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)

ANNUAL RESULTS ANNOUNCEMENT FOR THE YEAR ENDED DECEMBER 31, 2022

The Board of Akeso, Inc. hereby announces the audited consolidated results of the Group for the year ended December 31, 2022. These annual results have been reviewed by the Company's Audit Committee and audited by the Company's auditor, Ernst & Young.

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

FINANCIAL HIGHLIGHTS

1. Products Sales

The Group's total sales from products increased by 422% from RMB211.6 million for the year ended December 31, 2021 to RMB1,104.4 million for the year ended December 31, 2022. The rapid growth in sales was attributable to:

(i) Benefiting from strategically built-up of our sales platform ahead of the launch and highly productive sales force, our newly approved 開坦尼® (Cadonilimab, PD-1/CTLA-4) achieved strong sales results with product sales of RMB546.3 million for the year ended December 31, 2022.

(ii) Product sales from 安尼可® (Penpulimab, PD-1) which was approved in late August 2021, increased by 164% from RMB211.6 million for the year ended December 31, 2021 to RMB558.1 million for the year ended December 31, 2022.

	Products Sales*			Consolidated Revenue**		
million (RMB)	**2022**	2021	**% Change**	**2022**	2021	**% Change**
開坦尼® (Cadonilimab, PD-1/CTLA-4)	**546.3**	–	–	**546.3**	–	–
安尼可® (Penpulimab, PD-1)	**558.1**	211.6	164%	**287.4**	97.0	196%
Total	**1,104.4**	211.6	422%	**833.7**	97.0	759%

* Products sales is the Group's total sales from 安尼可® (Penpulimab, PD-1) and 開坦尼® (Cadonilimab, PD-1/CTLA-4).

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

2. Cost of Sales

The cost of sales increased by 201% from RMB31.3 million for the year ended December 31, 2021 to RMB94.1 million for the year ended December 31, 2022. The increase in cost of sales was mainly attributable to 開坦尼®'s (Cadonilimab, PD-1/CTLA-4) and 安尼可®'s (Penpulimab, PD-1) raw material, direct labor, depreciation of equipment and buildings and manufacturing overhead related to the production of these products.

3. Gross Profit

The Group's gross profit increased by 283% from RMB194.4 million for the year ended December 31, 2021 to RMB743.5 million. It was mainly attributable to the strong increase in revenues.

4. Research and Development Expenses

Research and development expenses increased by 18% from RMB1,123.0 million for the year ended December 31, 2021 to RMB1,323.1 million for the year ended December 31, 2022. The increase in research and development expenses was mainly due to more of our products entering into late-stage larger scale clinical trials including but not limited to Cadonilimab (AK104, PD-1/CTLA-4) combined with chemotherapy for first-line gastric cancer and chemotherapy for first-line cervical cancer; Phase III programs of Ivonescimab/(AK112, PD-1/VEGF), Penpulimab (AK105, PD-1), Ebronucimab (AK102, PCSK9), Ebdarokimab (AK101, IL-12/L-23); and Phase I/II program of Ligufalimab (AK117, CD47).

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.

5. Selling and Marketing Expenses

Selling and marketing expenses increased by 209% from RMB179.1 million for the year ended December 31, 2021 to RMB552.7 million for the year ended December 31, 2022. The expenses were mainly attributable to the marketing activities for the approved and commercialized products 開坦尼® (Cadonilimab, PD-1/CTLA-4), and 安尼可® (Penpulimab, PD-1).

MANAGEMENT DISCUSSION AND ANALYSIS

We are a biopharmaceutical company committed to the research, development, manufacturing and commercialization of either first-in-class or best-in-class therapies. We are dedicated to addressing global unmet medical needs in cancers, autoimmune diseases and metabolic disease.

開坦尼®, THE WORLD'S FIRST APPROVED DUAL IMMUNE CHECKPOINT INHIBITOR BI-SPECIFIC ANTIBODY, RECORDED STRONG SALES

On June 29, 2022, 開坦尼® (cadonilimab injection, PD-1/CTLA-4), the first-in-class PD-1/CTLA-4 bi-specific antibody independently developed by the Company, has been granted marketing approval by the NMPA for the treatment of recurrent or metastatic cervical cancer (R/M CC) patients who have progressed on or after platinum-based chemotherapy. 開坦尼® is the first approved dual immune checkpoint inhibitor bi-specific antibody globally, addressing a huge unmet medical needs for immunotherapy for advanced cervical cancer in China, and is also pioneering the development of bi-specific antibody in China.

開坦尼® is the second product of the Group obtaining marketing approval from the NMPA following the approval of 安尼可®, and is the first drug independently marketed by the Company. With excellent safety and efficacy profile, the well-established commercialization platform and the great efforts by the highly productive sales force, 開坦尼® recorded strong sales of RMB546.3 million for the financial year ended December 31, 2022.

安尼可® (penpulimab injection, PD-1), jointly developed by the Company and Sino Biopharmaceutical Limited (stock code: 1177.HK), recorded product sales of RMB558.1 million in 2022, increased by 164% from 2021. In April 2022, three indications were included into the 2022 CSCO Guideline, which are penpulimab for treatment of refractory/relapsed classic Hodgkin Lymphoma (r/r cHL), penpulimab in combination with chemotherapy as first-line treatment of squamous NSCLC, penpulimab as second-line treatment or salvage treatment of recurrent/metastatic nasopharyngeal carcinoma (r/m NPC). In January 2023, 安尼可® in combination with chemotherapy as first-line treatment of locally advanced or metastatic squamous non-small cell lung cancer was approved by NMPA. The marketing approval of this new indication positions 安尼可® for rapid growth and gaining larger market share on going forward.

On July 22, 2022, 普佑恒™ (pucotenlimab injection), an anti-PD-1 monoclonal antibody, which was licensed out by the Group and developed by Lepu Biopharma Co., Ltd. (stock code 2157.HK), received conditional marketing approval in China. The Company will receive milestone payment and 7% of royalty on net sales. During the Reporting Period, the license income of 普佑恒™ totalled RMB3.9 million.

EXPEDITING GLOBAL COLLABORATION AND DEVELOPMENT SIGNIFIED BY LANDMARK OUTLICENSING TRANSACTION OF IVONESCIMAB (PD-1/VEGF, AK112)

The Company has also achieved key milestones in global collaboration. On December 6, 2022, we have entered into a collaborative and licensing agreement with Summit Therapeutics Inc. (NASDAQ: SMMT) (the "**SUMMIT**") (the "**License Agreement**"), under which, we will grant an exclusive license to the Summit to develop and commercialize ivonescimab (PD-1/VEGF, AK112) in the United States, Canada, Europe and Japan. We shall receive an upfront payment of US$500 million and the total potential deal value is up to US$5 billion, including regulatory and commercial milestone payments. We will also receive low double-digit percentage of royalties on net product sales of ivonescimab. As of the date of this announcement, the Company has received an upfront payment equivalent to US$500 million. Dr. XIA Yu, Chairwoman, executive Director, chief executive officer and President of the Company, has been appointed to the board of directors of the Summit. The total upfront payment will further strengthen our cash position, and marks the successful completion of the first milestone of the collaboration and the License Agreement. Both the Summit and the Company are working diligently to expedite the development of ivonescimab overseas.

