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Zhaoke Ophthalmology Limited
兆科眼科有限公司

(Incorporated in the British Virgin Islands with limited liability and continued in the Cayman Islands)
(Stock Code: 6622)

ANNUAL RESULTS ANNOUNCEMENT
FOR THE YEAR ENDED DECEMBER 31, 2022

The Board and the Directors of our Company are pleased to announce the audited consolidated annual results of our Group for the year ended December 31, 2022, together with the comparative figures for the year ended December 31, 2021 as follows. These consolidated financial statements of our Group for the Reporting Period have been reviewed by the Audit Committee.

In this announcement, “Zhaoke Ophthalmology”, “we”, “us” and “our” refer to the Company and where the context otherwise requires, the Group. Certain amounts and percentage figures included in this announcement have been subject to rounding adjustments, or have been rounded to one or two decimal places. Any discrepancies in any table, chart or elsewhere between totals and sums of amounts listed therein are due to rounding.

BUSINESS HIGHLIGHTS

- **CsA Ophthalmic Gel:** In June 2022, our NDA submission for CsA Ophthalmic Gel, an innovative drug for DED, was accepted for review by the CDE. In January 2023, our CsA Ophthalmic Gel successively passed the on-site regulatory and clinical trial inspections by the NMPA, as well as the GMP compliance inspection conducted by the Guangdong Medical Products Administration. The passing of all three inspections marks a major milestone in our progress toward the final regulatory approval and commercialization of CsA Ophthalmic Gel.
- **NVK002:** In July 2022, Zhaoke Ophthalmology successfully completed patient recruitment of NVK002's Phase III clinical trials in China for myopia treatment. Despite the challenging environment for patient recruitment, we accomplished this milestone significantly ahead of schedule. Furthermore, we strengthened our leading position in the low-dose atropine market. Vyluma announced a successful conclusion to their global Phase III clinical study, a significant step in the lead-up to a NDA submission to FDA. Simultaneously, we have made rapid progress with our China-CHAMP and Mini-CHAMP Phase III studies in China. We also just announced our first partnership agreement for NVK002 for South Korea.
- **Glaucoma:** Our glaucoma franchise, which currently comprises seven drugs and one device for home-use IOP measurement, is advancing. In November 2022, we reached an exclusive distribution agreement to commercialize TONO-i in Greater China for self-measurement of intraocular pressure. In February 2023, Bimatoprost Timolol eye drop (晶贝莹®), the first generic drug of Bimatoprost Timolol eye drop for the treatment of glaucoma/ocular hypertension in China, received marketing authorization from the NMPA. It is also the first drug to be commercialized in our drug pipeline. In addition, the first prescription for Bimatoprost Timolol was issued in March 2023.
- **Heat Compress Eyepatch – first commercialized product:** In August 2022, we launched our online flagship store on Tmall with our first product 堡得视® the Heat Compress Eyepatch, a class II medical device for reducing symptoms of mild DED. The launch of this product marked the beginning of our commercialization strategy and has enabled us to directly engage with eye-health conscious consumers. It also exemplifies our belief that eye diseases frequently have multifactorial etiological mechanisms, and an optimized treatment regimen often requires the combination of drug(s) and device(s).
- **Presbyopia:** In May 2022, we successfully established an agreement with Visus Therapeutics and introduced an innovative drug BRIMOCHOL™ PF and Carbachol PF, to our portfolio. This makes us the first Chinese ophthalmic pharmaceutical company with advanced-staged (Phase III and above) drug candidates across all three major front-of-the-eye diseases, namely myopia, DED and presbyopia.

FINANCIAL HIGHLIGHTS

	Year ended December 31,	
	2022	2021
	RMB'000	RMB'000
Other income and gain, net	8,310	34,542
R&D expenses	(296,430)	(220,058)
General and administrative expenses	(86,109)	(162,080)
Selling and distribution expenses	(29,946)	(16,736)
Interest expenses	(3,142)	(1,949)
Changes in the carrying amount of preferred shares liability	—	(1,763,499)
Loss for the year	(407,317)	(2,129,780)
Total comprehensive income for the year	(196,415)	(2,180,971)
Non-HKFRS adjusted loss for the year ⁽¹⁾	<u>(360,633)</u>	<u>(228,311)</u>

Note:

(1) NON-HKFRS MEASURES

Non-HKFRS adjusted net loss for the year is defined as loss and total comprehensive income for the year adjusted by adding back non-cash adjustments and one-time events of (i) changes in the carrying amount of preferred shares liability in relation to the redemption amount and conversion features for our Series A Preferred Shares and Series B Preferred Shares; (ii) listing expenses; and (iii) equity-settled share-based payment expenses. The following table reconciles our non-HKFRS adjusted net loss for the year with our loss for the year.

	Year ended December 31,	
	2022	2021
	RMB'000	RMB'000
Loss for the year	(407,317)	(2,129,780)
Add:		
Changes in the carrying amount of preferred shares liability	—	1,763,499
Listing expenses	—	28,112
Equity-settled share-based payment expenses	46,684	109,858
Non-HKFRS adjusted loss for the year ⁽¹⁾	<u>(360,633)</u>	<u>(228,311)</u>

CORPORATE PROFILE

Overview

Pipeline Strategy

Zhaoke Ophthalmology is a leading ophthalmic pharmaceutical company dedicated to the research, development, manufacturing and commercialization of therapies that address significant unmet medical needs in China.

China has the largest number of eye disease patients in the world, and there is still significant unmet demand from a fast growing patient base. We are well positioned to capture the opportunity of a rapidly growing ophthalmology drug market, which is expected to reach approximately US\$11 billion in 2027, according to the information from CIC, driven by market demand and new supportive public policies in the healthcare sector in the PRC.

Zhaoke Ophthalmology's drug portfolio is one of the largest and most comprehensive in the ophthalmology industry, with innovative and generic treatments covering major diseases affecting both the front- and back-of-the-eye. In portfolio construction, we aim to strike a balance between being a "one-stop solutions provider" for ophthalmologists and focusing most of our precious resources on areas with the largest unmet needs and commercial potential. We are the only ophthalmology company in China with advanced programs, Phase III or later, in all three of the largest front-of-the-eye diseases: being DED, myopia, and presbyopia. We have several potential blockbuster innovative drug candidates in the pipeline, which we believe will be best-in-class or first-in-class, and make a significant contribution to our future revenue.

We are committed to our goal of becoming a leader in ophthalmology in China and globally and have made remarkable achievements in advancing our key clinical programs. During 2022, we filed two NDA submissions, including one of our Core Products, CsA Ophthalmology Gel, for the treatment of DED, strengthened our position in the vast market for the progression of myopia, and initiated our coverage in presbyopia by introducing an innovative drug, and received ANDA approval for Bimatoprost Timolol eye drop (晶贝莹®), our first commercialized in-house manufactured drug targeting glaucoma.

Ahead of the launch of 晶贝莹® and other innovative and generics products in the next two to three years, Zhaoke Ophthalmology has developed a robust commercialization strategy centered around an omnichannel model with multiple touchpoints with our key constituents across our online channels, including a WeChat account with high levels of ophthalmologist and eye health community engagement, as well as traditional offline channels through our experienced sales teams and partnerships with hospitals. In addition, we also launched our first commercialized product in 2022, the heat compress eyepatch 堡得视®, which is a class II medical device for patients with mild DED.

This marked our progress from a pure R&D company to a commercial pharmaceutical company. With the approval and launch of our first commercialized drug targeting glaucoma, Bimatoprost Timolol, as well as more OTC products to be included in our Tmall flagship and physical points of sales, the year ahead will help us further increase the brand awareness and accumulate experiences for the commercialization of the Company's robust drug pipeline, including the self-developed innovative treatment for DED, CsA Ophthalmic Gel and our innovative drug for myopia, NVK002.

At Zhaoke Ophthalmology, our vision is to be persistently patient- and physician-centric, harnessing our scientific rigor, and the large innovative and generic drug portfolio that we have built to address the major eye conditions affecting both the front- and back-of-the-eye. Our objective is to eliminate as far as possible all preventable eye diseases and contribute significantly to the visual health of millions of patients in China and globally. We are focused on delivering high-quality products to serve the unmet needs of patients and ophthalmologists. We are also committed to driving innovation via a state-of-the-art digitally enabled business model. We take our social responsibilities seriously and aim to help increase public awareness of eye diseases, including their detection and treatment solutions.

Our Portfolio

Our product pipeline is set out below as of the date of this announcement:

