clinical trial of AK111 for the treatment of moderate-to-severe psoriasis was published at *Dermotal Therapy*.

2. Recent Development After the Reporting Period

— In August, we completed patient enrollment of registration Phase III trial of AK111 for the treatment of moderate-to-severe psoriasis.

Manfidokimab(AK120, IL-4R)

1. Significant Clinical Progress in 2023H1

— In March, we completed patient enrollment of Phase II trial of AK120 for the treatment of moderate-to-severe psoriasis.

Warning under Rule 18A.08(3) of the Listing Rules: There is no assurance that the Company will continuously succeed in commercialization of 開坦尼® and ANNIKO®. There is no assurance that ivonescimab (AK112), ligufalimab (AK117), pulocimab (AK109), drebuxelimab (AK119), AK127 (TIGIT), AK115 (NGF), AK129 (PD-1/LAG-3), AK130 (TIGIT/TGF-β), AK131 (PD-1/CD73), AK132 (Claudin18.2/CD47) ebronucimab (AK102), ebdarokimab (AK101), gumokimab (AK111) and manfidokimab (AK120) will ultimately be successfully developed and marketed by the Company. As of the date of this announcement, no material adverse changes had occurred with respect to the regulatory approvals we had received in relation to our drug candidates.

HUMAN RESOURCES MANAGEMENT

As of June 30, 2023, we had a total of 2,520 employees. To fulfill our strategic goal of enhancing the integrated platform of R&D, manufacturing and commercialization, the Company will continue to recruit more talents, improve the training and career development system, and commit to creating a diversified, integrity, open and inclusive platform for employees.

	June 30, 2023 Number of employees	June 30, 2022 Number of employees
Research and Development (Pre-clinical)	**269**	264
Clinical	**642**	550
Manufacturing, quality assurance and quality control	**575**	598
Selling and Marketing	**753**	630
Sourcing, General and Administrative	**281**	247
Total	**2,520**	2,289

MANUFACTURING FACILITIES

The Company has a total production capacity of 54,000L in operation. We have a continuous and steady capacity expansion plan to cope with our future clinical development and commercialization requirement. Our GMP-compliant manufacturing facilities are designed and validated according to the FDA, the EMA, and the NMPA regulations, to support the entire drug development process, from drug discovery to process development, GMP-compliant pilots and commercial manufacturing, which will effectively support the Company's clinical and commercialization development.

— Zhongshan Torch Development District Manufacturing Site: The production capacity in operation is 3,500L.

— Guangzhou Commercialization and Manufacturing Site: The production capacity in operation is 36,000L.

— Zhongshan Cuiheng Manufacturing Site: The total capacity is 100,000L. Phase I project of 14,500L has been successfully completed.

FUTURE DEVELOPMENT

Looking forward, we will continue to optimise our drug discovery platform, accelerate the clinical development, and enhance the manufacturing and commercialization platform of our product portfolio globally.

In the area of oncology, we will advance the clinical development plan and commercialization preparation of the upcoming major large indications of 開坦尼® (cadonilimab, PD-1/CTLA-4), such as first-line cervical cancer, gastric cancer, liver cancer, and lung cancer, to further develop the extensive market potential and build high market barriers of 開坦尼®. We will also initiate the commercialization preparation of our second core bi-specific antibody ivonescimab (AK112, PD-1/VEGF). The NDA for its first indication has been accepted by the CDE in August 2023. We will also comprehensively accelerate the clinical development of ivonescimab in the area of NSCLC, including monotherapy versus pembrolizumab as the first-line treatment for NSCLC with PD-L1 positive expression, and ivonescimab in combination with chemotherapy versus tislelizumab in combination with chemotherapy as the first-line treatment for squamous NSCLC, etc. In addition to lung cancer, we are also conducting clinical trials in various types of solid tumors of ivonescimab, such as gastrointestinal tumours, hepatocellular carcinoma and colorectal cancer. Meanwhile, we will continue to promote our collaboration with SUMMIT to conduct global multiregional phase III clinical trials of ivonescimab to speed up the realization of the global development and commercialization of ivonescimab.

Focusing on the two core bi-specific antibodies 開坦尼® and ivonescimab as our backbone products, we will broaden our research and development of key links in oncology-immune cycle through combination therapy to improve treatment efficacy and prevent the development of drug resistance. We are conducting exploratory studies on 開坦尼® or ivonescimab in combination with ligufalimub (AK117, CD47), AK127 (TIGIT) and AK119 (CD73) for various types of solid tumours, including gastric cancer, colorectal cancer, breast cancer, esophageal cancer, etc.

In autoimmune and metabolic disease area, we will be well-prepared for the manufacturing and commercialization of ebronucimab (AK102, PCSK9) and ebdarokimab (AK101, IL-12/IL-23), and will also accelerate the phase III clinical development and commercialization of AK111(IL-17) and AK120 (IL-4R α).

In terms of R&D strategy and platform establishment, the Company is propelling high-potential technology platforms of new modalities, including ADC platform and cell therapy. Through the forward-looking strategic development plan, innovation and superior execution capabilities, the Company will continue to accelerate the progression of drug candidates to the clinical stage and then to the commercial stage, which will keep the great momentum of the Company's sustainable growth in the long term.

We will also take the mission and vision of "providing differentiated and innovative therapies that can bring significant clinical benefits to patients around the world", we will actively keep exploring strategic partnerships with value-added collaboration opportunities for the Company's independently-developed products globally.