From September to November 2022, ivonescimab has received three Breakthrough Therapy Designation(BTD)s from the CDE, including (i) in combination with chemotherapy for treatment of locally advanced or metastatic non-squamous NSCLC patients with EGFR-mutated who failed to prior EGFR-TKI treatment; (ii) as the first-line treatment for locally advanced or metastatic NSCLC patients with positive PD-L1 expression; and (iii) in combination with docetaxel for the treatment of locally advanced or metastatic NSCLC patients who failed to prior PD-(L)1 inhibitor combined with platinum-based doublet chemotherapy. Ivonescimab is the first biological product which received three BTDs from NMPA.

The above-mentioned Licensing Agreement and BTDs have further demonstrated ivonescimab's superior safety and efficacy profile, and huge market potential globally.

DEVELOPMENT OF PRODUCT PORTFOLIO

As of December 31, 2022, we have over 30 innovative programs covering the areas of oncology, autoimmune and metabolic diseases. 17 of these products are in the clinical trial stage (including four out-licensed products) and 6 of which are potential first-in-class or best-in-class bi-specific antibodies.

Oncology is one of our focused therapeutic areas. We are conducting clinical trials of 開坦尼® (cadonilimab, PD-1/CTLA-4), ivonescimab (PD-1/VEGF, AK112), ligufalimub (CD47, AK117), 安尼可® (Penpulimab, PD-1), drebuxelimab (CD73, AK119), pulocimab (VEGFR-2, AK109), AK127 (TIGIT), AK115 (NGF), AK129 (PD-1/LAG-3) and AK130 (TIGIT/TGF-β), which cover various indications including hematological tumors and solid tumors. We believe that some of these commercialized drugs and drug candidates have the potential to be the first-in-class or best-in-class therapies, as well as backbone drugs of combination therapies.

In the area of autoimmune disease, we also have strong pipeline including ebdarokimab (IL-12/IL-23, AK101), gumokimab (IL-17, AK111) and manfidokimab (IL-4R, AK120).

We also have ebronucimab* (PCSK9, AK102), an innovative product targeting metabolic diseases.

In 2022, we published 26 clinical trial results at global academic conferences or academic journals, which further demonstrated our strong innovation and effective execution in drug discovery and clinical development.

Note: * 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) and 安尼可® (penpulimab), and our major clinical-stage assets 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	
	Gastric cancer	+XELOX	1L G/GEJ	▲			Enrollment completed	
		+AK109 (VEGFR2) ±chemo	PD-1 r/r G/GEJ	▲				
		+AK117 (CD47) ±chemo	1L G/GEJ, ESCC	▲				
	Hepatocellular carcinoma	Mono	HCC Adjuvant therapy	▲			Enrollment in process	
		+Lenvatinib	1L HCC	▲				
		+Lenvatinib+TACE	HCC, intermediate stage	▲				
		+AK109	PD-1 r/r HCC	▲				
	Lung cancer	+Chiauranib	≥2L SCLC	▲				
		+Docetaxel	PD-1 r/r NSCLC	▲				
		+AK109±Docetaxel	PD-1 r/r NSCLC	▲				
	Pancreatic cancer	+chemo	1L PDAC					
	Others	+AK117 (CD47)	Adv. solid tumors	🌐				
		+AK119 (CD73)	Adv. solid tumors	🌐				
		+AK127 (TIGIT)	Adv. solid tumors	🌐				
Ivonescimab AK112 (PD-1/VEGF)	Lung cancer	+Chemo	EGFR-TKI resistant NSCLC	▲★			Enrollment completed	
		Mono	1L PD-L1(+) NSCLC	▲★			Enrollment in process	
		+Chemo	1L sqNSCLC	▲			Initiated	
		+Chemo	IO-r NSCLC	▲★				
		±Chemo	Neoadjuvant NSCLC	▲				
	Gastrointestinal cancer	+AK117 +/- Chemo	Adv. solid tumors (GC, BTC, PDAC)	▲				
	Breast cancer	+Chemo +/- AK117	1L TNBC	▲				
	Head and neck cancer	+AK117 +/- Chemo	HNSCC					
	Hepatocellular carcinoma	Mono	Unresectable HCC	▲				
	Colorectal cancer	+AK117 +/- Chemo	1L CRC	▲				
	Ovarian cancer	Mono	Platinum resistant OC	🌐				
	Others	Mono	Adv. solid tumors	🌐				
Ligufalimab AK117 (CD47)	Hematological tumor	+ azacitidine	1L MDS					
		+ azacitidine	1L AML					
	Solid tumor	+AK112 +/- Chemo	Adv. solid tumors (GC, BTC, PDAC)					
		+AK112 +/- Chemo	HNSCC					
		+AK112 +/- Chemo	1L CRC	▲				
		+Chemo +/- AK112	1L TNBC	▲				
		+AK104 +/- Chemo	1L GC/GEJ/ESCC	▲				
		Mono	Adv solid tumors	🌐				
	Others	Mono	Adv solid tumors/lymphoma					

🌐 Global ▲ Large Indications Approved 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 sqNSCLC ▲				Approved on 2023.1
	Mono	3L NPC				Submitted in China
	+Anlotinib	1L HCC ▲				
	+Chemo	1L NPC 🌐				
	+Anlotinib	dMMR solid tumors				
	+Anlotinib	NSCLC, SCLC, HNC, thyroid cancer, mesothelioma and thymic cancer				
	+Anlotinib	ESCC, UC, GC/GEJ, cholangiocarcinoma, neuroendocrine tumor (NET)				
AK119 (CD73)	+AK112	Adv. solid tumors				
	+AK112	EGFR-TKI resistant EGFRm NSCLC				
	Mono	Adv. solid tumors				
	+AK104	Adv. solid tumors				
AK109 (VEGFR-2)	+AK104 ±chemo	PD-1 r/r G/GEJ				
	+AK104	PD-1 r/r HCC				
	Mono	Adv. solid tumors				
AK127 (TIGIT)	+AK104	Adv. solid tumors 🌐				
	Mono	Adv. solid tumors				
AK115 (NGF)	Mono	Pain (including cancer pain)				
AK129 (PD-1/LAG-3)	Mono	Adv. solid tumors				
AK130 (TIGIT/TGF-β)	Mono	Adv. solid tumors				

🌐 Global ▲ Large Indications Approved 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
Ebronucimab AK102 (PCSK9)	+ Statin/Ezetimibe	Hypercholesterolemia			Reached endpoint	
	+ Statin/Ezetimibe	HeFH			Reached endpoint	
Ebdarokimab AK101 (IL-12/IL-23)	Mono	Moderate-to-severe psoriasis			Reached endpoint	
	Mono	Moderate-to-severe ulcerative colitis				
AK111 (IL-17)	Mono	Moderate-to-severe psoriasis				
	Mono	Ankylosing spondylitis				
AK120 (IL-4R)	Mono	Moderate-to-severe atopic dermatitis				

🌐 Global Registrational Trials

Oncology

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

  1. Commercialization and NDA progress in 2022:

  — On June 29, 開坦尼® was granted marketing approval for the treatment of recurrent or metastatic cervical cancer (R/M CC) patients who have progressed on or after platinum-based chemotherapy. 開坦尼® is globally first approved dual immune checkpoint inhibitor bi-specific antibody, addressing a huge unmet medical need for immunotherapy for advanced cervical cancer in China, and is also pioneering the development of bi-specific antibody in China.

  2. Significant Clinical Progress in 2022:

  — In January, we obtained CDE approval to initiate Phase III clinical trial of cadonilimab in combination with concurrent chemoradiotherapy (CCRT) for treatment of locally advanced cervical cancer.