Our Innovation Drugs

Drug Candidate 候選藥物	Source 來源	Commercial Rights 商業權利	Preclinical 臨床前	IND 新藥試驗申請	Phase I 第I期	Phase II 第II期	Phase III 第III期	NDA 新藥申請
Cyclosporine A (CsA) Ophthalmic Gel 環孢素 A 眼凝膠	ZHAOKE OPHTHALMOLOGY	Global 全球	China 中國	Passed the on-site regulatory and clinical inspections and GMP inspection 通過藥品註冊及臨床試驗現場核查以及 GMP 審查				
NTC010 (levofloxacin dexamethasone combination) NTC010 (左氧氟沙星與 地塞米松複方)	ntc	China 中國	China 中國				Certain Countries of the EU: Commercialized (NTC and Santen) 若干歐盟國家: 商業化(NTC及Santen)	
NVK002 (Atropine) NVK002(阿托品)	Vyluma	Greater China, South Korea and ASEAN ¹ 大中華區、南韓及若干東盟 國家 ¹	China 中國	US: Phase III trial top-line results announced (Vyluma, previously known as Nevakar) 美國: 第 III 期試驗頂線結果已公佈(Vyluma, 前稱 Nevakar)				
TAB014 (Bevacizumab) TAB014 (貝伐單抗)	東曜藥業	China 中國	China 中國					
ZKY001 (Functional fragment of Thymosin β4) ZKY001(胸腺肽β4的 功能片段)	ZHAOKE OPHTHALMOLOGY	Greater China excluding Macau 大中華區, 不包括澳門	China 中國					
BRIMOCHOL™ PF and Carbachol PF BRIMOCHOL™ PF 及 Carbachol PF	VISUS THERAPEUTICS	Greater China, South Korea and ASEAN ³ 大中華區、南韓及若干東盟 國家 ³	China 中國				US: Phase III trial ongoing (Visus) 美國: 第 III 期試驗進行中(Visus)	
NTC014 (levofloxacin and ketorolac trometamol combination) NTC014(左氧氟沙星 與酮咯酸氨丁三醇複方)	ntc	Greater China, South Korea and ASEAN ³ 大中華區、南韓及若干東盟 國家 ³	China 中國	EU: Preclinical (NTC) 歐盟: 臨床前 (NTC)				
Resolv ER (Liposome - loaded urea) Resolv ER (脂質體尿素)	KATO Pharmaceuticals	Greater China and ASEAN ¹ 大中華區及若干東盟國家 ¹	China 中國				US: Phase Ib trial ongoing (Kato) 美國: 第 Ib 期試驗進行中 (Kato)	
IC-270 (Syk inhibitor and antihistamine) IC-270 (Syk 酪氨酸激酶 抑制劑和抗組胺藥)	IACATA PHARMA	Greater China and ASEAN ¹ 大中華區及若干東盟國家 ¹	China 中國	US: Preclinical (IACATA) 美國: 臨床前 (IACATA)				
RGN-259 (Thymosin β4) RGN-259 (胸腺肽β4)	REGENEREX	Greater China 大中華區	China 中國				US: Phase III trial ongoing (RegeneRx) 美國: 第 III 期試驗進行中 (RegeneRx)	
IC-265 (Syk inhibitor) IC-265 (Syk 酪氨酸激酶 抑制劑)	IACATA PHARMA	Greater China and ASEAN ¹ 大中華區及若干東盟國家 ¹	China 中國				US: Phase II trial completed in allergic conjunctivitis (IACATA) 美國: 過敏性結膜炎第 II 期試驗完成 (IACATA)	
PAN-90806 (VEGFR2 inhibitor) PAN-90806 (VEGFR2 抑制劑)	PANOPTICA	Greater China, South Korea and ASEAN ² 大中華區、南韓及若干東盟 國家 ²	China 中國				US: Phase I/II trial completed (PanOptica) 美國: 第 I/II 期試驗完成 (PanOptica)	
CsA/Rebamipide Ophthalmic Gel 環孢素 A/瑞巴派特 眼凝膠	ZHAOKE OPHTHALMOLOGY	Global 全球	China 中國					
ZK002	ZHAOKE OPHTHALMOLOGY	Global 全球	China 中國					

▶ Our Progress 我們的進度
▶ Expected Next Step 預期下一階段
▶ Progress of Our Licensing Partner 我們許可方夥伴的進度

* May not require a Phase I clinical trial prior to initiating a Phase II clinical trial.

** May not require a Phase I and/or Phase II clinical trials prior to initiating a Phase III clinical trial.

- (1) Including Brunei, Myanmar (Burma), Cambodia, Timor-Leste, Indonesia, Laos, Malaysia, the Philippines, Singapore, Thailand and Vietnam
- (2) Including Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar (Burma), the Philippines, Singapore, Thailand and Vietnam
- (3) Including Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar (Burma), the Philippines, Singapore, Thailand, Vietnam and Sri Lanka

Our Generic Drugs

Drug Candidate 候選藥物	Indication 適應症	Reference Drug 參照藥	MOA 作用機制
Bimatoprost 貝美前列素	Glaucoma 青光眼	Lumigan	PGA monotherapy PGA單一療法
Bimatoprost Timolol 貝美素噁嗎洛爾	Glaucoma 青光眼	Ganfort	PGA and β blocking agent combotherapy PGA及 β 受體拮抗劑聯合療法
Latanoprost 拉坦前列素	Glaucoma 青光眼	Xalatan	PGA monotherapy PGA單一療法
Latanoprost Timolol 拉坦噁嗎	Glaucoma 青光眼	Xalacom	PGA and β blocking agent combotherapy PGA及 β 受體拮抗劑聯合療法
Travoprost 曲伏前列素	Glaucoma 青光眼	Travatan	PGA monotherapy PGA單一療法
Travoprost Timolol 曲伏噁嗎	Glaucoma 青光眼	DuoTrav	PGA and β blocking agent combotherapy PGA及 β 受體拮抗劑聯合療法
Levobetaxolol HCl 鹽酸左倍他洛爾	Glaucoma 青光眼	Betaxon	Monotherapy β blocker 單一療法的 β 受體拮抗劑
Epinastine HCl 鹽酸依匹斯汀	Allergic conjunctivitis 過敏性結膜炎	Elestat	Dual-acting antihistamine and mast cell stabilizers 雙效抗組胺藥及肥大細胞穩定劑
Natamycin 納他黴素	Fungal eye infections 眼部真菌感染	Natacyn	Antifungal 抗真菌
Proparacaine HCl 鹽酸丙美卡因	Surface anesthesia 表面麻醉	Alcaine	Block nerve conduction in the corneal tissue 阻礙角膜組織中的神經傳導
Povidone Iodine 聚維酮碘	Periocular and ocular surface disinfection 眼周及眼表消毒	Betadine	Microbicidal/Antimicrobial action by iodine 碘的殺菌/抗菌作用
Fluorescein Sodium 螢光素鈉	Diagnostic for certain eye injuries 眼表損傷診斷	Minims fluorescein sodium	Fluorescent dye 螢光染色

MANAGEMENT DISCUSSION AND ANALYSIS

BUSINESS REVIEW

Pipeline Strategy

Zhaoke Ophthalmology has established a comprehensive asset portfolio with innovative and generic drugs that address the six major eye diseases across both the front-and back-of-the-eye. The six major ophthalmic indications in terms of the market potential in China are DED, myopia, presbyopia, wAMD, DME and glaucoma. We have chosen multiple drug candidates to address these diseases, as we believe this is the best way to treat their multiple and complex underlying causes.

Innovative drugs

Our Company has several key potential blockbuster innovative drugs in the pipeline for the next few years.

CsA Ophthalmic Gel for DED (self-developed)

Overview

CsA Ophthalmic Gel is an innovative drug being developed by Zhaoke Ophthalmology for the treatment of DED. It is a single, daily dose hydrogel that eliminates daytime administration and the associated discomfort and inconvenience, and aims to dramatically improve patients' treatment compliance and quality of life. The proprietary hydrogel formulation is protected with patent approval in China and internationally. This novel formulation enhances the pharmacokinetic profiles of CsA on the ocular surface, allowing efficacy similar to that of Cyclosporine A products currently available for DED. However, unlike the current treatment, CsA Ophthalmic Gel's unique formulation stays on the eye for longer, requiring only once-a-day dosing (compared with traditional twice-a-day dosing). In Phase III clinical trial, the treatment also showed a faster onset of action by demonstrating efficacy at around the two-week time period.

Updates during the Reporting Period and up to the date of this announcement

On June 8, 2022, the NDA submission for CsA Ophthalmic Gel was accepted for review by the CDE.

On January 31, 2023, CsA Ophthalmic Gel passed the on-site regulatory and clinical trial inspections by the NMPA, and the GMP compliance inspection conducted by the Guangdong Medical Products Administration.

Zhaoke Ophthalmology continues to target regulatory approval and commercialization of CsA Ophthalmic Gel in China in early 2024. Given the prevalence of DED globally and the differentiated profile of CsA Ophthalmic Gel, the Company is also exploring opportunities outside of China. Specifically, the Company will continue the dialog with the FDA regarding a clinical development pathway for CsA in the U.S. with the aim of getting into the position for U.S. IND filing around the end of 2023.

NVK002 (Atropine) for Myopia (partnered with Vyluma)

Overview

To date, low concentration atropine is the only medication that is consistently effective in myopia progression control among children and adolescents. Zhaoke Ophthalmology's NVK002 is currently positioned as the first clinically proven pharmaceutical product approved for treating the progression of myopia globally. This treatment has a proprietary formulation that successfully addresses the instability of low-concentration atropine, with patent protection in the U.S. as well as in China, and is preservative-free with an expected shelf life of over 24 months.

Zhaoke Ophthalmology’s licensing partner for NVK002 is Vyluma, a wholly owned subsidiary of U.S.-based Nevakar Inc. Vyluma has successfully completed the Phase III clinical trial for NVK002 in the U.S. and EU and announced encouraging top-line results of the three-year trial in October 2022.

In September 2021, Zhaoke Ophthalmology received approval from the CDE to initiate two concurrent Phase III clinical trials, including a two-year Phase III clinical trial (“**China CHAMP**”) and a one-year Phase III bridging trial (“**Mini-CHAMP**”) in China.

The China CHAMP trial is led by Professor Wang Ningli from Beijing Tongren Hospital as the principal investigator and involves 19 centers and 777 patients. The Mini-CHAMP trial is jointly led by Professor Qu Xiaomei from the Eye and ENT Hospital of Fudan University and Professor Yang Xiao from the Zhongshan Ophthalmic Center of Sun Yat-Sen University as principal investigators and involves 18 centers and 526 patients.

Combined with global data from Vyluma’s Phase III clinical trial (CHAMP) in the U.S. and EU, we believe the overall CHAMP trial for NVK002 will be one of the largest, longest and most comprehensive Phase III clinical trials for low dose atropine use in the world.

Updates during the Reporting Period and up to the date of this announcement

Patient recruitment was completed significantly earlier than expected across both NVK002 trials in China, giving our Company a strong head start in moving towards its goal of becoming one of the first companies to commercialize myopia progression treatment in China and beyond, despite the challenging COVID-19 environment in 2022.

The China CHAMP trial completed enrolment on July 21, 2022, two months ahead of schedule; while the Mini-CHAMP trial completed enrolment on July 28, 2022, three months ahead of schedule.