FINANCIAL REVIEW

Six months ended June 30, 2023 compared to six months ended June 30, 2022.

	Six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Product sales	**794,650**	297,184
License income	**2,918,988**	–
Total sales from products and license	**3,713,638**	297,184
Less: distribution cost	**(36,779)**	(134,049)
REVENUE	**3,676,859**	163,135
Cost of sales	**(77,180)**	(28,109)
Gross profit	**3,599,679**	135,026
Other income and gains, net	**380,123**	75,966
Selling and marketing expenses	**(442,159)**	(149,501)
Administrative expenses	**(100,429)**	(92,741)
Research and development expenses	**(574,671)**	(595,384)
Share of loss of a long-term equity investment	**(173,121)**	–
Other expenses, net	**(161,468)**	(49,420)
Finance costs	**(38,410)**	(15,830)
PROFIT/(LOSS) BEFORE TAX	**2,489,544**	(691,884)
Income tax expense	**–**	–
PROFIT/(LOSS) FOR THE PERIOD	**2,489,544**	(691,884)
OTHER COMPREHENSIVE (LOSS)/INCOME		
Other comprehensive loss that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	**(192,897)**	(154,391)

	Six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods:		
Translation from functional currency to presentation currency	**201,508**	234,525
Other comprehensive income for the period, net of tax	**8,611**	80,134
Total comprehensive income/(loss) for the period	**2,498,155**	(611,750)

1. Products Sales

The Group's total product sales increased by 167.4% from RMB297.2 million for the six months ended June 30, 2022 to RMB794.7 million for the six months ended June 30, 2023. The rapid growth in sales was attributable to the following reasons:

(i) With the outstanding clinical value, the Company's innovative product 開坦尼® (cadonilimab, PD-1/CTLA-4), since its launch on June 29,2022, has recorded significant increase of the patients as well as product sales, which has contributed revenue of RMB605.8 million for the six months ended June 30, 2023;

(ii) Other products achieved sales of RMB188.9 million for the six months ended June 30, 2023, including Anniko® (penpulimab, PD1) which was approved and commercialized in late August 2021 and the investigational products for ivonescimab (AK112, PD-1/VEGF) supplied to SUMMIT.

	For the six months ended June 30					
	Products Sales*			Consolidated Revenue**		
Million (RMB)	**2023**	2022	% Change	**2023**	2022	% Change
開坦尼® (cadonilimab, PD-1/CTLA-4)	**605.8**	–	–	**605.8**	–	–
Other products	**188.9**	297.2	–36.4%	**152.1**	163.1	–6.7%
Total	**794.7**	297.2	167.4%	**757.9**	163.1	364.7%

* Products sales is the sales from 開坦尼® (cadonilimab, PD-1/CTLA-4) and other products;

** Consolidated revenue is the Group's total sales from products net of the distribution cost.

2. License Income

The Group's license income was RMB2,919.0 million for the six months ended June 30, 2023, as compared to nil for the six months ended June 30, 2022. It was mainly attributable to the collaborative and licensing agreement the Company entered into with SUMMIT for its independently-developed bi-specific antibody, ivonescimab (AK112, PD-1/VEGF).

3. Cost of Sales

The cost of sales increased by 174.7% from RMB28.1 million for the six months ended June 30, 2022 to RMB77.2 million for the six months ended June 30, 2023, which was mainly attributable to the increase of the sales volume of 開坦尼® (cadonilimab,PD-1/CTLA-4). Cost of sales of the Group mainly represents cost of raw materials, direct labor, depreciation and other manufacturing overhead.

4. Gross Profit

The Group's gross profit increased by 2,566.4% from RMB135.0 million for the six months ended June 30, 2022 to RMB3,599.7 million for the six months ended June 30, 2023. It was mainly attributable to the strong increase in the license income recognized by the Company.

5. Other Income and Gains, net

Other income and gains, net increased by 400.1% from RMB76.0 million for the six months ended June 30, 2022 to RMB380.1 million for the six months ended June 30, 2023. The Group's other income and gains primarily consisted of exchange gains, subsidies from local government, bank interest income and investment income from financial products.

6. Research and Development Expenses

Research and development expenses were RMB574.7 million for the six months ended June 30, 2023, which remained stable as compared to RMB595.4 million for the six months ended June 30, 2022, mainly due to the strong clinical team strategically built up by the Group, which had reduced the Group's reliance on CRO vendors. The Group's clinical trails of each pipelines are progressing smoothly and have reached the expected goals. The New Drug Applications (NDA) of the first-in-class ivonescimab (PD-1/VEGF, AK112), ebronucimab (PCSK9, AK102) and ebdarokimab (AK101, IL-12/IL-23) have been accepted by the National Medical Products Administration (NMPA).

The Group's research and development expenses primarily consisted of: (i) the costs of clinical trials for our drug candidates including third-party contracting costs with the engagement of CROs, clinical trial sites and other service providers in connection with clinical trials; (ii) employee salaries and related benefit costs in connection with our research and development activities; (iii) third-party contracting costs relating to testing expenses for pre-clinical programs; and (iv) costs associated with purchasing raw materials for research and development of our drug candidates.