  — In January, we obtained CDE approval to initiate Phase Ib/II clinical trial of cadonilimab in combination with AK112 +/- chemotherapy for treatment of advanced non-small cell lung cancer (NSCLC).

  — In January, we obtained CDE approval to initiate Phase II clinical trial of cadonilimab in combination with Lenvatinib + TACE for treatment of liver cancer.

  — In March, we obtained CDE approval to initiate Phase II clinical trial of cadonilimab in combination with Docetaxel for treatment of advanced NSCLC which patients previously treated with PD-(L)1.

  — In March, we commenced R&D collaboration with Chipscreen Biosciences, and initiated Phase Ib/II clinical trial of cadonilimab in combination with Chiauranib for treatment of extensive-stage small cell lung cancer (ES-SCLC) which patients previously treated with PD-(L)1.

  — In June, we obtained CDE approval to initiate Phase III clinical trial of cadonilimab as adjuvant treatment of hepatocellular carcinoma (HCC).

  — In June, we completed patient enrollment of Phase III trial of cadonilimab in combination with platinum-based chemotherapy +/- bevacizumab as first-line treatment of R/M CC.

3. Publication in 2022:

— In January, results of Phase Ib/II clinical trial of cadonilimab in combination with chemotherapy as the first-line treatment of advanced gastric cancer/gastroesophageal junction cancer (G/GEJ) were published at 2022 ASCO GI.

— In March, results of Phase II clinical trial of cadonilimab for treatment of R/M CC were orally reported at 2022 SGO.

— In June, results of Phase II clinical trial of cadonilimab in combination with standard of care as first-line treatment of R/M CC were orally reported at 2022 ASCO.

— In August, the review article "Cadonilimab: First Approval" independently written by Adis on cadonilimab of the Company was published at world-renowned pharmacy periodical *Drugs*.

- ***Ivonescimab (PD-1/VEGF, AK112):***

1. Significant Clinical Progress in 2022:

— In January, Phase III clinical trial of AK112 in combination with chemotherapy for treatment of advanced non-squamous NSCLC patients with EGFR-mutated who failed to prior EGFR-TKI treatment completed dosing of first patient.

— In January, we obtained CDE approval to initiate Phase II clinical trial of AK112 in combination with AK117 as first-line treatment of triple-negative breast cancer (TNBC).

— In March, Phase II clinical trial of AK112 monotherapy or in combination with chemotherapy as neoadjuvant/adjuvant treatment of resectable NSCLC completed first patient enrollment.

— In June, we obtained CDE approval to initiate Phase II clinical trial of AK112 for the treatment of unresectable HCC.

— In August, we initiated Phase III clinical trial of AK112 monotherapy versus Pembrolizumab as the first-line treatment for NSCLC patients with positive PD-L1 expression.

— In September, AK112 in combination with chemotherapy for the treatment of EGFR-mutated locally advanced or metastatic non-squamous NSCLC patients who have failed to EGFR-TKI treatment was granted breakthrough therapy designation by CDE.

— In October, AK112 as the first-line treatment for locally advanced or metastatic NSCLC patients with positive PD-L1 expression was granted breakthrough therapy designation by CDE.

— In October, AK112 in combination with AK119 obtained CDE approval to initiate Phase Ib/II clinical trial for treatment of advanced solid tumor.

— In November, AK112 in combination with docetaxel for the treatment of locally advanced of metastatic NSCLC patients who failed to prior PD-(L)1 inhibitor combined with platinum-based doublet chemotherapy was granted breakthrough therapy designation by CDE.

— In November, we completed patient enrollment of Phase III clinical trial of AK112 combined with chemotherapy for the treatment of EGFR-mutated locally advanced or metastatic non-squamous NSCLC patients who have failed to EGFR-TKI treatment.

2. *Publication in 2022:*

— In June, results of Phase Ib/II clinical trial of AK112 monotherapy for the treatment of advanced NSCLC were published at 2022 ASCO.

— In June, results of Phase II clinical trial of AK112 in combination with chemotherapy for the treatment of advanced NSCLC were published at 2022 ASCO. Three cohorts are included in this trial:

  • Cohort 1: previously untreated advanced NSCLC patients without EGFR/ALK alterations

  • Cohort 2: advanced NSCLC patients who failed to prior EGFR-TKI therapy

  • Cohort 3: advanced NSCLC patients who failed in prior platinum-based doublet chemo with PD-(L)1 therapy

— In October, the results Phase Ib clinical trial of AK112 in combination with chemotherapy as first-line treatment of extensive-stage small cell lung cancer (ES-SCLC) were published at 2022 ACLC.

— In November, pre-clinical results of AK112 were published at 2022 SITC.

3. *Recent Development After the Reporting Period:*

— In January 2023, we obtained CDE approval to initiate Phase III clinical trial of AK112 in combination with chemotherapy versus PD-1 in combination with chemotherapy for the treatment of squamous NSCLC.

- ***Ligufalimab (CD47, AK117):***

  1. *Significant Clinical Progress in 2022:*

     — In January, we obtained CDE approval to initiate Phase Ib/II clinical trial of AK117 in combination with AK112 +/- chemotherapy for treatment of advanced malignant tumors.

     — In January, we obtained CDE approval to initiate Phase II clinical trial of AK117 in combination with AK112 with chemotherapy as first-line treatment of TNBC.

  2. *Publication in 2022:*

     — In December, the results of AK117 mechanism were published at Journal for ImmunoTherapy of Cancer.

- ***安尼可® (penpulimab, AK105):***

  1. *Included in Guidelines in 2022:*

     — In April, 安尼可® combined with chemotherapy as the first line treatment of locally advanced or metastatic squamous NSCLC was included as Grade II recommendation in Guidelines for Non-Small Cell Lung Cancer Treatment (2022) of Chinese Society of Clinical Oncology (CSCO) and was included in Guidelines of Chinese Society of Clinical Oncology Immune Checkpoint Inhibitor Clinical Practice (2022).

  2. *Recent Development After the Reporting Period:*

     — In January 2023, 安尼可® combined with chemotherapy as the first line treatment of locally advanced or metastatic squamous NSCLC has been granted marketing approval by NMPA.

- ***Pulocimab (VEGFR-2, AK109):***

  Publication in 2022:

  — In June, results of Phase I clinical trial of AK109 for treatment of advanced or metastatic solid tumors were published at 2022 ASCO.

- ***AK127 (TIGIT):***

  1. *Significant Clinical Progress in 2022:*

     — In March, we obtained CDE approval to initiate Phase I clinical trial for treatment of malignant tumor.

  2. *Publication in 2022:*

     — In April, pre-clinical results of AK127 were published at 2022 AACR.

- ***AK115 (NGF):***

  1. *Significant Clinical Progress in 2022:*

     — In February, we obtained CDE approval to initiate Phase I clinical trial for alleviating pain (including cancer pain).

During the Reporting Period, two of our pre-clinical oncology drug candidates advanced into clinical stage.

- ***AK129 (PD-1/LAG-3):***

  1. *Significant Clinical Progress in 2022:*

     — In November, we obtained CDE approval of AK129 IND for the treatment of advanced malignant tumor.

  2. *Publication in 2022:*

     — In April, pre-clinical results of AK129 were published at 2022 AACR.

  3. *Recent Development After the Reporting Period:*

     — In March 2023, Phase I clinical trial of AK129 for treatment of advanced malignant tumor completed dosing of first patient.

