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Cutia Therapeutics

科笛集团

(Incorporated in the Cayman Islands with limited liability) (Stock code: 2487)

INTERIM RESULTS ANNOUNCEMENT FOR THE SIX MONTHS ENDED 30 JUNE 2023

The Board is pleased to announce the unaudited consolidated interim results of the Group for the six months ended 30 June 2023, together with the comparative figures for the same period in 2022.

BUSINESS HIGHLIGHTS

As at the date of this announcement, we have made significant progress in advancing our product pipeline as well as business operations:

- Commercialization: During the "618 campaign", our scalp diseases and care products recorded GMV exceeding RMB9.4 million, representing a growth of 4,348.0% year-over-year. Sales volume of CUP-MNDE (Bailleul® minoxidil spray) was ranked Top 1 on Tmall and JD platforms in the category of cross-border minoxidil single SKU. We have also launched certain scalp diseases and care products in Mainland China to complement our current scalp diseases and care product candidates under development.
- **CU-40102 (topical finasteride spray):** We are currently conducting a registrational Phase III clinical trial for CU-40102 for androgenetic alopecia in Mainland China and have completed database lock in May 2023.
- **CU-40101 (topical small molecule thyroid hormone receptor agonist liniment):** All enrolled patients have completed the Phase I dose escalation trial for CU-40101 in Mainland China in July 2023 and the clinical trial has completed database lock in August 2023. This clinical trial is to evaluate the safety and tolerability of CU-40101 as a therapeutic agent in promoting hair growth in patients with androgenetic alopecia.
- **CU-10201 (topical 4% minocycline foam):** We are currently conducting a registrational Phase III clinical trial for CU-10201 in Mainland China to evaluate the therapeutic potential of CU-10201 for the treatment of moderate to severe acne vulgaris. We completed the primary endpoint read-out for the Phase III clinical trial in February 2023. Results of the Phase III clinical trial data analysis in Mainland China have shown that CU-10201 has a significant efficacy and a favorable safety profile in the treatment of acne, with a reduction in the common side effects of oral minocycline. CU-10201 has been granted priority review designation by the CDE in August 2023.

- **CU-30101 (localized topical lidocaine and tetracaine cream):** We initiated a Phase III clinical trial for CU-30101 in Mainland China in April 2023. All enrolled patients have completed the clinical trial in August 2023.
- **Manufacturing facilities:** The construction of our commercial-scale GMP manufacturing facilities with three drug product production lines in Jiangsu province was completed in February 2023 and has commenced operation. The three production lines cover cream, ointment, aerosol, and foam products with an annual production capacity of approximately a total of five million doses.

FINANCIAL HIGHLIGHTS

- Revenue increased by approximately RMB33.6 million, or approximately 5,119.3%, from approximately RMB0.7 million for the six months ended 30 June 2022 to approximately RMB34.3 million for the six months ended 30 June 2023.
- The Group's total cash and cash equivalents, time deposits over three months and financial assets at fair value through profit or loss amounted to approximately RMB1,399.0 million.

MANAGEMENT DISCUSSION AND ANALYSIS

OVERVIEW

Founded in 2019, we are an R&D-driven, dermatology-focused biopharmaceutical company dedicated to developing comprehensive solutions that are tailored to meet the diverse and evolving needs of patients and consumers in the broader dermatology treatment and care market. We had built a broad portfolio of nine products and product candidates, targeting the four main sectors of the broader dermatology treatment and care market, namely localized adipose accumulation management medication, scalp diseases and care, skin diseases and care and topical anesthesia. We are developing five clinical-stage and four pre-clinical stage drug candidates. We also distributed two commercialized products developed by overseas collaboration partners and marketed several products in Mainland China.

We are one of the few players in the broader dermatology treatment and care market in Mainland China equipped with fully integrated capabilities. We have applied a customer-centric approach to bolster our product candidates and expand our integrated capabilities to the entire broader dermatology treatment and care industry value chain. Our platform spans from the early phase of identifying demands, developing core technologies, managing clinical trials and product registrations, to the manufacturing and marketing of products.