In March 2023, we entered into a distribution and supply agreement on NVK002 with Kwangdong Pharmaceutical Co., Ltd. (“**KDP**”), a Korean-based company principally engaged in the manufacturing and distribution of pharmaceutical products. Under the terms of the agreement, KDP was granted exclusive rights to import, promote, distribute, market, and sell NVK002 in South Korea. Such partnership marked we have taken a concrete step towards expanding our global footprint, while creating new business opportunities as well as developing new revenue streams for our Group.

We expect to complete the one-year Mini-CHAMP bridging trial of NVK002 in the second half of 2023, and the two-year China CHAMP trial in the second half of 2024. Zhaoke Ophthalmology is well-positioned as one of the first companies to commercialize a myopia drug in the mainland China market, with a widened lead, particularly if we are able to combine the data from Mini-CHAMP and those from the successful Phase III clinical study conducted by our partner Vyluma for NDA submission.

BRIMOCHOL™ PF and Carbachol PF (partnered with Visus)

Overview

BRIMOCHOL™ PF and Carbachol PF are pupil-modulating eye drops designed to be once-daily, preservative-free therapeutics to correct the loss of near vision associated with presbyopia. BRIMOCHOL™ PF is a fixed-dose combination of carbachol (a cholinergic agent) and brimonidine tartrate (an alpha-2 agonist). Carbachol PF is a proprietary, preservative-free formulation of carbachol monotherapy. Both investigational therapies reduce the size of the pupil resulting in a “pinhole effect” so that only centrally focused light rays are able to enter the eye, thereby sharpening both near and intermediate images.

Zhaoke Ophthalmology’s licensing partner for Brimochol is Visus, a clinical-stage pharmaceutical company focused on developing innovative ophthalmic therapies with offices in Seattle, Washington, and Irvine, California. In Visus’ Phase II study, VIVID, both formulations met primary and secondary endpoints, demonstrating a three-line improvement in near visual acuity with no loss of distant vision for up to nine hours. Both BRIMOCHOL™ PF and Carbachol PF were well tolerated with no serious adverse events. Visus is currently conducting Phase III pivotal trials.

Concurrent with the ongoing Phase III clinical study of BRIMOCHOL™ PF and Carbachol PF in the U.S., Zhaoke Ophthalmology plans to file IND for a Phase Ib/II study in China in late 2023 which, if successful, will be followed by a Phase III study.

TAB014 (Bevacizumab) for wAMD (partnered with TOT BIOPHARM)

Overview

TAB014 is the first clinical-stage bevacizumab-based antibody indicated for wAMD in China. Bevacizumab is a clinically validated anti-VEGF drug. Globally, bevacizumab is approved for oncology treatment through intravenous infusion. However, there has been increasing off-label use of bevacizumab via intravitreal injection for the treatment of wAMD.

Updates during the Reporting Period and up to the date of this announcement

In March 2022, Zhaoke Guangzhou, a wholly-owned subsidiary of the Company, and TOT BIOPHARM Co., Ltd., a wholly-owned subsidiary of TOT BIOPHARM, entered into a supplemental agreement, pursuant to which Zhaoke Guangzhou now has full control in the execution of clinical trials and the ultimate decision-making power in the development and commercialization of TAB014 in China, Hong Kong and Macau. Zhaoke Guangzhou has also been given the right to develop TAB014 for other ophthalmic indications besides wAMD and/or novel formulations for ophthalmic indications.

We recruited the first patient for the Phase III clinical trial on June 28, 2022, and expect to complete patient recruitment before the end of 2023.

The Phase III clinical trial of TAB014 is a randomized, double-blind and non-inferiority study. The main objective of the study is to evaluate the change from baseline in best corrected visual acuity at week 52 in TAB014-treated subjects group compared with the Lucentis®-treated subjects group. The study involves approximately 60 centers and a total of 488 patients, led by Professor Chen Youxin from Peking Union Medical College Hospital as the principal investigator.

ZKY001 (self-developed)

Overview

ZKY001 is a seven-amino acid peptide derived from the functional fragment of Thymosin β 4 that binds actin, a type of protein that plays a central role in cell structure and movement. ZKY001 has broad applications in the healing of corneal wounds and can potentially be used in multiple corneal repair indications. Zhaoke Ophthalmology has been exploring multiple indications for ZKY001, including CED; TPRK, a surgical treatment for myopia; pterygium, a growth in the cornea or the conjunctiva; and NK, a rare degenerative corneal disease.

Zhaoke Ophthalmology has conducted Phase II clinical trials of ZKY001 for CED, TPRK and Pterygium and an investigator initiated trial for NK. The research and clinical teams aim to analyze all the results across these studies to determine the direction for development of this asset and next steps.

NTC010 (Partnered with NTC)

Overview

NTC010 is a fixed dose combination of antibiotics and steroids to prevent infection and inflammation for patients undergoing cataract surgery. The drug belongs to a new generation of antibiotics, which increase efficiency and cover a wider range of bacteria. The drug also shortens the duration of the treatment by half – from 14 to seven days – making it beneficial to patients' overall health and helping to prevent antibiotic overuse.

The drug has already been approved across the EU and in 15 extra-Europe countries/areas and is expected to be further rolled out across extra-Europe countries. According to the information from CIC, NTC010 is the first eye drop product marketed in the EU that combines a quinolone antibiotic with an anti-inflammatory steroid.

The Company submitted an NDA in conjunction with a clinical trial exemption based on the existing European clinical data to the NMPA in November 2022.

PAN-90806 (VEGFR2 inhibitor) for wAMD and DME (partnered with PanOptica)

Overview

PAN-90806 is an innovative drug indicated in the treatment of wAMD, as well as DME, the leading cause of blindness in diabetic patients worldwide.

PAN-90806 is a novel eye drop formulation. The goal is to be applied as a maintenance therapy in order to reduce the frequency of intravitreal injections and other treatment issues associated with mainstream anti-VEGF therapies while at the same time maintaining visual stability. If successful, the use of PAN-90806 is expected to significantly reduce treatment discontinuation, and therefore slow underlying disease progression through improved patient comfort, acceptance, convenience and compliance.

Zhaoke Ophthalmology is currently focused on optimizing the formulation of PAN-90806. The Company plans to file IND for patient trials after the completion of requisite animal studies.

Generic drugs

We follow a balanced approach in designing our drug pipeline. In addition to innovative drug candidates, our Company has several key generic drugs in the pipeline. The market potential for the management and treatment of ocular disease in China is unmatched globally. Generic drugs address a substantial portion of current ophthalmic medical needs in China. From a market demand perspective, our generic pipeline complements our innovative pipeline and positions us to provide total solutions to ophthalmologists and patients.

We made meaningful progress across our generic programs in the Reporting Period. In particular, we obtained marketing authorization from the NMPA in February 2023 for Bimatoprost Timolol eye drop, known as 晶贝莹® in the PRC and researched, developed and manufactured by us, for the treatment of glaucoma.

Bimatoprost Timolol eye drop (晶贝莹®) is used to lower the IOP in patients with primary open-angle glaucoma or ocular hypertension who do not respond sufficiently to β -blockers or PGA. It is the first generic drug of Bimatoprost Timolol eye drop for the treatment of glaucoma or ocular hypertension in China.

Bimatoprost Timolol eye drop (晶贝莹®) is also our Company's first drug approved for commercialization. The first prescription for this drug was written on March 8, 2023 in Guangzhou. The launch of this product will help expand brand recognition of Zhaoke Ophthalmology to support the future commercial launch of our innovative drugs.

We also aim to file ANDA submissions for various candidates in our generic drug pipeline this year in glaucoma and other areas.

WARNING UNDER RULE 18A.08(3) OF THE LISTING RULES: WE MAY NOT BE ABLE TO ULTIMATELY DEVELOP AND MARKET OUR DRUG CANDIDATES SUCCESSFULLY.

Manufacturing

Zhaoke Ophthalmology has its own state-of-the-art manufacturing facility, located in Nansha New District, Guangzhou, Guangdong Province, China. This facility gives us the strategic advantage of full manufacturing capability inhouse, from production, dosing, filling and packaging to quality assurance. The facility occupies approximately 7,600 sq.m. with equipment and machinery from leading global manufacturers. It is designed in accordance with the highest international standards and requirements of major global regulators, including the FDA, the NMPA and the EMA. The facility currently has three manufacturing lines which are all ready for mass production.

In February 2023, our Bimatoprost Timolol eye drop (晶贝莹®) obtained marketing authorization in China from the NMPA. This eye drop will be manufactured in our manufacturing facility.

As Zhaoke Ophthalmology transforms from a pure R&D to a commercial pharmaceutical company, we have increased investment in our production facility to expand production capacity. For example, our production capacity for single dose drugs has already increased tenfold since its inception.

Commercialization

Having the right people in place to support commercialization is critical. Following the ANDA approval of our Bimatoprost Timolol eye drop (晶贝莹®), our Company is planning to expand our sales and marketing team from 45 people as at the end of 2022, to over 100 as at the end of 2023.

To prepare for the upcoming commercialization of our drug candidates, we have also established an omnichannel strategy leveraging both online and offline channels.

We recognize the rapidly shifting dynamics of the Chinese ophthalmic industry and believe that the traditional way of selling drugs must be complemented by new channels such as digital, social and e-commerce. Our innovative model does not rely solely on traditional channels such as public hospitals and private eye hospitals or institutions, but also builds brand visibility in the digital world through our innovative use of WeChat, the most commonly used mobile application in China, and other online platforms.

Since its launch in September 2021, our content-driven platform on WeChat, Zhaoke Boshi, has been growing rapidly. Zhaoke Boshi lends a stage to leading KOLs in the industry to share their knowledge and insights, while facilitating discussion amongst the broader Chinese ophthalmic community. As of the date of this announcement, Zhaoke Boshi has over 11,000 followers and over 60 leading KOLs and ophthalmologists have contributed content or participated in livestream discussions. We believe that this outreach will help solidate our position as the trusted partner for Chinese ophthalmologists and continue to differentiate and enhance Zhaoke Ophthalmology's leadership in the industry.

