This announcement contains forward-looking statements that involve risks and uncertainties. All statements other than statements of historical fact are forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors, some of which are beyond our Company's control that may cause the actual results, performance or achievements to be materially different from those expressed or implied by the forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. We undertake no obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

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, 2023

The Board and the Directors of our Company are pleased to announce the consolidated annual results of our Group for the year ended December 31, 2023, together with the comparative figures for the year ended December 31, 2022 as follows.

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

FINANCIAL HIGHLIGHTS

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Revenue	**18,750**	–
Cost of sales	**(4,503)**	–
Gross profit	**14,247**	–
Other income	**82,044**	38,041
Other net loss	**(3,515)**	(29,731)
R&D expenses	**(333,050)**	(296,430)
General and administrative expenses	**(84,404)**	(86,109)
Selling and distribution expenses	**(51,889)**	(29,946)
Finance costs	**(7,921)**	(3,142)
Loss before taxation	**(384,488)**	(407,317)
Income tax	**(550)**	–
Loss for the year	**(385,038)**	(407,317)
Total comprehensive income for the year	**(323,931)**	(196,415)
Non-HKFRS adjusted loss for the year[(1)]	**(363,015)**	(360,633)

Note:

(1) NON-HKFRS MEASURES

Non-HKFRS adjusted loss for the year is defined as loss for the year adjusted by adding back equity-settled share-based payment expenses. The following table reconciles our non-HKFRS adjusted loss for the year with our loss for the year.

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Loss for the year	**(385,038)**	(407,317)
Add:		
Equity-settled share-based payment expenses	**22,023**	46,684
Non-HKFRS adjusted loss for the year[(1)]	**(363,015)**	(360,633)

CORPORATE PROFILE

Overview

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

Zhaoke Ophthalmology's portfolio of innovative and generic assets spans major diseases affecting both the front- and back-of-the-eye. In constructing this portfolio, our goal has been to strike a delicate balance between serving as a comprehensive "one-stop solution provider" for physicians, and concentrating resources on areas with the most substantial unmet needs and commercial opportunities. Notably, we stand as the sole ophthalmology company in China with advanced programs (Phase III or later) addressing all three of the most prevalent front-of-the-eye diseases: DED, myopia, and presbyopia.

Our primary emphasis is on delivering high-quality products to fulfill the unmet needs of patients and ophthalmologists. Additionally, we are dedicated to fostering innovation through a multi-faceted and digitally-enabled business model. Whilst Greater China remains as our primary focus in terms of geography, we have started expanding our footprint in selected country markets beyond. Recognizing our social responsibilities, we also strive to address the pressing need for increased public awareness of eye disease, its detection and treatment solutions.

With a firm commitment to becoming a leader in ophthalmology, both in China and on a global scale, we have made substantial strides in advancing our key clinical programs.

BUSINESS HIGHLIGHTS

- ***2023 was the year in which we recognized sales revenue for the first time:*** In 2023, we recorded total revenue of RMB18.8 million, of which RMB4.7 million was derived from sales of ophthalmic drugs (including Bimatoprost Timolol and Eyprotor), and RMB8.4 million was from sales of OTC ophthalmic products (堡得视® series heat compress eyepatches). In addition, we recorded revenue of RMB5.6 million in payments from our distribution deal outside of China.

- ***We successfully launched our first pharmaceutical product, Bimatoprost Timolol eye drop, in China:*** We launched Bimatoprost Timolol eye drop 晶贝莹® upon obtaining regulatory approval in February 2023. Since it is not covered by National Reimbursement Drug List (NDRL), the primary focus for us with this product has been to get it into as many private hospitals as possible. In addition to traditional offline channels, the eye drop is available on JD Health, an e-commerce healthcare platform.

- ***Our NVK002 treatment for myopia successfully concluded its first Phase III clinical trial in China while the second Phase III clinical trial is ongoing:*** In August 2023, the one-year Phase III clinical trial for both 0.01% and 0.02% concentration of NVK002 in China ("**Mini-CHAMP**") completed its last patient last visit. In October, we announced the positive top-line results from Mini-CHAMP, which successfully met its primary efficacy endpoint with both doses of 0.01% and 0.02%. NVK002 achieving statistically and clinically meaningful differences versus placebo in terms of slowing myopia progress in the study population. We have submitted NDA documents to NMPA. Due to the issuance of new policies and regulations regarding the relevant registration classification by the relevant regulator in China, we are currently awaiting the detailed rules of relevant acceptance and registration guidelines.

- ***BRIMOCHOL PF and Carbachol PF obtained regulatory approval to initiate clinical trials in China:*** Just after the Reporting Period, in January 2024, we received approval from the NMPA to start clinical trials for BRIMOCHOL PF and Carbachol PF in China. BRIMOCHOL PF and Carbachol PF are innovative drugs for presbyopia that we jointly develop with our U.S. partner Visus Therapeutics Inc. ("**Visus**"), a clinical-stage U.S. pharmaceutical company focused on developing innovative ophthalmic therapies. In April 2023, Visus announced positive topline results from its first Phase III pivotal BRIO-I trial.

- ***The patient recruitment process for the Phase III clinical trial of TAB014 was successfully completed:*** In September 2023, we announced the completion, ahead of schedule, of patient recruitment to the trial of our innovative drug for wAMD. As a result, TAB014 became our first innovative drug focusing on back-of-the-eye diseases to enter Phase III trial.

- ***We filed six more ANDA submissions for our generic drugs, including five addressing glaucoma and one for Epinastine:*** In 2023, we successfully submitted ANDAs for five more drugs in our generic glaucoma franchise: Bimatoprost, Travoprost, Travoprost Timolol, Latanoprost and Latanoprost Timolol. After the Reporting Period, in February 2024, we submitted ANDA for Epinastine targeting allergic conjunctivitis.

- ***Strategic partnerships were established in South Korea, Malaysia and Thailand, further expanding our global presence:*** In March 2023, we started building our presence in other parts of Asia by entering into a distribution and supply agreement for NVK002 with Kwangdong Pharmaceutical Co., Ltd. ("**KDP**"), a leading Korean pharmaceutical company. We then deepened our relationship with KDP by reaching another distribution and supply agreement for BRIMOCHOL PF, as we announced in January 2024. In early March 2024, we extended our footprint to Malaysia by reaching a distribution and supply agreement with the leading Malaysian pharmaceutical group, Pharmaniaga Logistics Sdn. Bhd., for Bimatoprost Timolol. Also in March 2024, we finalized a distribution agreement with TRB Chemedica (Thailand) Ltd. ("**TRB Thailand**"), an affiliate of TRB Chemedica, a Swiss pharma and biotechnology company, to distribute one of our Company's products in Thailand.