- ***AK130 (TIGIT/TGF-β):***

  1. *Significant Clinical Progress in 2022:*

     — In November, we obtained CDE approval of AK130 for the treatment of advanced malignant tumor.

  2. *Publication in 2022:*

     — In September, pre-clinical results of AK130 were published at 2022 ESMO.

  3. *Recent Development After the Reporting Period:*

     — In February 2023, Phase I clinical trial of AK130 for treatment of advanced malignant tumor completed dosing of first patient.

Autoimmune and Other Therapeutic Areas

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

  1. *Significant Clinical Progress in 2022:*

     — In June, we completed patient enrollment of Phase III pivotal trial of AK101 for treatment of moderate-to-severe psoriasis.

  2. *Publication in 2022:*

     — In November, results of Phase I clinical trial of AK101 for the treatment of moderate to severe psoriasis were published at 2022 ACR.

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

- ***Ebronucimab (PCSK9, AK102):***

  1. *Significant Clinical Progress in 2022:*

     — In June, we completed patient enrollment of Phase III pivotal trial of AK102 for the treatment of hypercholesterolemia.

     — In June, we completed patient enrollment of Phase III registrational trial of AK102 for the treatment of heterozygous familial hypercholesterolaemia (HeFH).

     — In November, registrational Phase III clinical trial of AK102 for the treatment of essential hypercholesterolemia (including HeFH) and mixed hypercholesterolemia reached its primary endpoint.

  2. *Publication in 2022:*

     — In November, results of Phase II clinical trial of AK102 for the treatment of hypercholesterolemia were published at 2022 AHA.

     — In November, results of Phase I clinical trial of AK102 in healthy subjects were published at 2022 AHA.

- ***Gumokimab (IL-17, AK111):***

  Publication in 2022:

  — In May, results of Phase I clinical trial of AK111 in healthy subjects were published at 2022 AAPS.

  — In August, PK/PD results of Phase Ib clinical trial of AK111for treatment of moderate to severe plaque psoriasis were published at Front Pharmacol.

  — In September, results of Phase I clinical trial of AK111 for treatment of moderate to severe plaque psoriasis were published at Dermatol Ther.

- ***Manfidokimab (IL-4R, AK120):***

  Publication in 2022:

  — In October, results of Phase I clinical trial of AK120 for treatment of atopic dermatitis were published at 2022 EADV.

Warning under Rule 18A.08(3) of the Rules Governing the Listing of Securities on the Stock Exchange: There is no assurance that the Company will continuously succeed in commercialization of 開坦尼® and 安尼可®. 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), 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.

OUR SELECTED PRE-CLINICAL STAGE DRUG CANDIDATES

In addition to our clinical-stage drug candidates, we are also developing drug candidates in pre-clinical stage, including but not limited to:

Assets	Target(s)	Monotherapy/ Combo-therapy	Therapeutic Areas	Commercialization Rights
AK131	PD-1/CD73	Monotherapy	Oncology	Global
AK132	Claudin18.2/CD47	Monotherapy	Oncology	Global

CONTINUOUSLY EXPLORE FINANCING ALTERNATIVES TO FURTHER STRENGTHEN OUR CAPITAL RESERVE

On July 15, 2022, we completed a placement on the Hong Kong Stock Exchange. The net proceeds from the placement after deducting commission and other relevant expenses and professional fees was approximately US$73.46 million (equivalent to approximately HK$576.66 million). The net proceeds will be utilized for, among others, the R&D, marketing and commercialization of 開坦尼®, ivonescimab and other products.

On November 15, 2022, Guangzhou Hi-tech Investment Group announced to make a strategic investment to Akeso Pharma by providing RMB500 million cash to support the further development and commercialization of 開坦尼®.

On December 5, 2022, the Board resolved the Company's proposal to issue RMB shares to be listed on the Science and Technology Innovation Board of the Shanghai Stock Exchange.

With our continuous efforts on expanding financing channels, as of December 31, 2022, the Company has strong cash position of approximately RMB2.09 billion.

Since February 28, 2023, the Company's shares have been included into MSCI China All Shares Indexes.

On March 6, 2023, the Company received the entire upfront payment equivalent to US$500 million from SUMMIT, which included US$474.9 million cash and the consideration shares with value equivalent to US$25.10 million. The total upfront payment will further strengthen our cash position, marks the successful completion of the first milestone of the collaboration and the License Agreement, and provides a strong capital to support the continuous development of the Company.

HUMAN RESOURCES MANAGEMENT

As of December 31, 2022, we had a total of 2,341 employees. In order to fulfill our strategic goal of enhancing the integrated platform of R&D, manufacturing and commercialization, the Company continues to recruit more talents.

Function	**Number of employees As of December 31, 2022**	Number of employees As of December 31, 2021
Research and Development (Pre-clinical)	**275**	243
Clinical	**422**	496
Manufacturing, quality assurance and quality control	**605**	398
Selling and Marketing	**652**	512
Sourcing, General and Administrative	**387**	216
Total	**2,341**	1,865

MANUFACTURING FACILITIES

As of December 31, 2022, the Company has a total production capacity of 31,500L in operation. We have a 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.

FDA/NMPA-compliant GMP manufacturing facility to continuously support the Company's clinical and commercialization development.

- **Zhongshan Torch Development District Manufacturing Site:** GMP-compliant manufacturing capacity of 3,500L.

- **Guangzhou Commercialization and Manufacturing Site:** The production capacity in operation at the moment is 28,000L, with additional 32,000L capacity under construction.

  AD Pharmaceuticals Co., Ltd., a joint venture of the Company and Dawnrays Pharmaceutical, commenced operation with a new production capacity of 8,000L in Guangzhou in May.

- **Zhongshan Cuiheng Manufacturing Site:** The phase I and phase II projects under construction will provide up to 60,000L. Phase III of this project is in planning, which will provide a production capacity of up to 40,000L once completed.

IMPACT OF COVID-19 AND RESPONSE

Global Outbreak of COVID-19

The Company has developed defensive operation rules and fully prepared for company operation under outbreak of COVID-19. During the Reporting Period, we have experienced only minimal delay to our patient enrollment and clinical development due to business interruptions to hospitals and treatment centers. Based on information available as of the date of this announcement, we believe that the outbreak of COVID-19 will not cause material interruption to our business operation and will not have significant impact on our financial conditions and financial results.

FUTURE DEVELOPMENT

Looking forward, we will continue to keep up with the frontier of biotech industry and optimize our product portfolio's research and development plan. Through efficient execution and optimization of our global pipelines, we will expedite the development for new drug candidates with great market potential.

During 2023, we expect to submit sNDA application for 開坦尼® (cadonilimab, PD-1/CTLA-4) for first-line cervical cancer treatment, and accelerate clinical development for 開坦尼® in larger indications, such as first-line gastric cancer, liver cancer, lung cancer etc., to maximize the commercial potential of the product and build up a higher market barrier. We will also accelerate clinical development of ivonescimab (PD-1/VEGF, AK112), and we expect to submit NDA to CDE for ivonescimab for the indication of EGFR-mutated NSCLC patients who have failed to EGFR-TKI treatment in 2023. In addition, we will continue to initiate more clinical trials in large indications in lung cancer as well as gastrointestinal tumor, breast cancer, head and neck cancer and other solid tumors. We will further strengthen the cooperation with Summit to advance the overseas clinical development of ivonescimab overseas. Besides, we expect to initiate Phase III clinical trial of ligufalimab (CD47, AK117) as first line treatment of MDS, and accelerate its exploratory trials in combination with cadonilimab and ivonescimab for treatment of solid tumors.