In addition to building a digital community on WeChat, Zhaoke Ophthalmology launched a Tmall flagship store for our first commercialized product 堡得视® heat compress eyepatch on August 15, 2022. This eyepatch is an approved class II medical device for people with mild DED.

The successful launch of the product has strategic meaning for our Company as it exemplifies our core mission in two major significant areas. Firstly, many eye diseases are caused by multiple and complex pathogenic pathways, meaning that a single treatment may not always suffice. Although our R&D efforts will primarily focus on ophthalmic drugs, we believe a combination of drug regimen therapy and medical device will ultimately deliver better treatment options for patients. As such, our 堡得视® heat compress eyepatch is considered as a companion therapy for patients suffering from differing degrees of DED. We will continue this approach across multiple indications and opportunistically engage with potential partners to deliver diagnostic and therapeutic solutions alongside our drug assets. We are confident that this strategy will provide a meaningful benefit to patients and ophthalmologists over the short and long term.

Secondly, the launch of our Tmall flagship store and the heat compress eyepatch enables us to establish brand awareness directly amongst eye-health-conscious consumers in China. This lays a solid foundation for our Company ahead of the commercialization of our drugs.

Research and Development

Although our business encountered broad and macro challenges in 2022, we remained focused on R&D as the backbone, and we were able to significantly progress our R&D efforts during the Reporting Period.

The surge of COVID-19 cases in China in 2022 negatively affected various aspects of the ongoing clinical trials of our drug assets including patient recruitment. However, thanks to the effort and determination of our teams, we were able to broadly maintain the pace of our clinical programs. In fact, patient recruitment of the two concurrent Phase III trials of NVK002 was completed significantly ahead of schedule.

Our R&D team has a time-tested track record and is led by an international management team with decades of industry experience working in global biotechnology and pharmaceutical companies. In 2022, we increased the size of our R&D team, from approximately 80 professionals in 2021, to 100 at the end of the Reporting Period.

For the year ended December 31, 2022, our R&D expenses totaled approximately RMB296.4 million, showing an increase of approximately 34.7% from approximately RMB220.0 million for the year ended December 31, 2021.

Partnerships

Zhaoke Ophthalmology has established multiple licensing partnerships with leading companies in China, the U.S. and the EU, and will continue to build our global footprint.

In February 2022, Zhaoke Ophthalmology established a corporate gift agreement with John Hopkins University, one of the world's leading private research institutes, to support translational research and academic exchange. The donation will be used to benefit the Johns Hopkins' Wilmer Eye Institute as a current use gift over the coming year, supporting translational research at the Institute, academic exchanges and mentoring opportunities between Zhaoke Ophthalmology and the Wilmer Eye Institute.

In March 2022, Zhaoke Ophthalmology signed strategic partnership agreements with three of China's leading pharmaceutical supply chain service companies: Sinopharm Group Distribution Co., Ltd. (國藥控股分銷中心有限公司), Shanghai Pharmaceuticals Co., Ltd. (上藥控股有限公司), and China Resources Pharmaceutical Commercial Group Limited (華潤醫藥商業集團有限公司). Zhaoke Ophthalmology and the three leading Chinese pharmaceutical companies will collaborate on multiple aspects including but not limited to procurement models and logistics management. These collaborations will be critical to our distribution capabilities as a commercial-stage company.

We will continue to explore partnership and collaboration opportunities with leading domestic and international pharmaceutical firms and research institutions, thereby strengthening our R&D capability and expanding our drug portfolio, particularly in areas where we see white space in our current coverage of key ophthalmic indications. We will also have the chance to explore partnerships as we expand our footprint to adjacent country markets.

Environment, Social and Governance (“ESG”)

As a responsible enterprise, Zhaoke Ophthalmology is committed to the development of a sustainable healthcare industry in China. We rigorously monitor the environmental and social impact of our operations and implement measures to improve the sustainability of our business.

We clearly define the ESG responsibilities of the Board and senior management and have established a sustainability steering committee to assist the Board in its management and supervision of the progress and results of relevant initiatives.

As an example, since China’s announcement of its national target to achieve carbon neutrality by 2060, our Company has taken steps to reduce its carbon emissions. To effectively manage the risks and opportunities brought on by climate change, our Company has devised its own climate change policy and nurtured a top-down management culture to tackle the impact of climate change on the environment from five perspectives, namely governance, mitigation, adaptation, resistance and disclosure.

Zhaoke Ophthalmology has also invested in building a strong corporate culture and working environment within our Company for our people to continue to grow and develop their capabilities. Our mentoring and apprenticeship programs have been integral to our success in 2022 and illustrate the passion of our people to build the experience and know-how of their colleagues, and to ensure that our huge array of experience is shared across all of our teams wherever possible. Our Company supports a diverse and inclusive working environment and is committed to equal employment and advancement opportunities for all people. As at the end of the Reporting Period, about 53% of our total employees were women, with 42% of them managers and executives. Over half of our new employees hired in the past year were female.

We take our social responsibilities seriously and aim to address the urgent unmet need to increase public awareness of eye diseases, including their detection and treatment solutions. For example, during World Glaucoma Week in March 2022, we initiated the “Glaucoma Commonwealth Campaign”, inviting well-known glaucoma ophthalmologists in China for live streaming to improve public’s awareness of early screening of glaucoma and rational administration for better glaucoma management. On June 6, 2022, we ran the “National Eyecare Day Commonwealth Campaign” jointly with influential ophthalmic KOLs to raise the public’s awareness of children and adolescents in myopia control on various local TV channels and digital platforms.

Zhaoke Ophthalmology is committed to transparency and compliance, disclosing our ESG performance annually under ESG section in our annual report.

FUTURE AND OUTLOOK

2023 should be another transformative year for Zhaoke Ophthalmology. At the beginning of this year, we announced that our self-developed innovative drug CsA Ophthalmic Gel, passed the onsite inspections and clinical inspections conducted by the NMPA and GMP inspection by the Guangdong Medical Products Administration. Shortly after that, in February 2023, our generic treatment for glaucoma, Bimatoprost Timolol eye drop obtained the marketing authorization from the NMPA. Together with the launch of our heat compress eyepatch on our Tmall flagship store in August 2022, these milestones mark the transformation of Zhaoke Ophthalmology from a pure R&D company into a commercial pharmaceutical company.

Looking forward, we remain committed to our ambitious “dual-engine” growth strategy, which includes the advancement of clinical programs of our innovative and generic drug assets, and the execution of our comprehensive and innovative commercialization model leveraging both online and offline channels. We will also continue to explore mutually value-creating partnership opportunities with domestic and international organizations to support our goal to improve the visual health of people globally.

Regarding our commercial enterprise, we will continue to invest in omnichannel capabilities and sales marketing team to support our vision as we head into 2023. We strongly believe that combining multiple offline channels and interactions with physicians with online/social presence and e-commerce will be a paradigm shift in commercialization, and is key to future success.

Our content-driven WeChat account Zhaoke Boshi has created a dynamic conversation online around cutting-edge research and treatment for eye diseases amongst ophthalmologists. Having firmly established its reputation with high quality content, we are introducing new features and content categories in Zhaoke Boshi to increase interaction with younger physicians. We are excited to witness the growing influence of this online platform and the enhancement of our brand awareness amongst the physician community.

At the same time, we are adding more product SKUs to our 堡得视® flagship store on Tmall as we believe a more comprehensive range of OTC products can boost brand awareness for a broader range of consumers, some of whom we believe will undoubtedly become end-users of our prescription products. We are convinced that these efforts will enhance and further differentiate Zhaoke's leadership.

In terms of the product pipeline, we anticipate multiple milestones in 2023, led by the extremely large market opportunity with expanding prevalent rates of disease entities in refractive error (progressive myopia and presbyopia), DED, wAMD and others. Specifically:

- **CsA Ophthalmic Gel:** We look forward to making significant progress with the NDA review process for our flagship product, CsA Ophthalmic Gel, ahead of the commercial launch in 2024. In addition, we continue the dialog with FDA regarding a clinical development pathway for CsA in the U.S. and work towards a IND filing around the end of the year. We are also in active dialogs with potential partners for development in the EU.
- **NVK002:** We expect to complete the Mini-CHAMP clinical trial for NVK002 this summer. Assuming positive results and support from the CDE, we plan to make an NDA submission using the combined global CHAMP and Mini-CHAMP studies in China. With U.S. NDA submission by Vyluma expected within a relatively short order, NVK002 continues to be well positioned to become the first clinically proven and approved pharmaceutical product for treating myopia progression globally.
- **Glaucoma:** Our glaucoma franchise, comprised of seven drugs and one device for home-use IOP measurement, is advancing. We anticipate making additional five to six ANDA submissions in 2023.
- **Epinastine:** We anticipate the completion of the Phase III clinical trial for Epinastine, an antihistamine targeting allergic conjunctivitis with anti-inflammatory and mast cell stabilization properties, followed by an ANDA submission.

- **TAB014:** We aim to complete patient recruitment for the Phase III clinical trial for TAB014, the first clinical-stage bevacizumab-based antibody indicated for wAMD in China.
- **Brimochol:** We aim to file IND for a Phase Ib/II study in China later this year, which, if successful, will be followed by a Phase III study.
- **ZKY001:** We are actively reviewing the results from three recently completed Phase II studies (for CED, Pterygium and TPRK), and aim to crystalize the study design to progress to Phase III for this in-house developed asset.

In 2022, Zhaoke Ophthalmology continued its focus on prudent cash management. As at the end of the Reporting Period, we had RMB1,716.4 million cash or cash equivalents and time deposits, giving Zhaoke Ophthalmology a robust position from which to continue advancing the clinical programs of our innovative and generic drug candidates, and to further invest in our commercialization model as we prepare to launch further drugs.