MANAGEMENT DISCUSSION AND ANALYSIS

BUSINESS REVIEW

Pipeline Strategy

Zhaoke Ophthalmology has established a comprehensive asset portfolio of innovative and generic drugs that address major eye diseases across both the front- and back-of-the-eye including DED, myopia, presbyopia, wAMD/DME and glaucoma. In some areas, 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 a number of key, and potentially blockbuster, innovative drugs which we expect to move through the pipeline during the next few years.

NVK002 (low dose atropine) for Myopia (partnered with Vyluma)

Overview

To date, low concentration atropine has been widely studied and demonstrated to be effective in myopia progression control among children and adolescents. Zhaoke Ophthalmology's NVK002 is currently positioned as a second-to-market clinically-proven pharmaceutical products for treating the progression of myopia in China, potentially with two concentrations: 0.01% and 0.02%.

- This treatment has a proprietary formulation that successfully addresses the instability of low-concentration atropine. It has patent protection in both the U.S. and China, and is preservative-free with an expected shelf life of over 24 months.

- Zhaoke Ophthalmology's licensing partner for NVK002 is Vyluma Inc. ("**Vyluma**"), a wholly-owned subsidiary of U.S.-based Nevakar, Inc., a pharmaceutical company focused on developing innovative products in injectable and ophthalmic space and one of our licensing partners. Vyluma has successfully completed its Phase III clinical trial for NVK002 across the U.S. and Europe. This involved nearly 600 children and adolescents over a three-year study and one year observation period.

- Zhaoke Ophthalmology has two Phase III clinical trials for NVK002 in China: the Mini-CHAMP, and a two-year Phase III clinical trial ("**China CHAMP**").

- The Mini-CHAMP trial involved 16 centers and 526 patients, and was led by Principal Investigators Professor Qu Xiao Mei, from the Eye and ENT Hospital of Fudan University, and Professor Yang Xiao, from the Zhongshan Ophthalmic Center of Sun Yat-Sen University. The China CHAMP trial involves 18 centers and 777 patients, and is led by Professor Wang Ning Li from Beijing Tongren Hospital as the Principal Investigator.

Updates during the Reporting Period

- Our Company completed the last patient last visit for Mini-CHAMP on August 3, 2023 and announced positive topline results from the trial in October 2023. These demonstrate strong safety and efficacy for NVK002 as a potential treatment for the progression of myopia in children. The trial successfully met its primary efficacy endpoint with doses of both 0.01% and 0.02%.

- In March 2023, we entered into a distribution and supply agreement for NVK002 with KDP, a leading Korean pharmaceutical company.

    - Under the terms of the agreement, KDP was granted exclusive rights to import, promote, distribute, market and sell NVK002 in South Korea.

- We have submitted NDA documents to NMPA. Due to the issuance of new policies and regulations regarding the relevant registration classification by the relevant regulator in China, we are currently awaiting the detailed rules of relevant acceptance and registration guidelines.

- Meanwhile, following FDA's acceptance of an NDA for NVK002 in June 2023, our partner Vyluma continued to progress the regulatory approval process in the U.S.

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 which eliminates daytime administration and the associated discomfort and inconvenience. As such, it aims to dramatically improve patients' treatment compliance and quality of life.

- The proprietary hydrogel formulation is protected by 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 current treatments, CsA Ophthalmic Gel's unique formulation stays on the eye for longer, requiring only once-a-day dosing, compared with twice-a-day dosing for traditional products.

- In our Phase III clinical trial, the treatment also showed faster onset of action by demonstrating efficacy at around the two-week time period. By contrast, other CsA drugs often take around seven to eight weeks to display onset of action.

Updates during the Reporting Period

- On January 31, 2023, Zhaoke Ophthalmology announced that CsA Ophthalmic Gel had passed the NMPA's on-site regulatory and clinical trial inspections, as well as the GMP assessment conducted by the Guangdong Medical Products Administration.

- However, following several rounds of communication, the CDE requested additional information to support our NDA. It was apparent to us that we would require more time to complete this request than available through the statutory supplementary material process. As a result, and acting out of an abundance of caution, we took the prudent decision to voluntarily withdraw our NDA, in order to focus on compiling the required documentation in as complete a way as possible. We anticipate resubmitting the NDA in later 2024.

- Simultaneously, we continued our efforts to explore overseas opportunities for CsA Ophthalmic Gel, including ongoing discussions with the FDA regarding an IND filing. We had both the type C meetings and type D meetings with FDA during 2023 that has resulted in a clear clinical pathway for registration in U.S. Meanwhile, we have been exploring regulatory pathways for adjacent Asian markets.

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 PF and Carbachol PF is Visus. Visus is currently conducting Phase III pivotal trials.

Updates during and after the Reporting Period

- In April 2023, Visus announced positive topline results from its Phase III pivotal BRIO-I trial. BRIMOCHOL PF successfully met the pre-specified visual acuity primary endpoints for both the U.S. and EU/UK against its active comparators carbachol and brimonidine. In the trial, BRIMOCHOL PF demonstrated significant results in near and distance binocular visual acuity at multiple timepoints over carbachol and brimonidine.

    - Over eight hours, BRIMOCHOL PF achieved highly statistically significant near vision improvements and was well-tolerated.

    - An additional Phase III safety and efficacy trial, BRIO-II, is currently in progress, with the results expected to be disclosed in 2024.

- On January 24, 2024, we announced that the IND applications of BRIMOCHOL PF and Carbachol PF had been approved by the NMPA.

- On January 29, 2024, we announced that Zhaoke Ophthalmology entered into a distribution and supply agreement with KDP.

    - Under the terms of the agreement, KDP was granted exclusive distribution rights for BRIMOCHOL PF in South Korea. These include obtaining the relevant local drug registrations, as well as importing, promoting, distributing, marketing and selling the drug on an exclusive basis.

- In February 2024, we signed an amendment to our previous agreement with Visus to expand our licensed territories to Hong Kong, Macau, Taiwan, Australia, New Zealand, Saudi Arabia, the United Arab Emirates, Qatar, Bahrain, Kuwait and Oman, in addition to mainland China, South Korea and the ASEAN countries (Brunei, Cambodia, Indonesia, Laos, Malaysia, Myanmar, Philippines, Singapore, Thailand and Vietnam).

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 usage of bevacizumab via intravitreal injection for the treatment of wAMD.

- 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 (BCVA) at week 52 in a TAB014-treated subject group compared with the Lucentis®-treated subject group.