In autoimmune and metabolic disease area, we expect to submit NDA application for two products, ebdarokimab (IL-12/IL-23, AK101) for the treatment of moderate-to-severe psoriasis, and ebronucimab (PCSK9, AK102) for the treatment of hypercholesterolemia and HeFH in 2023.

We will continue to strengthen and optimize our commercialization efforts. Guided by "patient-centric" principle, we will strive to position our two core bispecific innovative antibodies as "the backbone drugs for the era of I/O therapy 2.0", and explore various therapeutic solutions through combination therapy with other drugs for multiple indications to address truly unmet medical needs. And we believe we will continuously achieve strong sales growth under this guiding principle.

We will continue to explore more strategic partners globally in the forms of partnership, joint venture, or licensing agreement.

FINANCIAL REVIEW

Year Ended December 31, 2022 Compared to Year Ended December 31, 2021

	2022	2021
	RMB'000	*RMB'000*
Product sales	**1,104,385**	211,623
License income	**3,920**	128,600
Total sales from products and license	**1,108,305**	340,223
Less: Distribution cost	**(270,649)**	(114,597)
Revenue	**837,656**	225,626
Cost of sales	**(94,117)**	(31,259)
Gross profit	**743,539**	194,367
Other income and gains, net	**158,613**	116,273
Research and development expenses	**(1,323,098)**	(1,122,957)
Selling and marketing expenses	**(552,661)**	(179,149)
Administrative expenses	**(199,007)**	(243,517)
Other expenses, net	**(206,312)**	(12,791)
Finance costs	**(43,290)**	(10,352)
LOSS BEFORE TAX	**(1,422,216)**	(1,258,126)
Income tax expense	**–**	–
LOSS FOR THE YEAR	**(1,422,216)**	(1,258,126)
OTHER COMPREHENSIVE LOSS		
Other comprehensive (loss)/income that may be reclassified to profit or loss in subsequent periods:		
Exchange differences on translation of foreign operations	**(294,663)**	43,534
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:		
Translation from functional currency to presentation currency	**423,297**	(97,226)
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR, NET OF TAX	**128,634**	(53,692)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR	**(1,293,582)**	(1,311,818)

1. Products Sales

The Group's total sales from products increased by 422% from RMB211.6 million for the year ended December 31, 2021 to RMB1,104.4 million for the year ended December 31, 2022. The rapid growth in sales was attributable to:

(i) Benefiting from strategically built-up of our sales platform ahead of the launch and highly productive sales force, our newly approved 開坦尼® (Cadonilimab, PD-1/CTLA-4) achieved strong sales results with product sales of RMB546.3 million for the year ended December 31, 2022.

(ii) Product sales from 安尼可® (Penpulimab, PD-1) which was approved in late August 2021, increased by 164% from RMB211.6 million for the year ended December 31, 2021 to RMB558.1 million for the year ended December 31, 2022.

	Products Sales*			**Consolidated Revenue****		
million (RMB)	**2022**	2021	**% Change**	**2022**	2021	**% Change**
開坦尼® (Cadonilimab, PD-1/CTLA-4)	**546.3**	–	–	**546.3**	–	–
安尼可® (Penpulimab, PD-1)	**558.1**	211.6	164%	**287.4**	97.0	196%
Total	**1,104.4**	211.6	422%	**833.7**	97.0	759%

* Products sales is the Group's total sales from 安尼可® (Penpulimab, PD-1) and 開坦尼® (Cadonilimab, PD-1/CTLA-4).

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

2. Cost of Sales

The cost of sales increased by 201% from RMB31.3 million for the year ended December 31, 2021 to RMB94.1 million for the year ended December 31, 2022. The increase in cost of sales was mainly attributable to 開坦尼®'s (Cadonilimab, PD-1/CTLA-4) and 安尼可®'s (Penpulimab, PD-1) raw material, direct labor, depreciation of equipment and buildings and manufacturing overhead related to the production of these products.

3. Gross Profit

The Group's gross profit increased by 283% from RMB194.4 million for the year ended December 31, 2021 to RMB743.5 million. It was mainly attributable to the strong increase in revenues.

4. Other Income and Gains, net

Other income and gains, net increased by 36.0% from RMB116.3 million for the year ended December 31, 2021 to RMB158.6 million for the year ended December 31, 2022. The Group's other income and gains primarily consisted of subsidies from local government for compensation on expenditure arising from research and development activities and awards for new drug development and capital expenditure incurred on certain projects including construction of manufacturing facilities;and interest income from bank balance.

5. Research and Development Expenses

Research and development expenses increased by 18% from RMB1,123.0 million for the year ended December 31, 2021 to RMB1,323.1 million for the year ended December 31, 2022. The increase in research and development expenses was mainly due to more of our products entering into late-stage larger scale clinical trials including but not limited to Cadonilimab (AK104, PD-1/CTLA-4) combined with chemotherapy for first-line gastric cancer and chemotherapy for first-line cervical cancer; Phase III programs of lvonescimab/(AK112, PD-1/VEGF), Penpulimab (AK105, PD-1), Ebronucimab (AK102, PCSK9), Ebdarokimab (AK101, IL-12/L-23); and Phase I/II program of Ligufalimab (AK117, CD47).

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.

6. Selling and Marketing Expenses

Selling and marketing expenses increased by 209% from RMB179.1 million for the year ended December 31, 2021 to RMB552.7 million for the year ended December 31, 2022. The expenses were mainly attributable to the marketing activities for the approved and commercialized products 開坦尼® (Cadonilimab, PD-1/CTLA-4), and 安尼可® (Penpulimab, PD-1).

7. Administrative Expenses

Administrative expenses decreased by 18% from RMB243.5 million for the year ended December 31, 2021 to RMB199.0 million for the year ended December 31, 2022. The decrease in administrative expenses was mainly due to consistent control of costs, prudent use of expenses and the decrease in RSU expenses.

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

8. Finance Costs

Finance costs were RMB43.3 million for the year ended December 31, 2022, as compared to RMB10.4 million for the year ended December 31, 2021. Finance costs mainly consisted of interest expenses on bank and other borrowings, and finance costs on lease liabilities.

9. Loss for the Year

For the reasons discussed above, loss for the year was RMB1,422.2 million for the year ended December 31, 2022, as compared to RMB1,258.1 million for the year ended December 31, 2021.

10. Liquidity and Source of Funding and Borrowing

In 2022, we actively explored financing channel 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 December 31, 2022, the current assets of the Group were RMB3,058.5 million, of which cash and cash equivalents amounted to RMB2,092.4 million and other current assets amounted to RMB966.1 million.

The Group's cash and cash equivalents decreased by RMB549.2 million to RMB2,092.4 million as of December 31, 2022 from RMB2,641.6 million as at December 31, 2021.

As of December 31, 2022, the current liabilities of the Group were RMB1,361.1 million, including trade payables of RMB308.9 million, other payables and accruals of RMB599.2 million and interest-bearing bank and other borrowings of RMB446.0 million.

As of December 31, 2022, the Group had short term loans of approximately RMB446.0 million and long term loans of approximately RMB1,421.3 million, bearing interest on commercial bank borrowings at fixed annual interest rates ranging from 2.8% to 5.39%.

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

11. Pledge of Assets

As at December 31, 2022, the Group had a total pledge of RMB519.2 million of buildings and land use rights pledged to secure its loans and banking facilities.