Moving into 2023, we are encouraged by positive sentiment particularly in Hong Kong and the PRC. As indicated by the National Eye Health Plan included as part of the “Fourteenth Five-Year Plan for National Economic and Social Development of the PRC and the Outline of Vision Goals for 2035 (中華人民共和國國民經濟和社會發展第十四個五年規劃和2035年遠景目標綱要)”, we are encouraged to see ophthalmology as a key focus area for the Chinese government as part of the overall development of the healthcare sector. At the same time, we are pleased to see that the Chinese government has designated three geographic areas as future centers of excellence for healthcare, including the Greater Bay Area, home to Zhaoke Ophthalmology’s state-of-art manufacturing facility.

2023 marks the beginning of a new chapter for Zhaoke Ophthalmology. Through our team’s continued hard work and dedication, we will see our product pipeline, commercial infrastructure, ophthalmologic community engagement and key partnerships coming together to deliver a truly transformative year. These efforts are continually inspired by the pursuit of our goal to address significant unmet medical needs across different eye diseases to improve public visual health through scientific research as quickly as possible.

FINANCIAL REVIEW

	Year ended December 31,	
	2022	2021
	RMB'000	RMB'000
Other income	38,041	21,133
Other net (loss)/gain	(29,731)	13,409
R&D expenses	(296,430)	(220,058)
General and administrative expenses	(86,109)	(162,080)
Selling and distribution expenses	(29,946)	(16,736)
Interest expenses	(3,142)	(1,949)
Changes in the carrying amount of preferred shares liability	—	(1,763,499)
Loss for the year	(407,317)	(2,129,780)
Other comprehensive income for the year		
Item that may be reclassified subsequently to profit or loss:		
Exchange differences on translation of financial statements of entities with functional currencies other than RMB	210,902	(51,191)
Total comprehensive income for the year	(196,415)	(2,180,971)
Non-HKFRS Measures		
Adjusted loss for the year	(360,633)	(228,311)

Overview

For the year ended December 31, 2022, we recorded total loss of approximately RMB407.3 million, as compared with approximately RMB2,129.8 million for the year ended December 31, 2021, mainly due to the changes in the carrying amount of preferred shares liability in relation to the redemption amount and conversion features for the Series A Preferred Shares and Series B Preferred Shares, before they were converted into ordinary Shares on the Listing Date being no longer recognized in 2022. Our R&D expenses for the year ended December 31, 2022 were approximately RMB296.4 million, representing an increase of approximately 34.7% from approximately RMB220.1 million for the year ended December 31, 2021, primarily due to the increased expenses incurred for clinical trials and R&D activities for our key innovative products, including Phase III clinical trial for NVK002 and three Phase II clinical trials of ZKY001 for CED, TPRK and Pterygium and an investigator initiated trial for NK, a rare degenerative corneal disease, during the Reporting Period.

Other Income

The Group's other income primarily consists of bank interest income and government grants received from government authorities. For the year ended December 31, 2022, the Group's other income increased to approximately RMB38.0 million, compared to approximately RMB21.1 million for the year ended December 31, 2021. The increase was primarily attributable to the increase of bank interest income received from fixed deposits of approximately RMB30.4 million in 2022, which was partially offset by the effect of the decrease in one-off government subsidies received from government authorities for our on-going R&D activities in 2022.

	Year ended December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Government grants	7,479	16,090
Bank interest income	30,415	5,036
Others	147	7
Total	<u>38,041</u>	<u>21,133</u>

Other Net (Loss)/Gain

For the year ended December 31, 2022, we recorded approximately RMB29.7 million of other net loss, compared to approximately RMB13.4 million of other net gain for the year ended December 31, 2021. Such net (loss)/gain primarily consists of net foreign exchange gain or loss in connection with fund transfers among bank accounts in different currencies and bank balances that are denominated in U.S. dollars.

R&D Expenses

The Group's R&D expenses primarily consisted of: (i) clinical trial professional service fees, primarily including payments to contract research organizations, hospitals and other medical institutions and testing fees incurred for preclinical studies and clinical trials; (ii) depreciation and amortization in relation to our R&D equipment and facilities; (iii) staff costs, including salaries, bonus and welfare payments for R&D personnel; (iv) costs of raw materials and consumables used for R&D of our drug candidates; (v) equity-settled share-based payment for R&D personnel; and (vi) utilities.

For the year ended December 31, 2022, our R&D expenses increased by approximately RMB76.4 million, or 34.7%, to approximately RMB296.4 million from approximately RMB220.1 million for the year ended December 31, 2021. The increase was mainly due to (i) the continuous advancement of our clinical trials and increased investments in the ongoing R&D projects (i.e. Phase III clinical trial for NVK002 and three Phase II clinical trials of ZKY001 for CED, TPRK and Pterygium and an investigator initiated trial for NK, a rare degenerative corneal disease during the Reporting Period); and (ii) increase in headcount of R&D personnel.

The following table sets forth the components of the Group's R&D expenses for the years indicated:

	Year ended December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Clinical trial professional service fee	155,631	113,207
Staff costs	49,391	29,992
Depreciation and amortization	31,625	23,928
Cost of raw materials and consumables used	21,662	10,362
Equity-settled share-based payment	10,697	21,972
Utilities	5,668	4,018
Other ⁽¹⁾	21,756	16,579
	<hr/>	<hr/>
Total	296,430	220,058
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Note:

⁽¹⁾ Represent travel and accommodation expenses, repair and maintenance expenses and other miscellaneous expenses in relation to our R&D activities.

General and Administrative Expenses

Our general and administrative expenses consist of: (i) staff costs; (ii) professional service fees for legal, consulting and auditing services; (iii) general operating expenses; (iv) depreciation in relation to our office equipment; and (v) equity-settled share-based payment for those other than R&D personnel and commercialization team.

For the year ended December 31, 2022, our general and administrative expenses were approximately RMB86.1 million, representing a decrease of approximately RMB76.0 million from approximately RMB162.1 million for the year ended December 31, 2021, which is primarily attributable to (i) the decrease in equity-settled share-based payment; and (ii) the listing expenses in connection with the IPO only incurred in the year of 2021.

The following table sets forth the components of our general and administrative expenses for the years indicated:

	Year ended December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Equity-settled share-based payment	33,317	81,532
Staff costs (include directors' fee)	31,931	27,583
Professional service fees	13,994	14,961
Depreciation	2,717	1,769
General operating expenses	2,429	3,385
Listing expenses	–	28,112
Donation	–	2,486
Other ⁽¹⁾	1,721	2,252
	<hr/>	<hr/>
Total	86,109	162,080
	<hr/> <hr/>	<hr/> <hr/>

Note:

⁽¹⁾ Represent certain tax expenses and other miscellaneous expenses.

Selling and Distribution Expenses

Our selling and marketing expenses mainly consist of staff costs for our commercialization team and marketing & conference expenses. Our selling and distribution expenses increased from RMB16.7 million for the year ended December 31, 2021 to approximately RMB29.9 million for the year ended December 31, 2022, primarily attributable to an increase in the headcount of our commercialization team and building-up of omnichannel marketing platform, together with pre-launch marketing activities for upcoming commercialization during the year.

The following table sets forth the components of our selling and distribution expenses for the years indicated:

	Year ended December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Staff costs	20,835	7,632
Equity-settled share-based payment	2,670	6,354
Marketing & Conference expenses	2,074	1,604
Depreciation	731	288
Other	3,636	858
	<hr/>	<hr/>
Total	29,946	16,736
	<hr/> <hr/>	<hr/> <hr/>

Finance Cost

Our finance costs primarily consist of (i) interest on lease liabilities related to our leases of office premises and manufacturing and R&D facilities; and (ii) interest on bank loan.

The following table sets forth the components of our finance costs for the years indicated:

	Year ended December 31,	
	2022	2021
	<i>RMB'000</i>	<i>RMB'000</i>
Changes in the carrying amount of preferred shares liability	–	1,763,499
Interest on lease liabilities	1,783	1,352
Interest on bank loan	1,359	597
	<hr/>	<hr/>
Total	3,142	1,765,448
	<hr/> <hr/>	<hr/> <hr/>

Income Tax

We did not incur any income tax during the years ended December 31, 2021 and 2022.

BVI and Cayman Islands

We were incorporated in the BVI in January 2017 and redomiciled to the Cayman Islands in April 2020. Pursuant to the laws and regulations of the BVI, we were not subject to any income tax there before we were redomiciled to the Cayman Islands. We are an exempted company with limited liability under the Companies Act of Cayman Islands and accordingly are exempted from Cayman Islands income tax.

Hong Kong

We did not make any provision for Hong Kong profit tax, because our Hong Kong subsidiary, Zhaoke (Hong Kong) Ophthalmology Pharmaceutical Limited (兆科(香港)眼科藥物有限公司), did not have assessable profits in Hong Kong during the Reporting Period.

The PRC

We did not make any provision for the PRC income tax, which is at the rate of 25% pursuant to relevant PRC laws and regulations, because our PRC subsidiary, Zhaoke Guangzhou, did not have assessable profits in the PRC during the Reporting Period.

Loss for the Year

As a result of the above factors, for the year ended December 31, 2022, we recorded a loss of approximately RMB407.3 million, as compared to a loss of approximately RMB2,129.8 million for the year ended December 31, 2021.

Non-HKFRS Measure

To supplement the Group's consolidated financial statements, which are presented in accordance with the HKFRS, the Company also uses adjusted total loss for the year and other adjusted figures as additional financial measures, which are not required by, or presented in accordance with, the HKFRS. The Company believes that these adjusted measures provide useful information to its Shareholders and potential investors in understanding and evaluating the Group's annual consolidated results of operations in the same manner as they help the Company's management.

Adjusted total loss for the year represents the total loss for the year excluding the effect of equity-settled share-based payment expenses, listing expenses and certain non-cash items and one-time events, namely changes in the carrying amount of preferred shares liability. The term adjusted total loss for the year is not defined under the HKFRS. However, the Company believes that this and other non-HKFRS measures are reflections of the Group's normal operating results by eliminating the potential impact of items that the management do not consider to be indicative of the Group's operating performance. The adjusted total loss for the year, as the management of the Group believes, is adopted in the industry where the Group is operating. However, the presentation of the adjusted total loss for the year is not intended to be (and should not be) considered in isolation or as a substitute for the financial information prepared and presented in accordance with the HKFRS. Shareholders and potential investors of the Company should not view the non-HKFRS measures (i.e. the adjusted total comprehensive loss for the year) on a stand-alone basis or as a substitute for results under the HKFRS, or as being comparable to results reported or forecasted by other companies.