- The study involves up to approximately 60 centers and a total of 488 patients and is led by Professor Chen Youxin from Peking Union Medical College Hospital as the Principal Investigator.

Updates during the Reporting Period

- On September 16, 2023, we completed patient recruitment for the Phase III clinical trial of TAB014, ahead of schedule.

ZKY001 (self-developed)

Overview

ZKY001 is a seven-amino acid peptide derived from the functional fragment of Thymosin β4 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 conducted Phase II clinical trials and an investigator-initiated trial of ZKY001 for multiple potential indications, including CED, TPRK, pterygium (a growth in the cornea or the conjunctiva), and NK.

Updates during the Reporting Period

- Following analysis of the results across these studies, our research and clinical teams chose to focus on TPRK, specifically the treatment of CEDs after eye surgery, as the indication for ZKY001 to advance into Phase III trials.

- Once approved for a first indication, we believe the adoption of ZKY001 will expand quickly into other corneal repair applications.

Generic drugs

We follow a balanced approach in designing our drug pipeline, encompassing both innovative drugs and generic drugs. 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.

- Bimatoprost Timolol eye drop 晶贝莹® is a drug researched, developed and manufactured by Zhaoke Ophthalmology for the treatment of glaucoma. In February 2023 it obtained marketing approval from the NMPA, and as a result became our first drug approved for commercialization. The first prescription was written on March 8, 2023 in Guangzhou.

- In May 2023, we also launched Bimatoprost Timolol eye drop 晶贝莹® on the JD Health ecommerce platform to extend its customer reach.

- The launch of Bimatoprost Timolol eye drop 晶贝莹® signifies not just the commencement of a new phase for Zhaoke Ophthalmology as a business entity, but also enhances our Company's brand presence in the Chinese ophthalmic market.

- Throughout the Reporting Period, we also filed ANDA submissions for five of our generic drugs addressing glaucoma: Bimatoprost, Travoprost, Travoprost Timolol, Latanoprost and Latanoprost Timolol. We anticipate obtaining approvals sequentially from the CDE over the next two years.

- The last patient last visit for Epinastine HCl was completed on September 28, 2023. Following completion of the trial, we submitted an ANDA for Epinastine HCl in China in February 2024.

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's facility in Guangdong provides our Company with the strategic advantage of a fully in-house manufacturing capability. State-of-the-art equipment and machinery sourced from leading global manufacturers are utilized for processes such as production, dosing, filling, and packaging, at all times following stringent quality assurance measures. The facility, which spans approximately 7,600 sq.m., adheres to the highest international standards and complies with the requirements of major global regulators, including the NMPA, FDA and the EMA.

Currently equipped with four manufacturing lines, the facility is ready for mass production. Following the NMPA marketing approval granted in February 2023, we manufacture our Bimatoprost Timolol eye drop 晶贝莹® there.

Commercialization

The year of 2023 marked the beginning of a new chapter for Zhaoke Ophthalmology with the launch of our first approved drug in February 2023, Bimatoprost Timolol eye drop 晶贝莹®. In November 2023, we also acquired the commercial rights to Eyprotor from Lee's Pharm, as we believe in the complementary nature of this product with our pipeline in tissue healing, as well as its potential for improving our commercial capabilities in preparation for the planned growth in commercialization activities. As our R&D organization works tirelessly to advance our products through late-stage clinical trials and regulatory approvals, the sales and marketing organization's focus has been to initiate sales ramp up and expand hospital coverage while keeping the size of the team relatively small. By the close of 2023, our sales and marketing team had a total of 71 individuals. This team now has direct coverage of over 1,200 hospitals, including most top tier public and private hospitals.

At the same time, our comprehensive omni-channel approach continues to drive sales growth and strengthen our brand reputation in the Chinese ophthalmic market. In particular, we focused on a number of new digital initiatives during 2023. These include the launch of our Bimatoprost Timolol eye drop 晶贝莹® on JD Health in May 2023, an e-commerce healthcare platform for pharmaceutical products. This complements our Tmall flagship store, launched in August 2022 as a sales venue for our 堡得视® series eye patches. This series consists of a 堡得视® heat compress eyepatch, an approved Class II medical device for people with mild DED, and a 堡得视® far infrared eye heat compress, a Class II medical device to improve pseudo myopia and visual fatigue in adolescents and children.

We also expanded our social media activities to include Little Red Book, using this high-profile platform to promote understanding of eye health issues. Initiatives such as this enable our Company to build awareness of eye disease and the Zhaoke Ophthalmology brand directly amongst consumers, laying a solid foundation for the future launch of our major drugs.

Complementing these commercial efforts is Zhaoke Boshi (兆科博視), our innovative, content-driven platform on WeChat targeting medical professionals. During 2023, it continued to serve as a preferred space for prominent ophthalmology KOLs to share insights and foster discussions within the broader Chinese ophthalmic community. It has expanded continuously since launch and now has over 15,000 followers, representing nearly half the ophthalmologist community in China. Zhaoke Boshi's success strengthens our position as a trusted partner for Chinese ophthalmologists and reinforces our leadership in this specialized field.

Additionally, we established a strategic partnership in August 2023 with Eyebright Medical, a Beijing-based pharmaceutical company focused on the R&D, manufacturing and commercialization of ophthalmic medical devices. We will have comprehensive collaborations in the ophthalmology field and explore opportunities to R&D and commercialize ophthalmic products together, as well as promote our products in eye hospitals, ophthalmic clinics, vision centers, and other terminal channels, in order to achieve a mutually beneficial goal by leveraging both companies' edges and strengths.

R&D

As a pharmaceutical company, R&D remains center to our growth. During the Reporting Period, we made significant R&D progress across our asset portfolio.

In August 2023, NVK002, our innovative treatment for myopia progression control, completed the last patient last visit for its one-year Phase III clinical trial, Mini-CHAMP. In October 2023, we announced the positive topline results from Mini-CHAMP. Mini-CHAMP successfully met its primary efficacy endpoint with both doses of 0.01% and 0.02%. NVK002 achieving statistically and clinically meaningful differences versus placebo in terms of slowing myopia progress in the study population, demonstrating strong safety and efficacy for NVK002 as a potential treatment for the progression of myopia in children.

In September 2023, we also announced the completion of patient recruitment for the Phase III trials of TAB014, our innovative drug for wAMD, and Epinastine HCl, our epinastine eye drop for the treatment of allergic conjunctivitis. The last patient last visit in the Epinastine HCl trial was completed the same month, following which we submitted an ANDA for the drug in China in February 2024.