7. Selling and Marketing Expenses

Selling and marketing expenses increased by 195.8% from RMB149.5 million for the six months ended June 30, 2022 to RMB442.2 million for the six months ended June 30, 2023. The increase in selling and marketing expenses was mainly attributable to the marketing activities for the approved and commercialized product 開坦尼® (cadonilimab, PD-1/CTLA-4), which was launched on June 29, 2022.

8. Administrative Expenses

Administrative expenses increased by 8.3% from RMB92.7 million for the six months ended June 30, 2022 to RMB100.4 million for the six months ended June 30, 2023, which was mainly due to the increase in taxes and surcharges and the increase in the number of administrative employees in line with the expansion of the Group's operations and development.

Administrative expenses primarily consisted of employee salaries and benefits, depreciation, professional fees, taxes and other administrative expenses include travel expenses and other expenses in connection with administrative activities.

9. Finance costs

Finance costs were RMB38.4 million for the six months ended June 30, 2023, as compared to RMB15.8 million for the six months ended June 30, 2022. The increase in finance costs was mainly due to the increase in interest expenses on bank and other borrowings, and finance costs on lease liabilities.

10. Profit for the Period

For the reasons discussed above, profit for the period was RMB2,489.5 million for the six months ended June 30, 2023, as compared to loss of RMB691.9 million for the six months ended June 30, 2022.

11. Liquidity and Source of Funding and Borrowing

In 2023, we actively explored financing channel, improved business capabilities and managed our cash to further enrich our cash position so as to provide strong capital support for the Company's sustainable and high efficient development.

As of June 30, 2023, the current assets of the Group were RMB5,999.7 million, of which aggregate balance of cash and cash equivalent, time deposits and financial products amounted to RMB5,390.5 million and other current assets amounted to RMB609.2 million.

The aggregate balance of cash and cash equivalent, time deposits and financial products of the Group increased by RMB3,102.1 million to RMB5,390.5 million as of June 30, 2023, from RMB2,288.4 million as of December 31, 2022.

As of June 30, 2023, the current liabilities of the Group were RMB933.3 million, including trade payables of RMB270.3 million, other payables and accruals of RMB349.1 million and interest-bearing bank and other borrowings of RMB304.0 million.

As of June 30, 2023, the Group had short term loans of RMB304.0 million and long term loans of RMB2,220.7 million, among which, interest rate of commercial bank borrowings ranging from 2.8% to 4.8% based on annual interest rate over or below LPR.

The Group follows a set of funding and treasury policies to manage its capital resources and mitigate potential risks.

12. Pledge of Assets

As at June 30, 2023, the Group had a total pledge of RMB708.3 million of buildings and land use right pledged to secure its loans and banking facilities.

13. Key Financial Ratios

The following table sets forth the key financial ratios for the dates indicated:

	As at June 30, 2023	As at December 31,2022
Quick ratio[(1)]	**6.12**	2.0
Gearing ratio[(2)]	**Not meaningful[(2)]**	Not meaningful[(2)]

Notes:

(1) Quick ratio is calculated by dividing current assets less inventories as of a given date by current liabilities as of such date.

(2) Gearing ratio is calculated using interest-bearing bank and other borrowings less cash and cash equivalents divided by total equity and multiplied by 100%. Gearing ratio is not meaningful as our interest-bearing bank and other borrowings less cash and cash equivalents were negative.

14. Significant Investments

As at June 30, 2023, the Group did not hold any significant investments. Save as disclosed in this announcement, the Group did not have other plans for significant investments or capital assets as at the date of this announcement.

15. Material Acquisitions and Disposals

The Group did not have material acquisitions or disposals of subsidiaries, associates and joint ventures for the six months ended June 30, 2023.

16. Contingent Liabilities

The Group did not have any material contingent liabilities as at June 30, 2023.

17. Capital Commitment

The capital commitments of the Group as at June 30, 2023 were RMB856.1 million, as compared to RMB981.1 million as at December 31, 2022, primarily attributable to the development of world-class manufacturing equipment in Zhongshan Cuiheng Manufacturing Site and Guangzhou Commercialization and Manufacturing Site. The project is currently under smooth progress and has been put into operation gradually.

18. Foreign Exchange Risk Exposure

For the six months ended June 30, 2023, the Group mainly operated in China and a majority of its transactions were settled in Renminbi, the functional currency of the Company's primary subsidiaries.

As at June 30, 2023, a portion of the Group's cash and cash equivalents were dominated in Hong Kong dollars and US dollars. Except for certain cash and cash equivalents, other receivables, payables, other payables and accrued expenses denominated in foreign currencies, the Group did not have significant foreign exchange risk exposure from its operations during the reporting period.

Our Group currently does not have a foreign currency hedging policy, however, we manage our foreign exchange risk by performing regular reviews of our net foreign exchange risks and uses forward contracts to eliminate the foreign exchange risk exposures.

19. Employees and Remuneration

As at June 30, 2023, the Group had a total of 2,520 employees.

The following table sets forth the total number of employees by function:

Function	**June 30, 2023 Number of employees**	June 30, 2022 Number of employees
Research and Development (Pre-clinical)	**269**	264
Clinical	**642**	550
Manufacturing, quality assurance and quality control	**575**	598
Selling and Marketing	**753**	630
Sourcing, General and Administrative	**281**	247
Total	**2,520**	2,289

The total remuneration cost incurred by the Group was RMB408.0 million for the six months ended June 30, 2023, and RMB255.5 million for the six months ended June 30, 2022. The increase in remuneration cost was primarily attributable to the increase in the number of employees, which led to an increase in employees' salaries and benefits.