The table below sets forth a reconciliation of the total comprehensive loss for the year to adjusted total comprehensive loss for the year during the years indicated:

	Year ended December 31,	
	2022	2021
	RMB'000	RMB'000
Loss for the year	(407,317)	(2,129,780)
<i>Add:</i>		
Changes in the carrying amount of preferred shares liability	–	1,763,499
Listing expenses	–	28,112
Equity-settled share-based payment expenses	46,684	109,858
Non-HKFRS adjusted loss for the year ⁽¹⁾	<u>(360,633)</u>	<u>(228,311)</u>

Note:

(1) Non-HKFRS Measures

Non-HKFRS adjusted net loss for the year is defined as loss and total comprehensive income for the year adjusted by adding back non-cash adjustments and one-time events of (i) changes in the carrying amount of preferred shares liability in relation to the redemption amount and conversion features for our Series A Preferred Shares and Series B Preferred Shares; (ii) listing expenses; and (iii) equity-settled share-based payment expenses. The above table reconciles our non-HKFRS adjusted net loss for the year with our loss for the year.

Selected Data from Statement of Financial Position

	As at December 31,	
	2022	2021
	RMB'000	RMB'000
Total current assets	1,972,747	2,208,894
Total non-current assets	597,876	396,513
Total assets	<u>2,570,623</u>	<u>2,605,407</u>
Total current liabilities	194,540	89,008
Total non-current liabilities	27,710	20,912
Total liabilities	<u>222,250</u>	<u>109,920</u>
Current assets		
Other receivables and prepayments	75,457	46,800
Pledged bank balances	172,066	25,508
Time deposits with original maturity over three months	8,873	8,157
Cash and cash equivalents	1,716,351	2,128,429
Total current assets	<u>1,972,747</u>	<u>2,208,894</u>
Current liabilities		
Other payables and accruals	83,418	59,153
Amounts due to related companies	6,897	13,684
Bank loans	94,500	10,289
Lease liabilities	9,725	5,882
Total current liabilities	<u>194,540</u>	<u>89,008</u>
Net current assets	<u>1,778,207</u>	<u>2,119,886</u>

Liquidity and Source of Funding and Borrowing

Our primary uses of cash are to fund our clinical trials, manufacturing, purchase of equipment and raw materials and other expenses. During the Reporting Period, we primarily funded our working capital requirements through net proceeds from the Global Offering and the pre-IPO investments. We closely monitor uses of cash and cash balances and strive to maintain a healthy liquidity for our operations.

As at December 31, 2022, the current assets of the Group were approximately RMB1,972.7 million, including cash and cash equivalents of approximately RMB1,716.4 million, time deposits with an original maturity over three months of approximately RMB8.9 million, pledged bank balance of approximately RMB172.1 million and other current assets of approximately RMB75.5 million. As at December 31, 2022, the current liabilities of the Group were approximately RMB194.5 million, including other payables and accruals of approximately RMB83.4 million, amounts due to related companies of approximately RMB6.9 million, bank borrowings of approximately RMB94.5 million and other current liabilities of approximately RMB9.7 million.

Amounts due to related companies composed of payable for contract research organization services and are unsecured, interest-free and repayable with maximum credit terms of 30 days or on demand.

As of December 31, 2022, the Group had secured bank loan of RMB94.5 million which was repayable within one year or on demand.

The Group adopts conservative treasury policies in cash and financial management. To achieve better risk control and minimize the cost of funds, the Group's treasury is centralized. Cash is generally placed in deposits mostly denominated in U.S. Dollars, Hong Kong dollars and RMB. The Group's liquidity and financing requirements are reviewed regularly.

Pledge of Bank Balance

Our pledged bank balance was approximately RMB172.1 million as of December 31, 2022 (2021: RMB25.5 million), representing bank balances we pledged with a bank required for the issue of a letter of credit for importing certain machines and equipment, and banking facility.

Key Financial Ratios

The following table sets forth the components of our key financial ratio for the dates indicated:

	As at December 31,	
	2022	2021
Current ratio ⁽¹⁾	10.1	24.8
Gearing ratio ⁽²⁾	N/A⁽³⁾	N/A ⁽³⁾

Notes:

- ⁽¹⁾ Current ratio represents current assets divided by current liabilities as of the same date.
- ⁽²⁾ Gearing ratio represents interest-bearing borrowings less cash and cash equivalents and time deposits with original maturity over three months, divided by total equity and multiplied by 100% as of the same date.
- ⁽³⁾ As of December 31, 2021 and 2022, we were in a net cash position and thus gearing ratio is not applicable.

Contingent Liabilities

As at December 31, 2022, the Group did not have any significant contingent liabilities.

Capital Commitment

The capital commitment of the Group as at December 31, 2022 was approximately RMB277.2 million, representing an increase of approximately RMB82.5 million as compared with that of approximately RMB194.7 million as at December 31, 2021, primarily attributable to progress made in the construction of manufacturing facilities and R&D activities.

Significant Investments

For the year ended December 31, 2022, we did not have any significant investment.

Future Plans for Material Investments or Capital Assets

As of December 31, 2022, we did not have any plans for material investments and capital assets.

Material Acquisitions and Disposals

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

Employees and Remuneration

As at December 31, 2022, the Group had a total of 293 employees. The following table sets forth the total number of employees by function as of December 31, 2022:

	Number of employees	% of the total
Management	6	2.0
R&D	100	34.1
Manufacturing	67	22.9
Quality control	43	14.7
Sales and marketing	45	15.4
Environmental, health and safety	1	0.3
Administrative	31	10.6
	<hr/>	<hr/>
Total	293	100.0

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-based payment.

The total remuneration cost incurred by the Group for the year ended December 31, 2022 was approximately RMB132.1 million, as compared to approximately RMB150.2 million for the year ended December 31, 2021. The decrease was primarily attributable to the decrease of equity-settled share-based payment of approximately RMB54.8 million which was net off by an increase of approximately RMB36.7 million in employee salaries and benefits in line with the expansion in headcount.

Foreign Exchange Exposure

During the year ended December 31, 2022, the Group mainly operated in China and a majority of its transactions were settled in RMB, the functional currency of the Company's primary subsidiaries. As at December 31, 2022, a significant amount of the Group's cash and cash equivalents was denominated in Hong Kong dollars. Except for certain cash and cash equivalents, prepayments on purchases of property, plant and equipment and other payables denominated in foreign currencies, the Group did not have significant foreign currency exposure from its operations as at December 31, 2022. Our Group manages its foreign exchange risk by performing regular reviews of our net foreign exchange exposures and seeks to minimize these exposures whenever possible.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE EXPENSE

For the year ended December 31, 2022

	<i>Notes</i>	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Revenue	3	–	–
Other income		38,041	21,133
Other net (loss)/gain		(29,731)	13,409
Research and development expenses	4(b)	(296,430)	(220,058)
General and administrative expenses		(86,109)	(162,080)
Selling and distribution expenses		(29,946)	(16,736)
Loss from operations		(404,175)	(364,332)
Interest expenses	4(a)	(3,142)	(1,949)
Changes in the carrying amount of preferred shares liability	4(a)	–	(1,763,499)
Loss before taxation	4	(407,317)	(2,129,780)
Income tax	5	–	–
Loss for the year		(407,317)	(2,129,780)
Other comprehensive income for the year			
Item that may be reclassified subsequently to profit or loss:			
Exchange differences on translation of financial statements of entities with functional currencies other than Renminbi (“RMB”)		210,902	(51,191)
Total comprehensive income for the year		(196,415)	(2,180,971)
Loss per share (RMB)			
Basic	6	(0.75)	(5.16)
Diluted		(0.75)	(5.16)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

		December 31, 2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
	<i>Notes</i>		
Non-current assets			
Property, plant and equipment		233,743	184,318
Intangible assets		334,623	162,383
Prepayments on purchases of property, plant and equipment		29,510	49,812
		597,876	396,513
Current assets			
Other receivables and prepayments	7	75,457	46,800
Pledged bank balances		172,066	25,508
Time deposits with original maturity over three months		8,873	8,157
Cash and cash equivalents		1,716,351	2,128,429
		1,972,747	2,208,894
Current liabilities			
Other payables and accruals	8	83,418	59,153
Amounts due to related companies		6,897	13,684
Bank loans		94,500	10,289
Lease liabilities		9,725	5,882
		194,540	89,008
Net current assets		1,778,207	2,119,886
Total assets less current liabilities		2,376,083	2,516,399
Non-current liabilities			
Lease liabilities		27,703	20,861
Deferred income		7	51
		27,710	20,912
Net assets		2,348,373	2,495,487
Capital and reserves			
Share capital		—*	—*
Reserves		2,348,373	2,495,487
Total equity		2,348,373	2,495,487

* The balance represents amount less than RMB1,000.

NOTES TO THE CONSOLIDATED FINANCIAL INFORMATION

1. GENERAL INFORMATION

Zhaoke Ophthalmology Limited (the “**Company**”) was incorporated in the British Virgin Islands (the “**BVI**”) on January 20, 2017. On April 29, 2020, the Company was redomiciled to the Cayman Islands with its registered office at Vistra (Cayman) Limited, Grand Pavilion, Hibiscus Way, 802 West Bay Road, George Town, Grand Cayman as an exempted company with limited liability under the Companies Act, Cap 22 (Law 3 of 1961, as consolidated and revised) of the Cayman Islands (the “**Cayman Companies Act**”).

The Company is an investment holding company. The Company and its subsidiaries (together, “**the Group**”) are principally engaged in the development, manufacturing and marketing of ophthalmic drugs.

2. STATEMENT OF COMPLIANCE

The consolidated annual results set out in this announcement do not constitute the Group’s consolidated financial statements for the year ended December 31, 2022 but are extracted from those financial statements.