Throughout the Reporting Period, we also filed ANDA submissions for five generic drugs addressing glaucoma, including Bimatoprost, Travoprost, Travoprost Timolol, Latanoprost and Latanoprost Timolol. In January 2024, our IND applications for BRIMOCHOL PF and Carbachol PF, innovative eye drops for presbyopia, were approved by the NMPA.

Our R&D team boasts a proven track record and is led by an international management team with decades of collective industry experience in global biotechnology and pharmaceutical companies. As at the end of the Reporting Period, our R&D team comprised approximately 100 professionals.

For the year ended December 31, 2023, our R&D expenses were RMB333.1 million, an increase of approximately 12.4% from RMB296.4 million in the year ended December 31, 2022.

Partnerships and Globalization Efforts

Throughout 2023 and after the Reporting Period, Zhaoke Ophthalmology continued to explore partnership and collaboration opportunities with leading domestic and international pharmaceutical firms and research institutions.

We have made critical strides towards establishing a global presence and taking our products outside China. In March 2023, we signed a distribution and supply agreement with KDP. Under the terms of the agreement, Zhaoke Ophthalmology grants KDP exclusive rights to import, promote, distribute, market and sell NVK002 in South Korea.

Just after the Reporting Period, in the first quarter of 2024, we concluded a number of additional licensing partnerships in South Korea, Malaysia and Thailand.

On January 29, 2024, Zhaoke Ophthalmology announced Zhaoke Ophthalmology entered into a second strategic partnership with KDP for BRIMOCHOL PF. Under the terms of the agreement, Zhaoke Ophthalmology is entitled to grant exclusive distribution rights for BRIMOCHOL PF to KDP in South Korea. Also under the terms, KDP will obtain, on behalf of Zhaoke Ophthalmology, the relevant local drug registrations, as well as import, promote, distribute, market and sell the product on an exclusive basis.

On March 5, 2024, we announced our expansion into Malaysia through a distribution and supply agreement for Bimatoprost Timolol eye drop 晶贝莹®, with Pharmaniaga Logistics Sdn. Bhd. ("**Pharmaniaga**"), one of Malaysia's largest integrated pharmaceutical groups. Under the terms of the agreement, Pharmaniaga is granted the non-exclusive right to register, import, promote, market, sell and distribute Bimatoprost Timolol eye drop 晶贝莹® in Malaysia. This is our first overseas distribution deal for an in-house developed drug.

On March 15, 2024, our Company finalized a distribution agreement with TRB Thailand. The agreement grants TRB Thailand the right to distribute, promote, market and sell EyeGiene® reusable eyemasks in Thailand. Its agreement with TRB Thailand represents further growth of our Company's footprint in the strategically important Southeast Asian market.

Furthermore, we have been actively seeking collaborations with excellent companies to enrich our product portfolio and establish more comprehensive and efficient sales channels. In June 2023, our Company entered into an exclusive license, supply and distribution agreement with Eyedetec Medical, Inc. ("**Eyedetec Medical**"), a leading U.S.-based company specializing in medical devices for the treatment of DED and meibomian gland dysfunction. Under the terms of the agreement, Eyedetec Medical grants Zhaoke Ophthalmology exclusive rights to register, import, promote, distribute, market and sell the Eye Lipid Mobilizer™, a medical device that is designed to treat DED and meibomian gland dysfunction, in Greater China, South Korea and the ASEAN countries.

Separately in August 2023, Zhaoke Ophthalmology established a strategic partnership with Eyebright Medical (Beijing) Co., Ltd, a Beijing-based pharmaceutical company focusing on the R&D, manufacturing and commercialization of ophthalmic medical devices. Our Company and Eyebright Medical will jointly explore opportunities to research, develop and commercialize ophthalmic products, including promotion of some of our products in eye hospitals, ophthalmic clinics, vision centers and other channels.

Environment, Social and Governance ("ESG")

Zhaoke Ophthalmology is dedicated to fostering the development of a sustainable healthcare industry in China. We conscientiously monitor the environmental and social impact of our operations, implementing measures to enhance the sustainability of our business.

Our overarching mission is to enhance global visual health, aligning with our broader social responsibilities. In 2023, we continued our efforts to promote educational activities aimed at increasing public awareness of eye disease, through our Zhaoke Boshi WeChat account as well as through specific campaigns.

For example, in March 2023 during World Glaucoma Awareness Week, we engaged well-known ophthalmologists in online education programs designed to enhance public awareness of glaucoma screening and treatment. Subsequently, in celebration of China's National Eye Care Day on June 6, 2023, we conducted in-person educational seminars. These seminars focused on public education about eye health and included the distribution of eye patches to consumers, receiving positive feedback from the audience.

Our commitment to our community is paralleled by our dedication to our people. Recognizing that our vision can only be realized by supporting our colleagues in their personal development, we place great emphasis on creating a diverse, supportive, and rewarding work environment. Over the past 12 months, we expanded our HR initiatives, introducing a tiered mentorship scheme, an apprenticeship program, and a rotational program to provide high-performing individuals the opportunity to gain insights into different aspects of the business. In addition, our HR and IT departments are collaborating to produce a large amount of digital educational content for the benefit of our employees.

Zhaoke Ophthalmology is committed to transparency and compliance, and discloses our ESG performance annually in our ESG report. In April 2023, we published our third ESG report to enhance our stakeholders' understanding of our current strategy regarding socially responsible practices.

FUTURE AND OUTLOOK

In the face of ongoing macroeconomic uncertainties, Zhaoke Ophthalmology is steadfastly committed to our focused areas and expects to achieve significant progress in our key programs over 2024.

We expect to complete the last patient last visit of China CHAMP in the summer of 2024. This is the two-year Phase III clinical trial for our innovative myopia drug NVK002. Its completion will mark another milestone for this potential blockbuster drug. We also anticipate the completion of the last patient visit in the Phase III study for the wAMD-targeted TAB014 in early fall of 2024. An NDA submission is expected to follow thereafter.

Meanwhile, having received regulatory approval in January 2024, we will initiate a clinical trial for BRIMOCHOL PF and Carbachol PF, potential innovative treatments for presbyopia, later in 2024 in China. We also plan to re-file the NDA submission in 2024 for our self-developed innovative drug for DED, CsA Ophthalmic Gel.

Turning to our generic franchise, where we have submitted ANDAs for the majority of our generic drugs for glaucoma, we expect to receive regulatory approvals sequentially in the next couple of years, with Bimatoprost expected first in 2024.

We have substantially strengthened our commercialization capabilities through refining our omni-channel approach and enhancing our brand equity. Both will be critical in supporting successful launches of our potential blockbuster drugs in China and globally.