Our proprietary CATAME[®] technology platform improves drugs to achieve topical or transdermal delivery by developing micron and nano-sized particulates, as well as evaluating formulation quality and stability, and performing cutaneous pharmacokinetic analysis. Our platform also helps design the most suitable product formats that are key to specific and successful drug delivery. Through this platform, we have built a competitive product pipeline of creams, sprays, ointments, aerosol foams and other dosage forms.

PRODUCT PIPELINE

The following chart summarizes the development stage of our product candidates as of the date of this announcement:

Therapeutic Areas	Candidate	Active Ingredients & Formulation	Indication	OTC / Prescription Drugs	Commercial Rights	Source	Pre- Clinical	IND	Phase I	Phase II	Phase III	Registration	Commercialization	Upcoming Milestone	Expected Commercial Launch	NMPA Registration Classification ²
Localized Adipose Accumulation Management	CU-20401	Recombinant mutant	Submental adipose accumulation (Submental fat)	Prescription	Asia	Acquired								Initiate Phase II in 3Q2023	2028	1
	20101	collagenase	Abdominal adipose accumulation (Abdominal fat)	drug		1								Complete Phase I in 2024	2028	
	CU-40102	Topical finasteride spray	Androgenetic	Prescription drug	Greater China ¹	In- licensed								NDA submission to NMPA in 4Q2023	4Q2024	5.1
Scalp Disease and	CU-40101	Topical small molecule thyroid hormone receptor agonist liniment	alopecia	Prescription drug	Asia	In- licensed								Obtain Phase I CSR in 4Q2023	TBD	1
Disease and Care	CU-40103	Topical minoxidil foam	Alopecia	OTC	Global	Self- developed								ANDA submission to NMPA in 3Q2024	2025	3
	CU-40104	Topical dutasteride agent	Androgenetic alopecia	Prescription drug	Global	Self- developed								IND application submission to NMPA in 4Q2024	TBD	2
	CU-10201	Topical 4% minocycline foam	Acne vulgaris	Prescription drug	Greater China 1	In- licensed								NDA submission to NMPA in 4Q2023	4Q2024	5.1
Skin Disease and Care	CU-10101	Topical novel small molecule agent	Atopic dermatitis	Prescription drug	Greater China ¹ , Japan, South Korea and SEA	In- licensed								IND application submission to NMPA in 2Q2024	TBD	1
	CU-10401	Topical tapinarof cream	Psoriasis	Prescription drug	Greater China ¹ , Japan, South Korea and SEA	Acquired								ANDA submission to NMPA in 2026	2027	4
Topical Anesthesia	CU-30101	Localized topical lidocaine and tetracaine cream	Surface dermatologic operations	Prescription drug	Greater China 1	Acquired								NDA submission to NMPA in 2025	2026	3

777 Denotes products in registrational trials in China with pilot commercialization in Lecheng, Hainan

Including Mainland China, Hong Kong, the Macau Special Administrative Region and Taiwan.
 For the product candidates that have not obtained IND approval, the NMPA Registration Classification is subject to the confirmation by the NMPA.

BUSINESS REVIEW

As at the date of this announcement, we have achieved significant advancements in both pipeline products and business operations.

Localized Adipose Accumulation Management Medication

Core Product CU-20401 (recombinant mutant collagenase)

- CU-20401 is an acquired recombinant mutant collagenase that targets obesity, overweight, or other localized adipose accumulation associated metabolic diseases. CU-20401 acts as a collagenase that degrades extracellular matrix collagen in the subcutaneous fat layer, leading to apoptosis of adipocytes.
- CU-20401 is modified with reduced rate to catalyze the collagen degradation and is effective to reduce adipose accumulation with mild catalytic activity, thus reducing the adverse effects of wild-type collagenase, such as bruising and pain.
- We have completed Phase I clinical trial on human subjects for CU-20401 for submental adipose accumulation (submental fat) and are conducting another Phase I clinical trial for abdominal adipose accumulation (abdominal fat). The significance of Phase I clinical trial is that its results suggested that CU-20401 is safe and well tolerated in subjects with submental adipose accumulation (submental fat). As we completed the Phase I clinical trial with no objection of entering a Phase II clinical trial, based on the NMPA's IND approval, we expect to initiate a Phase II clinical trial of CU-20401 for submental adipose accumulation (submental fat) in the third quarter of 2023 to evaluate its efficacy profiles.