The Group’s consolidated financial statements have been prepared in accordance with all applicable Hong Kong Financial Reporting Standards (“**HKFRSs**”), which collective term includes all applicable individual Hong Kong Financial Reporting Standards, Hong Kong Accounting Standards and Interpretations issued by the Hong Kong Institute of Certified Public Accountants (“**HKICPA**”), accounting principles generally accepted in Hong Kong and the disclosure requirements of the Hong Kong Companies Ordinance. The Group’s consolidated financial statements also comply with the applicable disclosure provisions of the Rules Governing the Listing of Securities on the Stock Exchange.

The HKICPA has issued certain amendments to HKFRSs that are first effective or available for early adoption for the current accounting period of the Group. None of these developments have had a material effect on how the Group’s results and financial position for the current or prior periods have been prepared or presented. The Group has not applied any new standard or interpretation that is not yet effective for the current accounting period.

3. REVENUE AND SEGMENT REPORTING

(a) Revenue

The principal activities of the Group are development, manufacturing and marketing of ophthalmic drugs. No revenue was derived from these activities during the current and prior years.

(b) Segment reporting

Operating segments are identified on the basis of internal reports that the Group’s most senior executive management reviews regularly in allocating resources to segments and in assessing their performances.

The Group’s most senior executive management makes resources allocation decisions based on internal management functions and assess the Group’s business performance as one integrated business instead of by separate business lines or geographical regions. Accordingly, the Group has only one operating segment and therefore, no segment information is presented.

4. LOSS BEFORE TAXATION

Loss before taxation is arrived at after charging:

(a) Finance costs

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Interest on bank loans	1,359	597
Interest on lease liabilities	1,783	1,352
	-----	-----
	3,142	1,949
Changes in the carrying amount of preferred shares liability:		
– Changes in present value of redemption amount	–	58,208
– Changes in fair value of conversion features	–	1,705,291
	-----	-----
	–	1,763,499
	-----	-----
	<u>3,142</u>	<u>1,765,448</u>

(b) Other items

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Amortization of intangible assets	2,249	2,106
Depreciation charge		
– owned property, plant and equipment	25,740	19,296
– right-of-use assets	7,085	4,429
Auditors' remuneration		
– audit services	2,180	1,837
– audit related services	700	735
– other services	347	120
Research and development expenses	296,430	220,058
Listing expenses	–	28,112
	-----	-----
	<u>–</u>	<u>28,112</u>

5. INCOME TAX IN THE CONSOLIDATED STATEMENT OF PROFIT OR LOSS

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 operated.

(a) Cayman Islands income tax

The Company is incorporated in the Cayman Islands as an exempted company with limited liability under the Cayman Companies Act.

There is no income tax in the Cayman Islands and accordingly, the operating results reported by the Company, is not subject to any income tax in the Cayman Islands.

(b) Hong Kong income tax

No provision for Hong Kong profits tax has been provided for at the rate of 16.5% as the Company has no estimated assessable profits.

(c) The PRC corporate income tax

No provision for Mainland China income tax has been provided for at a rate of 25% pursuant to the Corporate Income Tax Law of the PRC and the respective regulations, as the Group's PRC entity has no estimated assessable profits.

6. LOSS PER SHARE

(a) Basic loss per share

The calculation of basic loss per share is based on the loss attributable to ordinary equity shareholders of the Company of RMB407,317,000 (2021: RMB2,129,780,000) and the weighted average of 542,172,689 ordinary shares (2021: 412,383,886 ordinary shares) in issue during the year after taking into account the effect of capitalization issue, calculated as follows:

	2022 <i>Number of shares</i>	2021 <i>Number of shares</i>
Issued ordinary shares at the beginning of the year	541,946,928	377,480
Effect of capitalization issue	–	150,614,520
Effect of conversion of convertible redeemable preferred shares to ordinary shares upon IPO	–	175,634,564
Effect of shares issued upon IPO	–	83,281,110
Effect of shares issued related to equity-settled share-based transactions	<u>225,761</u>	<u>2,476,212</u>
Weighted average number of ordinary shares at the end of the year	<u><u>542,172,689</u></u>	<u><u>412,383,886</u></u>

(b) Diluted loss per share

Diluted loss per share is the same as basic loss per share for the years ended December 31, 2022 and 2021, as all of the potential ordinary shares are anti-dilutive.

7. OTHER RECEIVABLES AND PREPAYMENTS

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Value added tax recoverable	31,140	9,017
Prepayments to suppliers	27,383	32,232
Other receivables	16,934	5,551
	<u>75,457</u>	<u>46,800</u>

All other receivables and prepayments are expected to be recovered or recognized as expenses within one year.

8. OTHER PAYABLES AND ACCRUALS

	2022 <i>RMB'000</i>	2021 <i>RMB'000</i>
Payables for purchase of property, plant and equipment	16,252	28,394
Payroll payables	16,474	12,795
Accrued costs for research and development expenses	36,921	6,830
Payables for purchase of materials (<i>note(i)</i>)	4,154	1,001
Accrued office expenses and others	8,414	4,604
Other taxes payables (<i>note(ii)</i>)	1,203	5,529
	<u>83,418</u>	<u>59,153</u>

Notes:

- (i) As at 31 December 2022 and 2021, all payables for purchase of materials are aged within one year, based on invoice date.
- (ii) Accrued withholding taxes on the acquisitions of development and commercialization rights of ophthalmic products from third parties based on appropriate withholding tax rates applicable to the relevant jurisdictions.

All of the other payables and accruals are expected to be settled and expensed within one year or are repayable on demand.

9. DIVIDENDS

The directors do not recommend the payment of any dividend for the year ended December 31, 2022 (2021: Nil).

OTHER INFORMATION

Compliance with the Corporate Governance Code

Pursuant to code provision C.2.1 of Part 2 of the CG Code, the roles of chairman and chief executive should be separate and not be performed by the same individual. Dr. Li Xiaoyi currently serves as both the Chairman and the CEO. Dr. Li Xiaoyi has been operating and managing our Group since its establishment. The Board believes that vesting the roles of both CEO and Chairman in the same person has the benefit of ensuring consistent leadership and efficient discharge of executive functions within our Group. We consider that the balance of power and authority of the present arrangement will not be impaired as the Board comprises eight other experienced and high-caliber individuals who would be able to offer advice from various perspectives. In addition, for major decisions of our Group, the Board will make consultations with appropriate Board committees and senior management.

Therefore, our Directors consider that the present arrangement is beneficial to and in the interest of our Company and our Shareholders as a whole and the deviation from Code provision C.2.1 of Part 2 of the CG Code is appropriate in such circumstance. The Board will continue to review the effectiveness of the corporate governance structure of our Group in order to assess whether the separation of the roles of Chairman and CEO is necessary.

Our Company is committed to maintaining a high standard of corporate governance (which is of critical importance to our development) to protect the interest of the Shareholders. Save as disclosed above, our Directors consider that we have complied with all applicable code provisions of the CG Code as set out in Appendix 14 to the Listing Rules during the Reporting Period.

Compliance with the Model Code for Securities Transactions

We have adopted the Model Code set out in Appendix 10 to the Listing Rules as its securities code to regulate the dealing by the Directors in securities of our Company.

Having made specific inquiries of all Directors, all of them have confirmed that they have complied with the Model Code during the Reporting Period. No incident of non-compliance with the Model Code by the employees who are likely to be in possession of inside information of our Company was noted by us.

Use of Proceeds from the Global Offering

Our Company's Shares were listed on the Stock Exchange on April 29, 2021 with a total of 123,567,500 offer Shares issued. The net proceeds from the Global Offering amounted to approximately HK\$1,932.3 million, after deducting the underwriting fees, commissions and related listing expenses. As of December 31, 2022, such net proceeds were utilized as follows:

Use of proceeds from listing	Amount of net proceeds for planed applications <i>(HK\$ million)</i>	Percentage of total net proceeds <i>(%)</i>	Utilized net proceeds as of December 31, 2022 <i>(HK\$ million)</i>	Unutilized net proceeds as of December 31, 2022 <i>(HK\$ million)</i>	Expected time frame for unutilized amount
For the clinical development and commercialization of our two Core Products	618.34	32.00%	233.57	384.77	
1. Allocated to CsA Ophthalmic Gel	438.64	22.70%	161.17	277.47	By the end of 2025
2. Allocated to ZKY001	179.70	9.30%	72.40	107.30	By the end of 2025
The continuing R&D activities as well as commercialization of the other drug candidates in our pipeline	888.86	46.00%	305.02	583.84	
1. The continuing R&D activities of other key drug candidates	579.69	30.00%	158.35	421.34	By the end of 2025
2. The continuing R&D activities of other innovative and generic drug candidates	57.97	3.00%	57.97	–	–
3. The milestone payments of our other in-licensed drug candidate	96.62	5.00%	56.97	39.65	By the end of 2025

Use of proceeds from listing	Amount of net proceeds for planned applications <i>(HK\$ million)</i>	Percentage of total net proceeds <i>(%)</i>	Utilized net proceeds as of December 31, 2022 <i>(HK\$ million)</i>	Unutilized net proceeds as of December 31, 2022 <i>(HK\$ million)</i>	Expected time frame for unutilized amount
4. The further expansion of our sales and marketing team in anticipation of new product launches in the coming year	154.58	8.00%	31.73	122.85	By the end of 2025
Carrying out the production line expansion of our advanced Nansha manufacturing facility in anticipation of our product launches in the coming years	135.27	7.00%	135.27	–	
Our business development activities and the expansion of drug pipelines	96.62	5.00%	96.62	–	
Working capital and other general corporate purposes	193.23	10.00%	103.78	89.45	By the end of 2023
	<u>1,932.32</u>	<u>100.00%</u>	<u>874.26</u>	<u>1,058.06</u>	

As at December 31, 2022, all the unused net proceeds were held by us in short-term deposits with licensed banks or authorized financial institutions in Hong Kong and the PRC.