We are focused on building a sustainable business with operations in China, the wider Asian region and elsewhere in the world. Having successfully secured out-licensing agreements in South Korea, Malaysia and Thailand, we are actively exploring other opportunities in Southeast Asia and evaluating potential activities in Australia. At the same time, we continue to actively assess the potential for an IND filing for CsA Ophthalmic Gel in the U.S.

Operationally, we will continue to exercise rigorous control over our cash expenditures, optimize resource allocation, and take all prudent steps to mitigate any financial and business risks presented by the external business environment. At the end of 2023, we have a cash balance of approximately RMB1.5 billion, which affords us a comfortable runway to complete our key programs and reach the key inflection point of positive cashflow.

2023 marked the beginning of a new chapter for Zhaoke Ophthalmology, proving our resilience whilst providing us with invaluable experience through program advances as well as temporary setbacks. Looking forward to the rest of 2024, we are excited about the opportunities in the ophthalmology field both in China and globally, despite challenging external macroeconomic and geopolitical conditions. We have a strong team comprised of world-class talent from the pharmaceutical, sales and marketing disciplines. Together, we are well-positioned to navigate the complexities of the external environment and pursue excellence in the R&D, registration, manufacturing, and commercialization of our therapies. We will continue to dedicate ourselves to addressing significant unmet medical needs and helping improve the visual health of patients in China and around the world.

FINANCIAL REVIEW

	Year ended December 31,	
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Loss for the year	**(385,038)**	(407,317)
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	**61,107**	210,902
Total comprehensive income for the year	**(323,931)**	(196,415)
Non-HKFRS Measures		
Adjusted loss for the year	**(363,015)**	(360,633)

Overview

For the year ended December 31, 2023, we recorded total loss of approximately RMB385.0 million, as compared with approximately RMB407.3 million for the year ended December 31, 2022. The total loss in 2023 narrowed, mainly due to that sales revenue was recorded for the first time in 2023, together with additional interest income received during 2023 which benefited from higher deposit interest rates; the income increment was partially net off with the increase in R&D expenses led by the advancement of the development process of our clinical trials for our key innovative products, and increased investments in our ongoing R&D projects. Our selling and distribution expenses also increased accordingly since the introduction of our new product during 2023.

Our R&D expenses for the year ended December 31, 2023 were approximately RMB333.1 million, representing an increase of approximately 12.4% from approximately RMB296.4 million for the year ended December 31, 2022, primarily led by continuous investment over several late stage clinical trial projects which included, Phase III clinical trial for TAB014 and China CHAMP and Mini-CHAMP for NVK002, both of which projects commenced in mid 2022.

Following NMPA approval for our Bimatoprost Timolol eye drop (晶贝莹®), our sales and marketing team is rapidly expanding our coverage of key hospitals and launching different marketing promotion campaign to increase our Company's brand awareness in the market.

Revenue

Our Group recorded its first year of revenue with RMB18.8 million for the year ended December 31, 2023, which was mainly derived from sales of our first commercialized drug addressing glaucoma (Bimatoprost Timolol) and Type II medical device for mild DED (堡得视® heat compress eyepatch).

We also generated revenue of RMB5.6 million from granting the exclusive distribution right to our business partner, KDP, for the distribution of our innovative drug candidate (2022: nil). As at December 31, 2023, the aggregated amount of the transaction price allocated to the remaining performance obligations under our Group's existing contracts was around RMB14.1 million. This amount represents revenue expected to be recognized in the future from distribution and supply contracts entered into between the customer and our Group. We will recognize the expected revenue in future throughout the contract period.

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Point in time:		
Sales of ophthalmic drugs	**4,736**	–
Sales of ophthalmic products	**8,414**	–
Over time:		
Income from exclusive distribution rights	**5,600**	–
	18,750	–

Other Income

Our Group's other income primarily consists of bank interest income and government grants received, which represent one-off subsidies we have received from government authorities for our R&D activities.

For the year ended December 31, 2023, our Group's other income increased to approximately RMB82.0 million, compared to approximately RMB38.0 million for the year ended December 31, 2022. The increase was primarily attributable to the growth of approximately RMB47.0 million in bank interest income received from fixed deposits in 2023, benefiting from rapid increase of deposit interest rate in HKD and USD since the end of 2022, which was partially offset by a decrease of approximately RMB4.1 million in government grants.

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Bank interest income	**77,399**	30,415
Government grants	**3,387**	7,479
Others	**1,258**	147
Total	**82,044**	38,041

Other Net Loss

For the year ended December 31, 2023, we recorded approximately RMB3.5 million of other net loss, compared to approximately RMB29.7 million of other net loss for the year ended December 31, 2022. Such net loss primarily consists of net foreign exchange loss incurred during the translation of liabilities denominated in other foreign currency for example USD and HKD. A significant loss was noted when there was a great depreciation pressure on RMB against USD in 2022, but the loss amount was narrowed down when RMB exchange rate was more stable in 2023.

R&D Expenses

Our 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, 2023, our R&D expenses increased by approximately RMB36.7 million, or 12.4%, to approximately RMB333.1 million from approximately RMB296.4 million for the year ended December 31, 2022. 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) the increase in headcount of R&D personnel.

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

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Clinical trial professional service fee	**160,966**	155,631
Staff costs	**57,206**	49,391
Depreciation and amortization	**37,624**	31,625
Cost of raw materials and consumables used	**16,538**	21,662
Equity-settled share-based payment expenses	**1,942**	10,697
Utilities	**4,861**	5,668
Professional and consultation fee	**40,717**	14,579
Testing fee	**2,286**	2,077
Traveling expenses	**2,679**	961
Others[(1)]	**8,231**	4,139
Total	**333,050**	296,430

Note:

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

General and Administrative Expenses

Our general and administrative expenses primarily consisted of: staff costs, professional service fees for legal, consulting and auditing services, general operating expenses, depreciation in relation to our office equipment and equity-settled share-based payment expenses for those other than R&D personnel and commercialization team.

For the year ended December 31, 2023, our general and administrative expenses were approximately RMB84.4 million, representing a decrease of approximately RMB1.7 million from approximately RMB86.1 million for the year ended December 31, 2022, which is primarily attributable to the decrease in equity-settled share-based payment expenses, which was partially offset by the effect of the increase in amortization of digital foundation and system digitization for internal business model and management system with its first application during 2023.

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

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Staff costs (include Directors' fee)	**33,725**	31,931
Equity-settled share-based payment expenses	**18,200**	33,317
Professional service fees	**12,733**	13,994
Depreciation and amortization	**9,331**	2,717
General operating expenses	**3,574**	2,429
Others(1)	**6,841**	1,721
Total	**84,404**	86,109

Note:

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

Selling and Distribution Expenses

Our selling and distribution expenses mainly consisted of staff costs for our commercialization team and marketing & conference expenses.