The remuneration of the employees of the Group comprises salaries, bonuses, employees' provident fund and social security contributions, other welfare payments and equity-settled share award expenses. In accordance with applicable PRC laws, the Group has made contributions to social security insurance funds (including pension plans, medical insurance, work related injury insurance, unemployment insurance and maternity insurance) and housing funds for the Group's employees. We provide training programs to employees, including new hire orientation and continuous on-the-job training in order to accelerate the learning progress and improve the knowledge and skill levels of our employees.

The Company has adopted the Pre-IPO RSU Scheme on August 29, 2019 and the 2021 restricted share unit scheme on December 6, 2021. For details, please refer to the paragraph headed "D. Share Incentive Schemes — 1. Restricted Share Unit Scheme" in Appendix IV to the Prospectus and the announcement of the Company dated December 7, 2021, respectively.

The Company has also adopted the share option scheme on June 28, 2022. For details, please refer to the announcement of the Company dated June 1, 2022.

OTHER INFORMATION

INTERIM DIVIDEND

The Board does not recommend the payment of an interim dividend to the Shareholders for the Reporting Period (six months ended June 30, 2022: Nil).

CORPORATE GOVERNANCE PRACTICES

The Directors recognise the importance of good corporate governance in management and internal procedures so as to achieve effective accountability. The Company has adopted the code provisions as set out in the CG Code as its own code to govern its corporate governance practices.

The Company has adopted and complied with all applicable code provisions contained in Part 2 of the CG Code throughout the Reporting Period with the exception of code provision C.2.1.

Under the code provision C.2.1 of the CG Code, the roles of chairman and chief executive should be separate and should not be performed by the same individual. Under the current organisation structure of the Company, Dr. XIA Yu is the chairwoman and chief executive officer of the Company. With her extensive experience in the industry, the Board believes that vesting the roles of both chairwoman and chief executive officer in the same person provides the Company with strong and consistent leadership, allows for effective and efficient planning and implementation of business decisions and strategies, and is beneficial to the business prospects and management of the Group. Although Dr. XIA Yu performs both the roles of chairwoman and chief executive officer, the division of responsibilities between the chairwoman and chief executive officer is clearly established. In general, the chairwoman is responsible for supervising the functions and performance of the Board, while the chief executive officer is responsible for the management of the business of the Group. The two roles are performed by Dr. XIA Yu distinctly. We also consider that the current structure does not impair the balance of power and authority between the Board and the management of the Company given the appropriate delegation of the power of the Board and the effective functions of the independent non-executive Directors. However, it is the long-term objective of the Company to have these two roles performed by separate individuals when suitable candidates are identified.

The Board will continue to review and monitor the practices of the Company with an aim of maintaining a high standard of corporate governance.

MODEL CODE FOR SECURITIES TRANSACTIONS

The Company has adopted the Model Code as its own code of conduct regarding dealings in the securities of the Company by the Directors and the Group's senior management who, because of his/her office or employment, is likely to possess inside information in relation to the Company or its securities.

Upon specific enquiry, all Directors confirmed that they have complied with the Model Code throughout the Reporting Period. In addition, the Company is not aware of any non-compliance of the Model Code by the senior management of the Group throughout the Reporting Period.

PURCHASE, SALE OR REDEMPTION OF THE COMPANY'S LISTED SECURITIES

Neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the Company's listed securities during the Reporting Period.

EVENTS AFTER THE REPORTING PERIOD

In August 2023, the CDE has accepted the NDA for ebdarokimab (AK101, IL-12/IL-23) for the treatment of moderate to severe plaque psoriasis.

Save as disclosed above, as of the date of this announcement, the Group had no significant events after the Reporting Period.

REVIEW OF INTERIM RESULTS

The Audit Committee, comprising Mr. TAN Bo, Dr. XU Yan and Dr. ZENG Junwen, has jointly reviewed with the management the accounting principles and policies adopted by the Company and discussed internal control and financial reporting matters (including the review of the unaudited interim condensed consolidated financial information of the Group for the Reporting Period). The Audit Committee considered that the unaudited interim condensed consolidated financial results for the Reporting Period are in compliance with the relevant accounting standards, laws and regulations and the Company has made appropriate disclosures thereof. The interim condensed consolidated financial information of the Group for the Reporting Period has not been audited. The Company's independent auditor, Ernst & Young, has performed an independent review of the Group's interim financial information for the Reporting Period 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. There is no disagreement by the Audit Committee or the auditor of the Company with the accounting treatment adopted by the Company.

PUBLICATION OF RESULTS ANNOUNCEMENT AND INTERIM REPORT

This announcement is published on the website of the Stock Exchange at www.hkexnews.hk and on the website of the Company at www.akesobio.com. The interim report of the Company for the Reporting Period containing all the information required by the Listing Rules will be dispatched to Shareholders and published on the above websites in due course.