The expected timeline for utilizing the net proceeds from the Global Offering is based on the best estimation of future market conditions made by our Company and is subject to changes in accordance with our actual business operation. Going forward, the net proceeds will be applied in the manner as set out in “Future Plans and Use of Proceeds” of the Prospectus and there is no change in the intended use of net proceeds as previously disclosed in the Prospectus.

Purchase, Sale or Redemption of the Listed Securities

During the Reporting Period, neither our Company nor any of our subsidiaries have purchased, sold or redeemed any of our Company’s listed securities.

Review of the Annual Results by Audit Committee

The Audit Committee comprises one non-executive Director and two independent non-executive Directors, namely, Mr. Wong Hin Wing, Ms. Cai Li and Mr. Liew Fui Kiang. The chairman of the Audit Committee is Mr. Wong Hin Wing. The Audit Committee has reviewed the annual results of our Group for the year ended December 31, 2022 and has recommended for the Board's approval thereof.

The Audit Committee has reviewed together with the management the accounting principles and policies adopted by our Group and the consolidated financial statements for the year ended December 31, 2022. The Audit Committee considered that the annual results are in compliance with the applicable accounting standards, laws and regulations, and our Company has made appropriate disclosures thereof.

The Audit Committee reviews and assesses the effectiveness of our Company's risk management and internal control systems which cover all material financial, operational and compliance controls. The Audit Committee also reviews regularly the corporate governance structure and practices within our Company and monitors compliance fulfilment on an ongoing basis.

Scope Work of KPMG

The figures in respect of the Group's consolidated statement of financial position, consolidated statement of profit or loss and other comprehensive income and the related notes thereto for the year ended December 31, 2022 as set out in the preliminary announcement have been compared by the Company's auditors, KPMG, Certified Public Accountants, to the amounts set out in the Group's draft consolidated financial statements for the year and the amounts were found to be in agreement. The work performed by KPMG in this respect did not constitute an audit, review or other assurance engagement in accordance with Hong Kong Standards on 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 the auditors on this announcement.

Final Dividend

The Board does not recommend any payment of a final dividend for the year ended December 31, 2022.

Closure of the Register of Members

The AGM is scheduled to be held on May 25, 2023. A notice convening the AGM will be published and dispatched to the Shareholders of our Company in the manner required by the Listing Rules in due course.

The register of members of our Company will be closed from May 22, 2023 to May 25, 2023, both days inclusive, in order to determine the identity of the Shareholders who are entitled to attend the AGM, during which period no share transfers will be registered. To be eligible to attend the AGM, all properly completed transfer forms accompanied by the relevant share certificates must be lodged for registration with our Company's branch share registrar in Hong Kong, Computershare Hong Kong Investor Services Limited, at Shops 1712–1716, 17th Floor, Hopewell Centre, 183 Queen's Road East, Wanchai, Hong Kong not later than 4:30 p.m. on May 19, 2023.

Events After the Reporting Period

Save as disclosed above, there are no important events that have occurred after the end of the Reporting Period and up to the date of this announcement.

Publication of Annual Results and Annual Report

This announcement is published on the Stock Exchange's website (www.hkexnews.hk) and our Company's website (zkoph.com). The annual report of our Company for the year ended December 31, 2022 containing all the information in accordance with the requirements under the Listing Rules will be dispatched to the Shareholders and published on the respective websites of the Stock Exchange and our Company in due course.

Appreciation

The Board would like to express its sincere gratitude to our Shareholders, management, employees, business partners and customers for their support and contribution.

DEFINITIONS

“AGM”	the annual general meeting of our Company
“ANDA”	abbreviated new drug application, an application for a generic drug to an approved drug in China
“Audit Committee”	the audit committee of the Board
“Board”	the board of directors of our Company
“BVI”	the British Virgin Islands
“CDE”	the Center for Drug Evaluation of NMPA (國家藥品監督管理局藥品審評中心), a division of the NMPA mainly responsible for review and approval of IND and NDA

“CED”	corneal epithelial defect
“CEO”	the chief executive officer of our Company
“CG Code”	the Corporate Governance Code as set out in Appendix 14 to the Listing Rules
“Chairman”	chairman of the Board
“China” or “the PRC”	the People’s Republic of China excluding, for the purpose of this announcement and for geographical reference only and except where the context requires otherwise, Hong Kong, Macau Special Administrative Region and Taiwan
“CIC”	China Insights Industry Consultancy Limited, a market research and consulting company and an independent third party of our Company
“Company”, “our Company”, “we” or “us”	Zhaoke Ophthalmology Limited
“Core Product(s)”	has the meaning ascribed to it in Chapter 18A of the Listing Rules; for purposes of this announcement, our Core Products refer to CsA ophthalmic gel and ZKY001
“CsA”	a selective immuno-suppressant that inhibits calcineurin, an activator of T cells
“DED”	dry eye disease
“Director(s)”	the director(s) of our Company, including all executive directors, non-executive directors and independent non-executive directors
“DME”	diabetic macular edema
“EMA”	European Medicines Agency
“EU”	the European Union
“FDA”	the United States Food and Drug Administration

“Global Offering”	the Hong Kong Public Offering and the International Offering
“GMP”	good manufacturing practice
“Greater China”	the PRC, Hong Kong, the Macau Special Administrative Region of the PRC and Taiwan
“Group”, “our Group” or “we”	our Company and its subsidiaries
“HK\$”	Hong Kong dollars, the lawful currency of Hong Kong
“HKFRS”	Hong Kong Financial Reporting Standards
“Hong Kong”	the Hong Kong Special Administrative Region of the PRC
“Hong Kong Public Offering”, “International Offering”	the offer for subscription of the Shares
“IND”	investigational new drug, the application for which is the first step in the drug review process by regulatory authorities to decide whether to permit clinical trials. Also known as clinical trial application, or CTA, in China
“IOP”	Intraocular pressure
“IPO”	the initial public offering of the Shares of our Company on the Stock Exchange
“KOL(s)”	key opinion leaders, who are professionals that influence their peers’ medical practice, including but not limited to prescribing behavior
“Listing Date”	April 29, 2021, being the date on which dealings in our Shares first commence on the Main Board of the Stock Exchange
“Listing Rules”	the Rules Governing the Listing of Securities on the Stock Exchange, as amended or supplemented from time to time
“Main Board”	the stock exchange (excluding the option market) operated by the Stock Exchange which is independent from and operated in parallel with GEM of the Stock Exchange

“Model Code”	the Model Code for Securities Transactions by Directors of Listed Issuers as set out in Appendix 10 to the Listing Rules
“NDA”	new drug application, an application through which the drug sponsor formally proposes that the relevant regulatory authority approve a new drug for sales and marketing
“Nevakar”	Nevakar, Inc., a pharmaceutical company incorporated under the laws of Delaware of the United States in 2015 and one of our licensing partners
“NK”	neurotrophic keratitis
“NMPA”	National Medical Products Administration, the institution that performs the functions of CFDA instead according to the Institutional Reform Plan of the State Council of the PRC
“NTC”	NTC S.r.l, a pharmaceutical company incorporated under the laws of Italy and one of our licensing partners
“OTC”	Over the counter drug
“PanOptica”	PanOptica, Inc., a biopharmaceutical company incorporated under the laws of Delaware of the United States in 2009 and one of our licensing partners
“PGA”	Prostaglandin analogues
“Prospectus”	the prospectus issued by our Company dated April 16, 2021
“Reporting Period”	the year ended December 31, 2022
“RMB”	Renminbi
“R&D”	research and development
“Series A Preferred Shares”	the convertible series A preferred shares of our Company which were subsequently converted to ordinary Shares on the Listing Date
“Series B Preferred Shares”	the convertible series B preferred shares of our Company which were subsequently converted to ordinary Shares on the Listing Date

“Share(s)”	ordinary shares in the share capital of our Company of US\$0.00000025 each
“Shareholder(s)”	holder(s) of Shares
“Stock Exchange”	the Stock Exchange of Hong Kong Limited, a wholly owned subsidiary of Hong Kong Exchanges and Clearing Limited
“sq.m.”	square meters
“TOT BIOPHARM”	TOT BIOPHARM International Company Limited (東曜藥業股份有限公司), formerly known as TOT BIOPHARM International Company Limited (東源國際醫藥股份有限公司), a limited liability company established under the laws of Hong Kong in 2009 and one of our licensing partners, whose shares are listed on the Stock Exchange (stock code: 1875)
“TPRK”	transepithelial photorefractive keratectomy
“United States” or “U.S.”	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
“VEGF”	vascular endothelial growth factor, a signal protein produced by cells that stimulates the formation of blood vessels
“VEGFR2”	vascular endothelial growth factor receptor 2, a type of VEGF that is a primary responder to vascular endothelial growth factor signal, and thereby regulates endothelial migration and proliferation
“Visus”	VISUS THERAPEUTICS INC., a pharmaceutical company incorporated under the law of Delaware of the U.S. in 2019 and one of our licensing partners
“Vyluma”	Vyluma Inc., a pharmaceutical company incorporated under the law of Delaware of the U.S. in 2021 and one of our licensing partners
“wAMD”	wet age-related macular degeneration

“Zhaoke Guangzhou”

Zhaoke (Guangzhou) Ophthalmology Pharmaceutical Co., Ltd. (兆科(廣州)眼科藥物有限公司), a limited liability company established in the PRC on June 16, 2016 and an indirect wholly owned subsidiary of our Company

By order of the Board
Zhaoke Ophthalmology Limited
Dr. Li Xiaoyi
Chairman and Executive Director

Hong Kong, March 27, 2023

As at the date of this announcement, the Board comprises Dr. Li Xiaoyi and Mr. Dai Xiangrong as executive Directors, Ms. Leelalertsuphakun Wanee, Ms. Tiantian Zhang, Ms. Cai Li and Mr. Chen Yu as non-executive Directors, and Mr. Wong Hin Wing, Prof. Lo Yuk Lam and Mr. Liew Fui Kiang as independent non-executive Directors.