Our selling and distribution expenses increased from RMB29.9 million for the year ended December 31, 2022 to approximately RMB51.9 million for the year ended December 31, 2023, primarily attributable to an increase in the headcount of our commercialization team and building-up of omnichannel marketing platform, together with market launch activities and campaigns to increase brand awareness for our first pharmaceutical product, Bimatoprost Timolol eye drop, carried out during 2023.

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

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Staff costs	**28,404**	20,835
Marketing & conference expenses	**15,030**	2,074
Depreciation	**1,592**	731
Equity-settled share-based payment expenses	**1,881**	2,670
Others	**4,982**	3,636
Total	**51,889**	29,946

Finance Costs

Our finance costs increased from approximately RMB3.1 million for the year ended December 31, 2022 to approximately RMB7.9 million for the year ended December 31, 2023, which was primarily attributable to the increased interest expenses on bank loan related to cross boarder funding arrangement during 2023.

Income Tax

The income tax recognized during the year ended December 31, 2023 represented provision for withholding tax incurred from granting of exclusive distribution rights in Korea for the year.

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 the Cayman Islands and accordingly are exempted from Cayman Islands income tax.

Hong Kong

We did not make any provision for Hong Kong profits tax, because our Hong Kong subsidiary, Zhaoke HK, did not have any 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 subsidiaries did not have any assessable profits in the PRC during the Reporting Period.

Withholding Tax

The Group is subject to withholding tax on income from exclusive distribution rights granted to a customer based on a withholding tax rate of 10% under the tax law in Korea.

Loss for the Year

As a result of the above factors, for the year ended December 31, 2023, we recorded a loss of approximately RMB385.0 million, as compared to a loss of approximately RMB407.3 million for the year ended December 31, 2022.

Non-HKFRS Measure

To supplement the Financial Statements, which are presented in accordance with the HKFRS, our Company also uses adjusted loss for the year as an additional financial measure, which is not required by, or presented in accordance with, the HKFRS. Our Company believes that this adjusted measure will provide useful information to its Shareholders and potential investors in understanding and evaluating our Group's annual consolidated results of operations in the same manner as they help our Company's management.

Adjusted loss for the year represents the loss for the year excluding the effect of equity-settled share-based payment expenses. The term adjusted loss for the year is not defined under the HKFRS. However, our Company believes that this non-HKFRS measure is a reflection of our Group's normal operating results by eliminating the potential impact of items that the management do not consider to be indicative of our Group's operating performance. The adjusted loss for the year, as the management of our Group believes, is adopted in the industry where our Group is operating. However, the presentation of the adjusted 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 our Company should not view this non-HKFRS measure 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 loss for the year to adjusted loss for the year during the years indicated:

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Loss for the year	**(385,038)**	(407,317)
Add:		
Equity-settled share-based payment expenses	**22,023**	46,684
Non-HKFRS adjusted loss for the year[(1)]	**(363,015)**	(360,633)

Note:

(1) Non-HKFRS Measures

Non-HKFRS adjusted loss for the year is defined as loss for the year adjusted by adding back equity-settled share-based payment expenses. The above table reconciles our non-HKFRS adjusted loss for the year with our loss for the year.

Selected Data from Statement of Financial Position

	As at December 31,	
	2023	2022
	RMB'000	*RMB'000*
Total current assets	**1,794,569**	1,972,747
Total non-current assets	**625,769**	597,876
Total assets	**2,420,338**	2,570,623
Total current liabilities	**336,451**	194,540
Total non-current liabilities	**35,569**	27,710
Total liabilities	**372,020**	222,250
Current assets		
Inventories	**6,141**	–
Trade and other receivables	**61,147**	75,457
Pledged bank balances	**265,658**	172,066
Time deposits with original maturity over three months	**–**	8,873
Cash and cash equivalents	**1,461,623**	1,716,351
Total current assets	**1,794,569**	1,972,747
Current liabilities		
Trade and other payables	**116,637**	83,418
Contract liabilities	**1,179**	–
Amounts due to related companies	**2,473**	6,897
Bank loans	**206,577**	94,500
Lease liabilities	**9,585**	9,725
Total current liabilities	**336,451**	194,540
Net current assets	**1,458,118**	1,778,207

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. We closely monitor uses of cash and cash balances and strive to maintain a healthy liquidity for our operations.

As at December 31, 2023, the current assets of our Group were approximately RMB1,794.6 million, including cash and cash equivalents of approximately RMB1,461.6 million, pledged bank balance of approximately RMB265.7 million and other current assets of approximately RMB67.3 million. As at December 31, 2023, the current liabilities of our Group were approximately RMB336.5 million, including trade and other payables of approximately RMB116.6 million, amounts due to related companies of approximately RMB2.5 million, bank loans of approximately RMB206.6 million and other current liabilities of approximately RMB10.8 million.

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

As of December 31, 2023, our Group had unsecured bank loans of RMB206.6 million which was repayable within one year or on demand.

Our Group adopts conservative treasury policies in cash and financial management. To achieve better risk control and minimize the cost of funds, our Group's treasury is centralized. Cash is generally placed in deposits mostly denominated in US$, HK$ and RMB. Our Group's liquidity and financing requirements are reviewed regularly.

Pledge of Bank Balance

Our pledged bank balances were approximately RMB265.7 million as of December 31, 2023 (2022: RMB172.1 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 ratios for the dates indicated:

	As at December 31,	
	2023	2022
Current ratio[(1)]	**5.3**	10.1
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, 2022 and 2023, we were in a net cash position and thus gearing ratio is not applicable.

Contingent Liabilities

As at December 31, 2023, our Group did not have any significant contingent liabilities.

Capital Commitment

The capital commitment of our Group as at December 31, 2023 was approximately RMB58.3 million, representing a decrease of approximately RMB218.9 million as compared with approximately RMB277.2 million as at December 31, 2022, primarily attributable to the completion in phase of our construction of manufacturing facilities and R&D activities.

Significant Investments

For the year ended December 31, 2023, we did not have any significant investment.

Future Plans for Material Investments or Capital Assets

As of December 31, 2023, 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, 2023.

Employees and Remuneration

As at December 31, 2023, our Group had a total of 313 employees. The following table sets forth the total number of employees by function as of December 31, 2023:

	Number of employees	% of the total
Management	6	2.0
R&D	102	32.5
Manufacturing	61	19.5
Quality control	35	11.2
Sales and marketing	71	22.7
Environmental, health and safety	1	0.3
Administrative	37	11.8
Total	313	100.0

The remuneration of the employees of our Group comprises salaries, bonuses, employees provident fund and social security contributions, other welfare payments and equity-settled share-based payment.