Scalp Diseases and Care

Key Product CU-40102 (topical finasteride spray)

- CU-40102 is the first and only topical finasteride product approved for androgenetic alopecia treatment globally and the only topical finasteride under clinical development in Mainland China. Finasteride can treat androgenetic alopecia in male patients by acting as a competitive and specific inhibitor of Type II 5-alpha reductase to inhibit the conversion of testosterone to DHT in the scalp.
- Unlike oral finasteride, CU-40102's topical formulation allows patients to apply the drug directly to the surface of the scalp, thereby maintaining a high concentration at the affected site while reducing the side effects commonly associated with oral formulations. As a topical formulation, CU-40102 reduces systemic absorption of finasteride and avoids exposure of other areas of the skin to finasteride.
- We are currently conducting a Phase I clinical trial for PK and a registrational Phase III clinical trial for CU-40102 in Mainland China. We have completed database lock for the Phase III clinical trial in May 2023. We expect to complete primary endpoint read-out for the Phase III clinical trial in the fourth quarter of 2023. We plan to submit the NDA to the NMPA in the fourth quarter of 2023, and we expect to obtain regulatory approval for commercialization in Mainland China in 2024.

CU-40101 (topical small molecule thyroid hormone receptor agonist liniment)

- CU-40101 contains a potent small molecule thyroid hormone receptor agonist that binds to thyroid receptor in hair follicle cells and induces hair growth. CU-40101 is to be applied to the scalp directly, reducing systemic exposure and the associated adverse effects. CU-40101 is differentiated from currently available androgenetic alopecia treatment in its mechanism of action and the potential to be used in both male and female patients.
- We are currently conducting a Phase I dose escalation trial in Mainland China to evaluate the safety and tolerability of CU-40101 as an alternative therapeutic agent in promoting hair growth in patients with androgenetic alopecia. All enrolled patients have completed the Phase I clinical trial of CU-40101 in July 2023 and the clinical trial has completed database lock in August 2023. We expect to complete primary endpoint read-out for the Phase I clinical trial in the fourth quarter of 2023.

CU-40103 (topical minoxidil foam)

- CU-40103 is a self-developed topical minoxidil foam for the treatment of alopecia. CU-40103 is expected to adopt a differentiated elegant foam formulation and become an alternative addition to the existing minoxidil tinctures and liniments in the market. It features a much less greasy texture that enables better user experience. We are currently conducting the pre-clinical study of CU-40103 and plan to submit an ANDA for alopecia to the NMPA in the third quarter of 2024.

CU-40104 (topical dutasteride agent)

CU-40104 is a self-developed topical dutasteride to treat androgenetic alopecia. CU-40104's topical formulation is being developed for direct dutasteride application to the site of action on the scalp. The topical formulation is expected to reduce systemic exposure and side effects as compared with oral dutasteride and is expected to be approved for the treatment of androgenetic alopecia. We are currently conducting the pre-clinical study of CU-40104 and plan to submit an IND application to the NMPA in the fourth quarter of 2024.

Skin Diseases and Care

Key Product CU-10201 (topical 4% minocycline foam)

- CU-10201 is the first and only topical minocycline approved for acne vulgaris treatment globally and the only topical minocycline under clinical development in China. Minocycline is a tetracycline antibiotic used to treat a number of bacterial infections and acne vulgaris. Minocycline blocks amino acid from getting into ribosome such that the formation of peptide chains of bacteria is inhibited.
- Compared to other major anti-acne antibiotics and conventional oral drugs, topical minocycline foam has lower systemic drug exposure, fewer side effects, lower rate of drug resistance, and likely higher patient compliance.