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

For the six months ended 30 June 2023

	Notes	Six months ended 30 June	
		2023	2022
		RMB'000	*RMB'000*
		(Unaudited)	(Unaudited)
Product sales		**794,650**	297,184
License income		**2,918,988**	–
Total sales from products and license		**3,713,638**	297,184
Less: distribution cost		**(36,779)**	(134,049)
REVENUE	*3*	**3,676,859**	163,135
Cost of sales		**(77,180)**	(28,109)
Gross profit		**3,599,679**	135,026
Other income and gains, net	*4*	**380,123**	75,966
Selling and marketing expenses		**(442,159)**	(149,501)
Administrative expenses		**(100,429)**	(92,741)
Research and development expenses		**(574,671)**	(595,384)
Share of loss of a long-term equity investment		**(173,121)**	–
Other expenses, net		**(161,468)**	(49,420)
Finance costs		**(38,410)**	(15,830)
PROFIT/(LOSS) BEFORE TAX		**2,489,544**	(691,884)
Income tax expense	*5*	**–**	–
PROFIT/(LOSS) FOR THE PERIOD		**2,489,544**	(691,884)
OTHER COMPREHENSIVE (LOSS)/INCOME			
Other comprehensive loss that may be reclassified to profit or loss in subsequent periods:			
Exchange differences on translation of foreign operations		**(192,897)**	(154,391)

	Note	Six months ended 30 June	
		2023	2022
		RMB'000	*RMB'000*
		(Unaudited)	(Unaudited)
Other comprehensive income that will not be reclassified to profit or loss in subsequent periods:			
Translation from functional currency to presentation currency		**201,508**	234,525
OTHER COMPREHENSIVE INCOME FOR THE PERIOD, NET OF TAX		**8,611**	80,134
TOTAL COMPREHENSIVE INCOME/(LOSS) FOR THE PERIOD		**2,498,155**	(611,750)
Profit/(loss) attributable to:			
Owners of the parent		**2,525,045**	(630,434)
Non-controlling interests		**(35,501)**	(61,450)
		2,489,544	(691,884)
Total comprehensive income/(loss) attributable to:			
Owners of the parent		**2,533,656**	(550,300)
Non-controlling interests		**(35,501)**	(61,450)
		2,498,155	(611,750)
EARNING/(LOSS) PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT	*7*		
Basic and diluted			
— For profit/(loss) for the period		**RMB3.01 yuan**	RMB(0.77) yuan

INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION

30 June 2023

	Notes	**30 June 2023** ***RMB'000*** **(Unaudited)**	31 December 2022 *RMB'000* (Audited)
NON-CURRENT ASSETS			
Property, plant and equipment		**2,203,567**	1,999,616
Right-of-use assets		**208,345**	163,074
Intangible assets		**7,551**	8,496
Financial assets at fair value through profit or loss		**10,000**	10,000
Long-term equity investment		**321,844**	–
Other non-current assets		**259,052**	256,291
Total non-current assets		**3,010,359**	2,437,477
CURRENT ASSETS			
Inventories		**287,709**	341,832
Trade receivables	*8*	**248,368**	271,046
Prepayments, other receivables and other assets		**73,128**	157,199
Financial asset at fair value through profit or loss		**517,960**	195,912
Pledged deposits and time deposits with original maturity of more than three months		**587,421**	94
Cash and cash equivalents		**4,285,141**	2,092,388
Total current assets		**5,999,727**	3,058,471
CURRENT LIABILITIES			
Trade payables	*9*	**270,312**	308,948
Other payables and accruals		**349,140**	599,178
Interest-bearing bank and other borrowings		**304,027**	445,979
Lease liabilities		**8,628**	5,898
Tax payable		**1,175**	1,133
Total current liabilities		**933,282**	1,361,136
NET CURRENT ASSETS		**5,066,445**	1,697,335
TOTAL ASSETS LESS CURRENT LIABILITIES		**8,076,804**	4,134,812

	30 June 2023	31 December 2022
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
NON-CURRENT LIABILITIES		
Interest-bearing bank and other borrowings	**2,220,711**	1,421,278
Contract liabilities	**631,921**	–
Lease liabilities	**10,775**	5,954
Deferred income	**162,986**	159,566
Total non-current liabilities	**3,026,393**	1,586,798
Net assets	**5,050,411**	2,548,014
EQUITY		
Equity attributable to owners of the parent		
Share capital	**59**	59
Shares held for restricted share unit schemes	**(84,452)**	(84,452)
Reserves	**5,257,918**	2,720,020
	5,173,525	2,635,627
Non-controlling interests	**(123,114)**	(87,613)
Total equity	**5,050,411**	2,548,014

INTERIM CONDENSED CONSOLIDATED STATEMENT OF CASH FLOWS

Six months ended 30 June 2023

	Six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Net cash flows from/(used in) operating activities	**2,871,241**	(580,675)
Net cash flows used in investing activities	**(1,377,471)**	(282,935)
Net cash flows from financing activities	**590,746**	406,524
NET INCREASE/(DECREASE) IN CASH AND CASH EQUIVALENTS	**2,084,516**	(457,086)
Cash and cash equivalents at beginning of period	**2,092,388**	2,641,625
Effect of foreign exchange rate changes, net	**108,237**	36,145
CASH AND CASH EQUIVALENTS AT END OF PERIOD	**4,285,141**	2,220,684

NOTES TO THE INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION

Six months ended 30 June 2023

1. CORPORATE INFORMATION

The Company was incorporated in the Cayman Islands as an exempted company with limited liability on 30 January 2019. The address of the registered office of the Company is Floor 4, Willow House, Cricket Square, Grand Cayman KY1-9010, Cayman Islands. The Company's principal place of business in Hong Kong is Room 1901, 19/F, Lee Garden One, 33 Hysan Avenue, Causeway Bay, Hong Kong.