12. Key Financial Ratios

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

	As at December 31, 2022	As at December 31, 2021
Quick ratio[(1)]	**2.0**	4.5
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.

13. Significant Investments

As at December 31, 2022, 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.

14. Material Acquisitions and Disposals

The Group did not have material acquisitions or disposals of subsidiaries, associates and joint ventures for the year ended December 31, 2022.

15. Contingent Liabilities

The Group did not have any material contingent liabilities as at December 31, 2022.

16. Capital Commitment

The capital commitments of the Group as at December 31, 2022 were RMB981.1 million, as compared to RMB594.1 million as at December 31, 2021, 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 is planned to be ready for use in 2023.

17. Foreign Exchange Risk Exposure

As at December 31, 2022, 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.

While a portion of the Group's transactions were dominated in Hong Kong dollars, 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 its foreign exchange risk by performing regular reviews of our net foreign exchange risks and uses forward contracts to eliminate the foreign exchange risk exposures.

18. Employees and Remuneration

As at December 31, 2022, the Group had a total of 2,341 employees. The following table sets forth the total number of employees by function as of December 31, 2022 and 2021:

Function	**Number of employees As at December 31, 2022**	Number of employees As at December 31, 2021
Research and Development (Pre-clinical)	**275**	243
Clinical	**422**	496
Manufacturing, quality assurance and quality control	**605**	398
Selling and Marketing	**652**	512
Sourcing, General and Administrative	**387**	216
Total	**2,341**	1,865

The total remuneration cost incurred by the Group was RMB624.1 million for the year ended December 31, 2022, and RMB536.7 million for the year ended December 31, 2021. The increase in remuneration cost was primarily attributable to the increase in the number of employees, which leads to an increasing 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 restricted share unit 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 circular of the company dated June 1, 2022.

OTHER INFORMATION

FINAL DIVIDEND

The Board does not recommend the payment of a final dividend to the Shareholders for the Reporting Period (year ended December 31, 2021: 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

On July 8, 2022, an aggregate of 24,000,000 new shares were issued at a price of HK$24.27 per share (the "**2022 Placing**") to not less than six professional, institutional or other investors that are Independent Third Parties pursuant to the share placing agreement (the "**Placing Agreement**") dated July 8, 2022, representing approximately 2.85% of the enlarged issued share capital of the Company immediately following the 2022 Placing. The placing price of HK$24.27 per share represented (i) a discount of approximately 7.0% to the closing price of HK$26.10 per Share as quoted on the Stock Exchange on July 7, 2022, being the last full trading day prior to the date of the Placing Agreement and (ii) a discount of approximately 5.5% to the average closing price of HK$25.67 per Share as quoted on the Stock Exchange for the five consecutive trading days of the Shares prior to and including the last full trading day prior to the date of the Placing Agreement.

The net price per share for the subscription after deducting related costs and expenses was approximately HK$24.03 per share and the net proceeds raised from the 2022 Placing were US$73,459,261 (equivalent to approximately HK$576,655,200 based on the exchange rate of US$1:HK$7.85 for illustration purpose). The subscription of shares have a market value of approximately HK$589.2 million based on the closing price of HK$24.55 per share as at July 8, 2022 and an aggregate nominal value of US$240. The 2022 Placing is being taken to support the research and development works of the Group.

Further details of the 2022 Placing were set out in the announcements of the Company dated July 8, 2022 and July 15, 2022, respectively. For details of the use of proceeds from the 2022 Placing, please refer to the section headed "Use of Net Proceeds" to be disclosed in the annual report.

Save as disclosed above, neither the Company nor any of its subsidiaries had purchased, sold or redeemed any of the Company's listed securities during the Reporting Period.

AUDIT COMMITTEE

The Company has established an Audit Committee with written terms of reference in compliance with Rule 3.21 of the Listing Rules and paragraph A.2 and paragraph D.3 of the CG Code. The primary duties of the Audit Committee are to assist the Board by providing an independent view of the effectiveness of the financial reporting process, internal control and risk management systems of the Group, overseeing the audit process and performing other duties and responsibilities as assigned by the Board. The Audit Committee consists of three independent non-executive Directors being Dr. ZENG Junwen, Dr. XU Yan and Mr. TAN Bo. The chairman of the Audit Committee is Mr. TAN Bo. Mr. TAN Bo holds the appropriate professional qualifications as required under Rules 3.10(2) and 3.21 of the Listing rules.

The Audit Committee had reviewed together with the management the accounting principles and policies adopted by the Group and discussed internal controls and financial reporting matters including a review of the consolidated financial statements and annual results of the Group for the year ended December 31, 2022.

SCOPE OF WORK OF THE COMPANY'S AUDITOR IN RESPECT OF THIS ANNUAL RESULTS ANNOUNCEMENT

The figures in respect of the Group's consolidated statement of financial position as at December 31, 2022, consolidated statement of profit or loss and other comprehensive income for the year then ended and the related notes thereto as set out in this announcement have been agreed by the Company's auditor to the amounts set out in the Group's audited consolidated financial statements for the year. The work performed by the Company's auditor, Ernst & Young in this respect did not constitute an assurance engagement in accordance with Hong Kong Standards in Auditing, Hong Kong Standards on Review Engagements or Hong Kong Standards on Assurance Engagements issued by the Hong Kong Institute of Certified Public Accountants and consequently no assurance has been expressed by Ernst & Young on this announcement.

EVENTS AFTER THE REPORTING PERIOD

On January 16, 2023, 安尼可® in combination with chemotherapy for treatment of advanced or metastatic squamous NSCLC patients had obtained marketing approved from NMPA.

On February 28, 2023, the Company's shares had been admitted to MSCI China All Shares Indexes.

On March 6, 2023, the Company received the entire upfront payment equivalent to US$500 million from SUMMIT in accordance with the License Agreement, which included US$474.9 million cash and the consideration shares with value equivalent to US$25.10 million. The receipt of all upfront payment with an amount equivalent to US$500 million under the License Agreement will lead to significant increase in the Company's cash on hand, and it also implies the successful completion of the first step of this cooperation. On the next step, the Company will further strengthen the cooperation with SUMMIT to accelerate the global development of ivonescimab.

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

PUBLICATION OF ANNUAL RESULTS ANNOUNCEMENT AND ANNUAL 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 annual report of the Company for the year ended December 31, 2022 containing all the information required by the Listing Rules will be dispatched to Shareholders and published on the above websites in due course.