The total staff cost incurred by our Group for the year ended December 31, 2023 was approximately RMB126.8 million, as compared to approximately RMB132.1 million for the year ended December 31, 2022. The decrease was primarily attributable to the decrease of equity-settled share-based payment expenses of approximately RMB21.0 million, which was partially net off by an increase of approximately RMB15.7 million in employee salaries and benefits in line with the expansion in headcount.

Foreign Exchange Exposure

During the year ended December 31, 2023, our Group mainly operated in China and a majority of its transactions was settled in RMB, the functional currency of our Company's principal subsidiaries. As at December 31, 2023, a significant amount of our Group's cash and cash equivalents was denominated in US$. Except for certain cash and cash equivalents, prepayments on purchases of property, plant and equipment and other payables denominated in foreign currencies, our Group did not have significant foreign currency exposure from its operations as at December 31, 2023. 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. We currently do not adopt any long-term contracts, currency borrowings or other means to hedge our foreign currency exposure.

CONSOLIDATED STATEMENT OF PROFIT OR LOSS AND OTHER COMPREHENSIVE INCOME

		Year ended December 31,	
		2023	2022
	Notes	***RMB'000***	*RMB'000*
Revenue	3	**18,750**	–
Cost of sales		**(4,503)**	–
Gross profit		**14,247**	–
Other income	4	**82,044**	38,041
Other net loss		**(3,515)**	(29,731)
R&D expenses		**(333,050)**	(296,430)
General and administrative expenses		**(84,404)**	(86,109)
Selling and distribution expenses		**(51,889)**	(29,946)
Loss from operations		**(376,567)**	(404,175)
Finance costs	5(a)	**(7,921)**	(3,142)
Loss before taxation	5	**(384,488)**	(407,317)
Income tax	6	**(550)**	–
Loss for the year		**(385,038)**	(407,317)
Loss per share *(RMB)*	7		
Basic		**(0.71)**	(0.75)
Diluted		**(0.71)**	(0.75)
Loss for the year		**(385,038)**	(407,317)
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**")		**61,107**	210,902
Total comprehensive income for the year		**(323,931)**	(196,415)

CONSOLIDATED STATEMENT OF FINANCIAL POSITION

	Notes	As at December 31, 2023 RMB'000	2022 RMB'000
Non-current assets			
Property, plant and equipment		**223,648**	233,743
Intangible assets		**392,463**	334,623
Prepayments on purchases of property, plant and equipment		**9,658**	29,510
		625,769	597,876
Current assets			
Inventories		**6,141**	–
Trade and other receivables	8	**61,147**	75,457
Pledged bank balances		**265,658**	172,066
Time deposits with original maturity over three months		**–**	8,873
Cash and cash equivalents		**1,461,623**	1,716,351
		1,794,569	1,972,747
Current liabilities			
Trade and other payables	9	**116,637**	83,418
Contract liabilities		**1,179**	–
Amounts due to related companies		**2,473**	6,897
Bank loans		**206,577**	94,500
Lease liabilities		**9,585**	9,725
		336,451	194,540
Net current assets		**1,458,118**	1,778,207
Total assets less current liabilities		**2,083,887**	2,376,083
Non-current liabilities			
Lease liabilities		**21,864**	27,703
Contract liabilities		**12,956**	–
Deferred income		**749**	7
		35,569	27,710
Net assets		**2,048,318**	2,348,373
Capital and reserves			
Share capital		**–***	–*
Reserves		**2,048,318**	2,348,373
Total equity		**2,048,318**	2,348,373

* 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 and products.

2. MATERIAL ACCOUNTING POLICIES

(a) 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, 2023 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 HKFRSs, Hong Kong Accounting Standards ("**HKASs**") and Interpretations issued by the Hong Kong Institute of Certified Public Accountants ("**HKICPA**") 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 of Hong Kong Limited.

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. Note 2(b) provides information on any changes in accounting policies resulting from initial application of these developments to the extent that they are relevant to the Group for the current accounting period.

(b) Changes in accounting policies

The HKICPA has issued a new HKFRS and certain amendments to HKFRSs that are first effective for the current accounting period of the Group. The HKICPA also published "Accounting implications of the abolition of the MPF-LSP offsetting mechanism in Hong Kong" that provides guidance on the accounting consideration relating to the offsetting mechanism and the abolition of the mechanism. 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 and products.

Disaggregation of revenue

Disaggregation of revenue from contracts with customers by major products or service lines is as follows:

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Revenue from contracts with customers within the scope of HKFRS 15		
Point in time:		
Sales of ophthalmic drugs	**4,736**	–
Sales of ophthalmic products	**8,414**	–
Over time:		
Income from exclusive distribution rights	**5,600**	–
	18,750	–

(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. OTHER INCOME

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Bank interest income	**77,399**	30,415
Government grants		
– Employment support grants *(note (i))*	**303**	544
– Other government grants *(note (ii))*	**3,084**	6,935
Others	**1,258**	147
	82,044	38,041

Notes:

(i) The amount represents government grants received from various PRC government authorities in connection with the fiscal subsidies for providing financial support to enterprises and paying wages to the employees.

(ii) The amount represents subsidies received from government for encouragement of technology research and development and compensation on the capital expenditure of production lines.

5. LOSS BEFORE TAXATION

Loss before taxation is arrived at after charging:

(a) Finance costs

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Interest on bank loans	**6,165**	1,359
Interest on lease liabilities	**1,756**	1,783
	7,921	3,142

(b) Staff costs

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Salaries, wages and other benefits	**100,232**	85,163
Contribution to defined benefit retirement plans	**6,291**	5,590
Equity-settled share-based payment expenses	**20,321**	41,362
	126,844	132,115

(c) Other items

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Amortization of intangible assets	**8,660**	2,249
Depreciation charge		
– owned property, plant and equipment	**31,633**	25,740
– right-of-use assets	**8,411**	7,085
Auditors' remuneration		
– audit services	**2,150**	2,150
– other services	**1,107**	1,077

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

Taxation in the consolidated statement of profit or loss represents:

	Year ended December 31,	
	2023	2022
	RMB'000	*RMB'000*
Current tax – Overseas	**550**	–

7. 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 RMB385,038,000 (2022: RMB407,317,000) and the weighted average of 543,922,707 ordinary shares (2022: 542,172,689 ordinary shares) in issue during the year calculated as follows:

	2023	2022
	Number of shares	*Number of shares*
Issued ordinary shares at the beginning of the year	**543,843,992**	541,946,928
Effect of shares issued related to equity-settled share-based transactions	**78,715**	225,761
Weighted average number of ordinary shares at the end of the year	**543,922,707**	542,172,689

(b) Diluted loss per share

Diluted loss per share is the same as basic loss per share for the years ended December 31, 2023 and 2022, as all of the potential ordinary shares are anti-dilutive.