The Company is an investment holding company. The Company's subsidiaries were involved in research and development, production and sale of biopharmaceutical products.

The shares of the Company were listed on the Main Board of the Stock Exchange of Hong Kong Limited (the "**Stock Exchange**") on 24 April 2020.

2.1 BASIS OF PREPARATION

The unaudited interim condensed consolidated financial information for the six months ended 30 June 2023 has been prepared in accordance with IAS 34 Interim Financial Reporting issued by the International Accounting Standards Board. The unaudited 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 2022. The unaudited 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 2022, except for the adoption of the following new and revised International Financial Reporting Standards ("**IFRSs**") for the first time for the current period's financial information.

IFRS 17	*Insurance Contracts*
Amendments to IFRS 17	*Insurance Contracts*
Amendment to IFRS 17	*Initial Application of IFRS 17 and IFRS 9 — Comparative Information*
Amendments to IAS 1 and IFRSs Practice Statement 2	*Disclosure of Accounting Policies*
Amendment to IAS 8	*Definition of Accounting Estimates*
Amendment to IAS 12	*Deferred Tax related to Assets and Liabilities arising from a Single Transaction*
Amendment to IAS 12	*International Tax Reform — Pillar Two Model Rules*

The nature and impact of the new and revised IFRSs that are applicable to the Group are described below:

(a) Amendments to IAS 1 require entities to disclose their material accounting policy information rather than their significant accounting policies. Accounting policy information is material if, when considered together with other information included in an entity's financial statements, it can reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements. Amendments to IFRS Practice Statement 2 provide non-mandatory guidance on how to apply the concept of materiality to accounting policy disclosures. The Group has applied the amendments since 1 January 2023. The amendments did not have any impact on the Group's interim condensed consolidated financial information but are expected to affect the accounting policy disclosures in the Group's annual consolidated financial statements.

(b) Amendments to IAS 8 clarify the distinction between changes in accounting estimates and changes in accounting policies. Accounting estimates are defined as monetary amounts in financial statements that are subject to measurement uncertainty. The amendments also clarify how entities use measurement techniques and inputs to develop accounting estimates. The Group has applied the amendments to changes in accounting policies and changes in accounting estimates that occur on or after 1 January 2023. Since the Group's policy of determining accounting estimates aligns with the amendments, the amendments did not have any impact on the financial position or performance of the Group.

(c) Amendments to IAS 12 *Deferred Tax related to Assets and Liabilities arising from a Single Transaction* narrow the scope of the initial recognition exception in IAS 12 so that it no longer applies to transactions that give rise to equal taxable and deductible temporary differences, such as leases and decommissioning obligations. Therefore, entities are required to recognise a deferred tax asset (provided that sufficient taxable profit is available) and a deferred tax liability for temporary differences arising from these transactions. The Group has applied the amendments on temporary differences related to as at 1 January 2022, with any cumulative effect recognised as an adjustment to the balance of retained profits or other component of equity as appropriate at that date. In addition, the Group has applied the amendments prospectively to transactions other than that occurred on or after 1 January 2022, if any. The amendments did not have significant impact on the financial position or performance of the Group.

(d) Amendments to IAS 12 *International Tax Reform — Pillar Two Model Rules* introduce a mandatory temporary exception from the recognition and disclosure of deferred taxes arising from the implementation of the Pillar Two model rules published by the Organisation for Economic Co-operation and Development. The amendments also introduce disclosure requirements for the affected entities to help users of the financial statements better understand the entities' exposure to Pillar Two income taxes, including the disclosure of current tax related to Pillar Two income taxes separately in the periods when Pillar Two legislation is effective and the disclosure of known or reasonably estimable information of their exposure to Pillar Two income taxes in periods in which the legislation is enacted or substantively enacted but not yet in effect. Entities are required to disclose the information relating to their exposure to Pillar Two income taxes in annual periods beginning on or after 1 January 2023, but are not required to disclose such information for any interim periods ending on or before 31 December 2023. The Group has applied the amendments retrospectively. Since the Group did not fall within the scope of the Pillar Two model rules, the amendments did not have significant impact to the Group.

3. REVENUE AND OPERATING SEGMENT INFORMATION

Revenue

An analysis of revenue is as follows:

Revenue from contracts with customers

(a) Disaggregated revenue information

	Six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Types of goods or services		
Product sales	**794,650**	297,184
License income	**2,918,988**	–
Total sales from products and license	**3,713,638**	297,184
Less: distribution cost relevant to the product sales	**(36,779)**	(134,049)
Revenue	**3,676,859**	163,135
Timing of revenue recognition		
Transferred at a point in time	**3,676,859**	163,135

Distribution cost is relevant to the product sales, and it represents the distribution fee paid or payable by the Group to customers.

The following table shows the amounts of revenue recognised in the current reporting period that were included in the contract liabilities at the beginning of the reporting period and recognised from performance obligations satisfied in previous periods:

	Six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Products Sales	**5,959**	–

(b) Performance obligations

Information about the Group's performance obligations is summarised below:

Revenue from license income

The performance obligation is satisfied at a point in time when the customer obtains the rights to the underlying technology. For arrangements that include sales-based royalties, including milestone payments based on the level of sales, and the license is deemed to be the predominant item to which the royalties relate, the Company recognises revenue at a point in time when the related sales occur.