CONSOLIDATED STATEMENTS OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

For the year ended 31 December 2022

	Notes	**2022** ***RMB'000***	2021 *RMB'000*
Product sales	*3*	**1,104,385**	211,623
License income	*3*	**3,920**	128,600
Total sales from products and license		**1,108,305**	340,223
Less: Distribution cost	*3*	**(270,649)**	(114,597)
Revenue	*3*	**837,656**	225,626
Cost of sales		**(94,117)**	(31,259)
Gross profit		**743,539**	194,367
Other income and gains, net	*4*	**158,613**	116,273
Research and development expenses		**(1,323,098)**	(1,122,957)
Selling and marketing expenses		**(552,661)**	(179,149)
Administrative expenses		**(199,007)**	(243,517)
Other expenses, net		**(206,312)**	(12,791)
Finance costs		**(43,290)**	(10,352)
LOSS BEFORE TAX		**(1,422,216)**	(1,258,126)
Income tax expense	*5*	**–**	–
LOSS FOR THE YEAR		**(1,422,216)**	(1,258,126)

	Note	2022 *RMB'000*	2021 *RMB'000*
OTHER COMPREHENSIVE LOSS			
Other comprehensive income/(loss) that may be reclassified to profit or loss in subsequent periods:			
Exchange differences on translation of foreign operations		**(294,663)**	43,534
Other comprehensive income/(loss) that will not be reclassified to profit or loss in subsequent periods:			
Translation from functional currency to presentation currency		**423,297**	(97,226)
OTHER COMPREHENSIVE INCOME/(LOSS) FOR THE YEAR, NET OF TAX		**128,634**	(53,692)
TOTAL COMPREHENSIVE LOSS FOR THE YEAR		**(1,293,582)**	(1,311,818)
Loss attributable to:			
Owners of the parent		**(1,168,393)**	(1,074,933)
Non-controlling interests		**(253,823)**	(183,193)
		(1,422,216)	(1,258,126)
Total comprehensive loss attributable to:			
Owners of the parent		**(1,039,759)**	(1,128,625)
Non-controlling interests		**(253,823)**	(183,193)
		(1,293,582)	(1,311,818)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted	*7*	**RMB(1.42) yuan**	RMB(1.32) yuan

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

31 December 2022

	Notes	**2022** ***RMB'000***	2021 *RMB'000*
NON-CURRENT ASSETS			
Property, plant and equipment		**1,999,616**	1,352,913
Right-of-use assets		**163,074**	151,727
Intangible assets		**8,496**	3,980
Financial assets at fair value through profit or loss		**10,000**	–
Other non-current assets		**256,291**	144,913
Total non-current assets		**2,437,477**	1,653,533
CURRENT ASSETS			
Inventories		**341,832**	196,619
Trade and bills receivables	*8*	**271,046**	101,849
Prepayments, other receivables and other assets		**157,199**	212,071
Financial assets at fair value through profit or loss		**195,912**	–
Pledged deposits		**94**	92
Cash and cash equivalents		**2,092,388**	2,641,625
Total current assets		**3,058,471**	3,152,256
CURRENT LIABILITIES			
Trade payables	*9*	**308,948**	206,315
Other payables and accruals		**599,178**	394,891
Interest-bearing bank and other borrowings		**445,979**	45,598
Lease liabilities		**5,898**	7,854
Tax payable		**1,133**	1,037
Total current liabilities		**1,361,136**	655,695
NET CURRENT ASSETS		**1,697,335**	2,496,561
TOTAL ASSETS LESS CURRENT LIABILITIES		**4,134,812**	4,150,094

	2022	2021
	RMB'000	*RMB'000*
NON-CURRENT LIABILITIES		
Interest-bearing bank and other borrowings	**1,421,278**	803,733
Lease liabilities	**5,954**	2,237
Deferred income	**159,566**	63,858
Total non-current liabilities	**1,586,798**	869,828
Net assets	**2,548,014**	3,280,266
EQUITY		
Equity attributable to owners of the parent		
Share capital	**59**	57
Shares held for restricted share unit schemes	**(84,452)**	(51,718)
Reserves	**2,720,020**	3,215,717
	2,635,627	3,164,056
Non-controlling interests	**(87,613)**	116,210
Total equity	**2,548,014**	3,280,266

CONSOLIDATED STATEMENT OF CASH FLOWS

Year ended 31 December 2022

	2022	2021
	RMB'000	*RMB'000*
Net cash flows used in operating activities	**(1,240,413)**	(1,001,238)
Net cash flows used in investing activities	**(889,747)**	(579,585)
Net cash flows from financing activities	**1,485,850**	1,586,555
NET (DECREASE)/INCREASE IN CASH AND CASH EQUIVALENTS	**(644,310)**	5,732
Cash and cash equivalents at beginning of year	**2,641,625**	2,684,499
Effect of foreign exchange rate changes, net	**95,073**	(48,606)
CASH AND CASH EQUIVALENTS AT END OF YEAR	**2,092,388**	2,641,625

1. CORPORATE AND GROUP 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 on 24 April 2020.

2.1 BASIS OF PREPARATION

These financial statements have been prepared in accordance with International Financial Reporting Standards ("**IFRSs**") (which include all International Financial Reporting Standards, International Accounting Standards ("**IASs**") and Interpretations) issued by the International Accounting Standards Board ("**IASB**") and the disclosure requirements of the Hong Kong Companies Ordinance. They have been prepared under the historical cost convention, except for the financial assets at fair value through profit or loss which have been measured at fair value. These financial statements are 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 Group has adopted the following revised IFRSs for the first time for the current year's financial statements.

Amendments to IFRS 3	*Reference to the Conceptual Framework*
Amendment to IFRS 16	*Covid-19-Related Rent Concessions beyond 30 June 2021* (early adopted)
Amendments to IAS 16	*Property, Plant and Equipment: Proceeds before Intended Use*
Amendments to IAS 37	*Onerous Contracts — Cost of Fulfilling a Contract*
Annual Improvements to IFRSs 2018–2020	Amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41

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

(a) Amendments to IFRS 3 replace a reference to the previous *Framework for the Preparation and Presentation of Financial Statements* with a reference to the *Conceptual Framework for Financial Reporting* (the "**Conceptual Framework**") issued in May 2020 without significantly changing its requirements. The amendments also add to IFRS 3 an exception to its recognition principle for an entity to refer to the Conceptual Framework to determine what constitutes an asset or a liability. The exception specifies that, for liabilities and contingent liabilities that would be within the scope of IAS 37 or IFRIC-Int 21 if they were incurred separately rather than assumed in a business combination, an entity applying IFRS 3 should refer to IAS 37 or IFRIC-Int 21 respectively instead of the Conceptual Framework. Furthermore, the amendments clarify that contingent assets do not qualify for recognition at the acquisition date. The Group has applied the amendments prospectively to business combinations that occurred on or after 1 January 2022. As there were no business combinations during the year, the amendments did not have any impact on the financial position and performance of the Group.

(b) Amendment to IFRS 16 issued in March 2021 extends the availability of the practical expedient for lessees to elect not to apply lease modification accounting for rent concessions arising as a direct consequence of the covid-19 pandemic by 12 months. Accordingly, the practical expedient applies to rent concessions for which any reduction in lease payments affects only payments originally due on or before 30 June 2022, provided the other conditions for applying the practical expedient are met. The amendment is effective retrospectively for annual periods in which they first apply the amendment with any cumulative effect of initially applying the amendment recognised as an adjustment to the opening balance of retained profits at the beginning of the current accounting period. Earlier application is permitted.

The Group has early adopted the amendment on 1 January 2021 and applied the practical expedient during the year ended 31 December 2022 to all rent concessions granted by the lessors that affected only payments originally due on or before 30 June 2021 as a direct consequence of the covid-19 pandemic. A reduction in the lease payments arising from the rent concessions of RMB206,000 has been accounted for as a variable lease payment by derecognising part of the lease liabilities and crediting to profit or loss for the year ended 31 December 2022. There was no impact on the opening balance of equity as at 1 January 2021.

(c) Amendments to IAS 16 prohibit an entity from deducting from the cost of an item of property, plant and equipment any proceeds from selling items produced while bringing that asset to the location and condition necessary for it to be capable of operating in the manner intended by management. Instead, an entity recognises the proceeds from selling any such items, and the cost of those items as determined by IAS 2 Inventories, in profit or loss. The Group has applied the amendments retrospectively to items of property, plant and equipment made available for use on or after 1 January 2021. Since there was no sale of items produced prior to the property, plant and equipment being available for use, the amendments did not have any impact on the financial position or performance of the Group.