8. TRADE AND OTHER RECEIVABLES

	As at December 31,	
	2023	2022
	RMB'000	*RMB'000*
Trade receivables, net of loss allowance	**3,710**	–
Value-added tax recoverable	**643**	31,140
Prepayments to suppliers	**38,605**	27,383
Other receivables	**18,189**	16,934
	61,147	75,457

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

	As at December 31,	
	2023	2022
	RMB'000	*RMB'000*
Within 1 month	**1,381**	–
1 to 2 months	**667**	–
2 to 3 months	**–***	–
Over 3 months but within 6 months	**1,662**	–
	3,710	–

* The balance represents amount less than RMB1,000.

9. TRADE AND OTHER PAYABLES

	As at December 31,	
	2023	2022
	RMB'000	*RMB'000*
Trade payables	**1,166**	–
Payables for purchase of property, plant and equipment	**6,775**	16,252
Payroll payables	**16,383**	16,474
Accrued costs for research and development expenses	**74,656**	36,921
Payables for purchase of materials	**8,101**	4,154
Accrued office expenses and others	**7,954**	8,414
Other taxes payables	**1,602**	1,203
	116,637	83,418

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

	As at December 31,	
	2023	2022
	RMB'000	*RMB'000*
Within 1 month	**433**	–
1 to 3 months	**137**	–
Over 3 months but within 6 months	**596**	–
	1,166	–

10. DIVIDENDS

The directors do not recommend the payment of any dividend for the year ended December 31, 2023 (2022: Nil).

OTHER INFORMATION

Compliance with the CG Code

Pursuant to code provision C.2.1 in 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. Our 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 our Board comprises seven other experienced and high-caliber individuals who would be able to offer advice from various perspectives. In addition, for major decisions of our Group, our 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 in Part 2 of the CG Code is appropriate in such circumstance. Our Board will continue to review the effectiveness of the corporate governance structure of our Group in order to assess whether separation of the roles of Chairman and CEO is necessary.

We are 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 C1 to the Listing Rules during the Reporting Period and up to the date of this announcement.

Compliance with the Model Code

We have adopted the Model Code set out in Appendix C3 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, 2023, such net proceeds were utilized as follows:

Use of proceeds from Listing	Amount of net proceeds for planned applications *(HK$ million)*	Percentage of total net proceeds	Utilized net proceeds as of December 31, 2023 *(HK$ million)*	Utilized net proceeds from January 1, 2023 to December 31, 2023 *(HK$ million)*	Unutilized net proceeds as of December 31, 2023 *(HK$ million)*	Expected time frame for unutilized amount
For the clinical development and commercialization of our two Core Products	618.34	32.00%	270.37	36.80	347.97	
1. Allocated to CsA Ophthalmic Gel	438.64	22.70%	182.93	21.76	255.71	By the end of 2025
2. Allocated to ZKY001	179.70	9.30%	87.44	15.04	92.26	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%	557.73	252.71	331.13	
1. The continuing R&D activities of other key drug candidates	579.69	30.00%	342.05	183.70	237.64	By the end of 2025
2. The continuing R&D activities of other innovative and generic drug candidates	57.97	3.00%	57.97	–	–	–

Use of proceeds from Listing	Amount of net proceeds for planned applications *(HK$ million)*	Percentage of total net proceeds	Utilized net proceeds as of December 31, 2023 *(HK$ million)*	Utilized net proceeds from January 1, 2023 to December 31, 2023 *(HK$ million)*	Unutilized net proceeds as of December 31, 2023 *(HK$ million)*	Expected time frame for unutilized amount
3. The milestone payments of our other in-licensed drug candidate	96.62	5.00%	94.02	37.05	2.6	By the end of 2025
4. The further expansion of our sales and marketing team in anticipation of new product launches in the coming year	154.58	8.00%	63.69	31.96	90.89	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%	193.23	89.45	–	–
	1,932.32	100.00%	1,253.22	378.96	679.1	

As at December 31, 2023, all the unused net proceeds are held by our Company 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 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. Tiantian Zhang 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, 2023 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, 2023. 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 fulfillment on an ongoing basis.

Scope Work of KPMG

The figures in respect of our 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, 2023 as set out in this annual results announcement have been compared by our Company's auditors, KPMG, Certified Public Accountants, to the amounts set out in our Group's 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, 2023.

Closure of the Register of Members

The AGM is scheduled to be held on May 31, 2024. 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 28, 2024 to May 31, 2024, 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 27, 2024.

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, 2023 containing all the information in accordance with the requirements under the Listing Rules will be published on the above websites and dispatched to the Shareholders (if requested) 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 C1 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 of the PRC and Taiwan

"Company", "our Company", "we", "us" or "Zhaoke Ophthalmology"	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 offer for subscription and placing of the shares as described in the Prospectus
"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" or "HKD"	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

"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
"KOL(s)"	key opinion leaders, who are professionals that influence their peers' medical practice, including but not limited to prescribing behavior
"Lee's Pharm"	Lee's Pharmaceutical Holdings Limited (李氏大藥廠控股有限公司), an exempted company incorporated in the Cayman Islands with limited liability whose shares are listed on the Main Board of the Stock Exchange (stock code: 950)
"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 C3 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
"NK"	neurotrophic keratitis
"NMPA"	National Medical Products Administration
"Prospectus"	the prospectus issued by our Company dated April 16, 2021
"Reporting Period"	the year ended December 31, 2023
"RMB"	Renminbi

"R&D"	research and development
"Share(s)"	ordinary shares in the share capital of our Company of US$0.00000025 each
"Shareholder(s)"	holder(s) of Shares
"Stock Exchange"	The Stock Exchange of Hong Kong Limited, a wholly-owned subsidiary of Hong Kong Exchanges and Clearing Limited
"sq.m."	square meters
"TOT BIOPHARM"	TOT BIOPHARM International Company Limited (東曜藥業股份有限公司), formerly known as TOT BIOPHARM International Company Limited (東源國際醫藥股份有限公司), a limited liability company established under the laws of Hong Kong in 2009 and one of our licensing partners, whose shares are listed on the Stock Exchange (stock code: 1875)
"TPRK"	transepithelial photorefractive keratectomy
"United States" or "U.S."	the United States of America, its territories, its possessions and all areas subject to its jurisdiction
"US$" or "USD"	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
"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, 2024

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 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.