Sale of products

The performance obligation is satisfied upon delivery of the products and payment is generally due within 1 year from delivery. Some contracts provide customers with sales rebates which give rise to variable consideration subject to constraint.

Other segment information

The Group is engaged in research, development, production and sale of biopharmaceutical products, which is regarded as a single reportable segment in a manner consistent with the way in which information is reported internally to the Group's senior management for purposes of resource allocation and performance assessment. Therefore, no analysis by operating segment is presented.

Geographical information

(a) Revenue from external customers

	Six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Mainland China	**756,189**	163,135
United States of America (the "**USA**")	**2,920,093**	–
Others	**577**	–
	3,676,859	163,135

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

(b) Non-current assets

	As at 30 June 2023	As at 31 December 2022
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Mainland China	**2,678,421**	2,426,959
USA	**321,844**	–
Other regions	**94**	518
	3,000,359	2,427,477

The non-current asset information above is based on the locations of the assets and excludes financial instruments.

Information about a major customer

Revenue from the customers contributing over 10% of revenue of the Group is as follows:

	Six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Customer A	**2,920,093**	*
Customer B	*****	90,346
	2,920,093	90,346

* The corresponding revenue of the customer is not disclosed as the revenue individually did not account for 10% or more of the Group's revenue for the six months ended 30 June 2023 and 2022.

4. OTHER INCOME AND GAINS, NET

Other income and gains, net

	Six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Bank interest income	**40,698**	5,758
Investment income from financial products	**38,162**	2,736
Net changes in fair value of financial assets	**11,302**	–
Government grant released*	**92,558**	65,397
Value-added tax credits	**1,725**	1,070
Foreign exchange differences, net	**195,664**	–
Others	**14**	1,005
	380,123	75,966

* The government grants mainly represent subsidies received from the local governments for the purpose of compensation for expenses arising from research activities and clinical trials, award for new drug development and capital expenditure incurred on certain projects.

5. 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.

Pursuant to the rules and regulations of the Cayman Islands and the BVI, the Group is not subject to any income tax in the Cayman Islands or the BVI.

The subsidiary incorporated in Hong Kong is subject to Hong Kong profits tax at the rate of 16.5% (six months ended 30 June 2022: 16.5%) on any estimated assessable profits arising in Hong Kong. No provision for Hong Kong profits tax has been made as the Group has no assessable profits derived from or earned in Hong Kong during the six months ended 30 June 2023 (six months ended 30 June 2022: Nil).

The provision for corporate income tax in Mainland China is based on the statutory rate of 25% of the assessable profits are determined in accordance with the PRC Corporate Income Tax Law which was approved and became effective on 1 January 2008 except for 中山康方生物醫藥有限公司 (Akeso Biopharma Co., Ltd.^) which was qualified as a High and New Technology Enterprise and was subject to a preferential income tax rate of 15% for the six months ended 30 June 2023 and 2022.

The subsidiary incorporated in the USA is subject to American federal and California income tax. America federal income tax was provided at the rate of 21% and California income tax was provided at the rate of 8.84% for the six months ended 30 June 2023 and 2022 on the estimated assessable profits arising in the USA.

The subsidiary incorporated in the Australia is subject to Australia income tax. Australia corporate income tax has been provided at the rate of 30% on the estimated assessable profits arising in Australia.

^ The English name is for identification purposes only.

The income tax expense of the Group for the periods presented is analysed as follows:

	Six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Current		
Charge for the period	**–**	–
Deferred	**–**	–
Total tax charge for the period	**–**	–

6. DIVIDEND

No dividend has been paid or declared by the Company during the six months ended 30 June 2023 and subsequent to the end of the reporting period (six months ended 30 June 2022: Nil).

7. EARNING/(LOSS) PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of basic earning/(loss) per share amounts is based on the profit/(loss) for the period attributable to ordinary equity holders of the parent, and the weighted average number of ordinary shares of 837,551,176 (six months ended 30 June 2022: 814,074,905) in issue, during the period.

The Group had no potentially dilutive ordinary shares in issue during the six months ended 30 June 2023 and 2022.

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

	Six months ended 30 June	
	2023	2022
	RMB'000	*RMB'000*
	(Unaudited)	(Unaudited)
Earnings/(Loss)		
Profit/(Loss) attributable to ordinary equity holders of the parent, used in the basic and diluted earning/(loss) per share calculation	**2,525,045**	(630,434)

	Number of shares Six months ended 30 June	
	2023	2022
	(Unaudited)	(Unaudited)
Shares		
Weighted average number of ordinary shares in issue during the period used in the basic and diluted earning/(loss) per share calculation	**837,551,176**	814,074,905

8. TRADE RECEIVABLES

	30 June 2023	31 December 2022
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Trade receivables	**249,481**	271,511
Impairment	**(1,113)**	(465)
	248,368	271,046

Included in the Group's trade receivables is an amount due from a non-controlling shareholder of the Group of RMB29,788,000 (31 December 2022: RMB245,928,000).