(d) Amendments to IAS 37 clarify that for the purpose of assessing whether a contract is onerous under IAS 37, the cost of fulfilling the contract comprises the costs that relate directly to the contract. Costs that relate directly to a contract include both the incremental costs of fulfilling that contract (e.g., direct labour and materials) and an allocation of other costs that relate directly to fulfilling that contract (e.g., an allocation of the depreciation charge for an item of property, plant and equipment used in fulfilling the contract as well as contract management and supervision costs). General and administrative costs do not relate directly to a contract and are excluded unless they are explicitly chargeable to the counterparty under the contract. The Group has applied the amendments prospectively to contracts for which it has not yet fulfilled all its obligations at 1 January 2022 and no onerous contracts were identified. Therefore, the amendments did not have any impact on the financial position or performance of the Group.

(e) Annual Improvements to *IFRSs 2018–2020* sets out amendments to IFRS 1, IFRS 9, Illustrative Examples accompanying IFRS 16, and IAS 41. Details of the amendments that are applicable to the Group are as follows:

- IFRS 9 *Financial Instruments:* clarifies the fees that an entity includes when assessing whether the terms of a new or modified financial liability are substantially different from the terms of the original financial liability. These fees include only those paid or received between the borrower and the lender, including fees paid or received by either the borrower or lender on the other's behalf. The Group has applied the amendment prospectively from 1 January 2022. As there was no modification or exchange of the Group's financial liabilities during the year, the amendment did not have any impact on the financial position or performance of the Group.

3. REVENUE AND OPERATING SEGMENT INFORMATION

Revenue

An analysis of revenue is as follows:

Revenue from contracts with customers

Disaggregated revenue information

	2022	2021
	RMB'000	*RMB'000*
Types of goods or services		
Product sales	**1,104,385**	211,623
License income	**3,920**	128,600
Total sales from products and license	**1,108,305**	340,223
Less: Distribution cost relevant to the product sales	**(270,649)**	(114,597)
Revenue	**837,656**	225,626
Timing of revenue recognition		
Transfer at a point in time	**837,656**	225,626

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

Operating segment information

The Group is engaged in research, development, production and sale of biological 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 customers

	2022	2021
	RMB'000	*RMB'000*
Mainland China	**837,656**	97,026
USA	**–**	128,600
	837,656	225,626

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

(b) Non-current assets

	2022	2021
	RMB'000	*RMB'000*
Mainland China	**2,436,959**	1,652,287
Other regions	**518**	1,246
	2,437,477	1,653,533

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

Information about major customers

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

	2022	2021
	RMB'000	*RMB'000*
Customer A	**118,563**	11,782
Customer B	**–**	128,600
	118,563	140,382

4. OTHER INCOME AND GAINS, NET

Other income and gains, net

	2022	2021
	RMB'000	*RMB'000*
Bank interest income	**21,972**	14,236
Investment income from financial products	**5,548**	8,522
Government grant released*	**109,205**	84,822
Value-added tax credits	**20,126**	–
Net income from lab testing services	**752**	3,392
Foreign exchange differences, net	**–**	5,162
Others	**1,010**	139
	158,613	116,273

* 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% on any estimated assessable profits arising in Hong Kong during the reporting period. 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 year.

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 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 year.

The subsidiary incorporated in the USA is subject to U.S. federal and California income taxes which has an effective statutory tax rate of 21% and 8.84%, respectively, for the reporting year.

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 income tax expense of the Group is analysed as follows:

	2022	2021
	RMB'000	*RMB'000*
Current		
Charge for the year	**–**	–
Deferred	**–**	–
Total tax charge for the year	**–**	–

6. DIVIDENDS

No dividend has been paid or proposed by the Company during the year ended 31 December 2022 and subsequent to the end of the reporting period (2021: Nil).

7. LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT

The calculation of basic loss per share is based on the loss for the year attributable to ordinary equity holders of the parent, and the weighted average number of shares of 824,989,858 (2021: 815,931,798) in issue during the year.

As the Group incurred losses, no adjustment has been made to the basic loss per share amounts presented for the years ended 31 December 2022 and 2021 in respect of a dilution as the impact of the restricted share units had an anti-dilutive effect on the basic loss per share amounts presented.

The calculations of basic and diluted loss per share are based on:

	2022	2021
	RMB'000	*RMB'000*
Loss		
Loss attributable to ordinary equity holders of the parent, used in the basic and diluted loss per share calculation	**(1,168,393)**	(1,074,933)

	Number of shares	
	2022	2021
Shares		
Weighted average number of shares in issue during the year used in the basic and diluted loss per share calculation	**824,989,858**	815,931,798

8. TRADE AND BILLS RECEIVABLES

	2022	2021
	RMB'000	*RMB'000*
Trade receivables	**271,511**	101,532
Bills receivable	**–**	347
	271,511	101,879
Impairment	**(465)**	(30)
	271,046	101,849

Included in the Group's trade and bills receivables are amounts due from a non-controlling shareholder of the Group of RMB246,269,000 (2021: RMB101,532,000), which are repayable on credit terms similar to those offered to the other customers of the Group.

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:

	2022	2021
	RMB'000	*RMB'000*
Within 3 months	**36,496**	99,971
3 to 6 months	**91,508**	1,531
6 to 9 months	**143,042**	–
	271,046	101,502

The Group's bills receivable as at 31 December 2021 were aged within two months and were neither past due nor impaired, and will be mature within two months.

The movements in the loss allowance for impairment of trade receivables is as follows:

	2022	2021
	RMB'000	*RMB'000*
At beginning of year	**30**	–
Impairment losses, net	**435**	30
	465	30

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:

	2022	2021
	RMB'000	*RMB'000*
Within 3 months	**193,041**	188,700
3 to 6 months	**39,171**	10,043
6 months to 1 year	**13,227**	6,066
Over 1 year	**63,509**	1,506
	308,948	206,315

10. EVENTS AFTER THE REPORTING PERIOD

In December 2022, the Group entered into a collaborative and licensing agreement with SUMMIT which the Group will grant an exclusive license to SUMMIT to develop and commercialise a biopharmaceutical product. Subsequent to the reporting period, the Group has received the entire upfront fee payment of US$500 million from SUMMIT.

DEFINITIONS

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

"AACR"	American Association for Cancer Research
"AAPS"	American Association of Pharmaceutical Sciences
"ACLC"	Asia Conference on Lung Cancer
"ACR"	American College of Rheumatology
"AHA"	American Heart Association
"安尼可®", "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
"Chipscreen Biosciences"	Shenzhen Chipscreen Biosciences Co., Ltd., a company listed on the Shanghai Stock Exchange (Stock code: 688321.SH)

"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
"Director(s)"	the director(s) of the Company
"EMA"	European Medicines Agency
"EADV"	European Academy of Dermatology and Venereology
"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 financial year ended December 31, 2022
"RMB"	Renminbi, the lawful currency of the PRC
"SGO"	Society of Gynecologic Oncology
"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)
"SITC"	Society for Immunotherapy of Cancer

"Stock Exchange"	The Stock Exchange of Hong Kong Limited
"TACE"	transcatheter arterial chemoembolization
"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, March 15, 2023

As at the date of this announcement, the Board 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.