An ageing analysis of the trade receivables as at the end of the reporting period, based on the invoice date and net of loss allowance, is as follows:

	30 June 2023	31 December 2022
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Within 3 months	**248,239**	36,496
3 to 6 months	**129**	91,508
6 to 9 months	**–**	143,042
	248,368	271,046

9. TRADE PAYABLES

An ageing analysis of the trade payables as at the end of the reporting period, based on the invoice date, is as follows:

	30 June 2023	31 December 2022
	RMB'000	*RMB'000*
	(Unaudited)	(Audited)
Within 3 months	**160,809**	193,041
3 to 6 months	**1,817**	39,171
6 months to 1 year	**35,171**	13,227
Over 1 year	**72,515**	63,509
	270,312	308,948

The trade payables are non-interest-bearing and are normally settled on terms of 30 to 90 days except for the balances due to a non-controlling shareholder of the Group of RMB83,788,000 (31 December 2022: RMB101,927,000), which are repayable on demand.

DEFINITIONS

In this interim results announcement, unless the context otherwise requires, the following expressions shall have the following meanings.

"ANNIKO®", "penpulimab" or "AK105"	penpulimab antibody injection, a new PD-1 monoclonal antibody with IgG1 subtype and Fc segment modification, which is structurally stable and less prone to aggregation
"ASCO"	American Society of Clinical Oncology Annual Meeting
"ASCO GI"	Gastrointestinal Cancers Symposium
"Audit Committee"	the audit committee of the Board
"Board of Directors" or "Board"	the board of Directors
"BVI"	British Virgin Islands
"CDE"	Center for Drug Evaluation of NMPA
"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
"Company", "our Company"	Akeso, Inc. (康方生物科技(開曼)有限公司), an exempted company with limited liability incorporated under the laws of the Cayman Islands on January 30, 2019
"CRO"	contract research organization
"CSCO"	Chinese Society of Clinical Oncology Annual Meeting

"CTTQ" or "Chia Tai Tianqing"	Chia Tai Tianqing Pharmaceutical Group Co., Ltd., the principal subsidiary of Sino Biopharmaceutical Limited (stock code: 1177), is a multinational pharmaceutical company based in the PRC. It is one of the shareholders in our subsidiary , CTTQ-Akeso
"CTTQ-Akeso"	CTTQ-Akeso (Shanghai) Biomed. Tech. Co., Ltd (正大天晴康方 (上海) 生物醫藥科技有限公司), a limited liability company incorporated under the law of the PRC on August 30, 2019, one of our Group's subsidiaries
"Director(s)"	the director(s) of the Company
"EGFR"	epidermal growth factor receptor
"EMA"	European Medicines Agency
"ESMO"	European Society for Medical Oncology
"FDA"	the Food and Drug Administration of the United States
"GMP"	good manufacturing practice
"Group", "our Group", "our", "we", "us" or "Akeso Group"	the Company and all of its subsidiaries, or any one of them as the context may require or, where the context refers to any time prior to its incorporation, the business which its predecessors or the predecessors of its present subsidiaries, or any one of them as the context may require, were or was engaged in and which were subsequently assumed by it
"HCC"	hepatocellular carcinoma
"Hong Kong"	the Hong Kong Special Administrative Region of the PRC
"Hong Kong dollars" or "HK dollars" or "HK$"	Hong Kong dollars and cents respectively, the lawful currency of Hong Kong
"IFRS"	International Financial Reporting Standards, as issued from time to time by the International Accounting Standards Board

"IND"	investigational new drug or investigational new drug application, also known as clinical trial application in China or clinical trial notification in Australia
"Independent Third Party" or "Independent Third Parties"	a person or entity who is not a connected person of the Company under the Listing Rules
"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)
"Model Code"	the "Model Code for Securities Transactions by Directors of Listed Issuers" set out in Appendix 10 to the Listing Rules
"NDA"	new drug application
"NMPA"	the National Medical Products Administration of the PRC (國家藥品監督管理局) (formerly known as the China National Drug Administration and the China Food and Drug Administration)
"NSCLC"	non-small-cell lung cancer, any carcinoma (as an adenocarcinoma or squamous cell carcinoma) of the lungs that is not a small-cell lung carcinoma
"Pre-IPO RSU Scheme" or "Restricted Share Unit Scheme"	the restricted share unit scheme approved and adopted by our Company on August 29, 2019 as amended from time to time, for the benefit of any director, employee, adviser or consultant of the Company or any of our subsidiaries
"Prospectus"	the prospectus of the Company dated April 14, 2020
"R&D"	Research and Development
"Reporting Period"	the six months ended June 30, 2023
"RMB"	Renminbi, the lawful currency of the PRC
"RSU(s)	restricted share unit(s)
"Share(s)"	ordinary share(s) with nominal value of US$0.00001 each in the share capital of the Company

"Shareholder(s)"	holder(s) of the Share(s)
"Stock Exchange"	The Stock Exchange of Hong Kong Limited
"TACE"	transcatheter arterial chemoembolization
"TKI"	tyrosine kinase inhibitor
"United States"	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
"US$"	United States dollars, the lawful currency of the United States
"%"	per cent

By Order of the Board
Akeso, Inc.
Dr. XIA Yu
Chairwoman and executive director

Hong Kong, August 29, 2023

As at the date of this announcement, the Board of Directors of the Company comprises Dr. XIA Yu as chairwoman and executive director, Dr. LI Baiyong, Dr. WANG Zhongmin Maxwell and Mr. XIA Yu (Ph.D.) as executive directors, Dr. ZHOU Yi and Mr. XIE Ronggang as non-executive directors, and Dr. ZENG Junwen, Dr. XU Yan and Mr. TAN Bo as independent non-executive directors.