- We are currently conducting a registrational Phase III clinical trial for CU-10201 in Mainland China to evaluate the therapeutic potential of CU-10201 for the treatment of moderate to severe acne vulgaris. We completed the primary endpoint read-out for the Phase III clinical trial in February 2023. Results of Phase III clinical trial data analysis in Mainland China show that CU-10201 has a significant efficacy and a favorable safety profile in the treatment of acne, with a reduction in the common side effects of oral minocycline. CU-10201 has been granted priority review designation by the CDE in August 2023. We expect to submit the NDA to the NMPA in the fourth quarter of 2023 and obtain regulatory approval for commercialization in Mainland China in 2024.

CU-10101 (topical novel small molecule agent)

- CU-10101 is a non-hormonal, small molecule drug targeting atopic dermatitis. The non-hormonal properties of CU-10101 may reduce the side effects and restrictions associated with corticosteroids and it features a topical formulation that can reach the affected areas directly. We are currently conducting the pre-clinical study of CU-10101 and plan to submit an IND application to the NMPA in the second quarter of 2024.

CU-10401 (topical tapinarof cream)

 CU-10401 is a generic tapinarof cream targeting psoriasis currently being developed in pre-clinical stage. Tapinarof is reported to bind and activate hydrocarbon receptor (AhR), decrease pro-inflammatory cytokines, and regulate skin barrier protein expression to promote skin barrier normalization. We are currently conducting the pre-clinical study of CU-10401 and plan to submit an ANDA to the NMPA in 2026.

Topical Anesthesia

CU-30101 (localized topical lidocaine and tetracaine cream)

- CU-30101 is a localized lidocaine and tetracaine compound topical anesthesia cream. The formulation of lidocaine and tetracaine combination in CU-30101 may produce rapid and long-lasting anesthetic effects due to its ingredients' pharmacokinetic properties.
- Lidocaine diffuses more rapidly, and more extensively than tetracaine, whereas tetracaine, a long-acting amino acid ester, is more lipophilic than lidocaine and can be concentrated in the topical stratum corneum. Systemic absorption of the anesthetic component ingredients is also limited from the topical cream formulation.
- We received the NMPA's IND approval for CU-30101 in November 2022 and initiated the Phase III clinical trial in Mainland China in April 2023. All enrolled patients have completed the Phase III clinical trial in August 2023. We plan to submit the NDA to the NMPA in 2025.

Warning: There is no assurance that each of CU-20401, CU-40102, CU-40101, CU-40103, CU-40104, CU-10201, CU-10101, CU-10401 and CU-30101 will ultimately be successfully developed and marketed by the Company. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the Shares.

Commercialization

We have adopted a well-tailored commercialization strategy to penetrate the broader dermatology treatment and care market in Mainland China. Online marketing has always been one of our strategic priorities. We have a dedicated marketing team with strong market insights focusing on the development of marketing campaigns on various e-commerce platforms and social media platforms such as Tmall, JD, Bilibili, Douyin, Zhihu and Xiaohongshu. Driven by our deep expertise in sales and marketing, and close collaboration with e-commerce platforms, we achieved encouraging results during the Reporting Period.

During the "618 campaign", our scalp diseases and care products recorded GMV exceeding RMB9.4 million, representing a growth of 4,348.0% year-over-year. The sales volume of our product CUP-MNDE (Bailleul[®] minoxidil spray) ranked Top 1 on Tmall and JD platforms in the category of cross-border minoxidil single SKU.

As of the date of this announcement, our commercialized scalp diseases and care products include CUP-MNDE (Bailleul[®] minoxidil spray), CUP-SFJH (ESTHECIN[®] hair growth serum) and certain scalp diseases and care products which were launched under the "HAIRGEOGRA[®]" brand in Mainland China during the Reporting Period to complement our current scalp diseases and care product candidates under development.

Our comprehensive commercialized product portfolio could address distinctive demands from a wide range of population groups as their needs evolve with disease progression or improvement to gain customer stickiness. Our products have features that are differentiated from other products in the market.

Manufacturing Facilities

The construction of our commercial-scale GMP manufacturing facilities with three drug product production lines in Jiangsu province was completed in February 2023 and has commenced operation. The three production lines cover topical cream, ointment, aerosol, and foam products with an annual production capacity of approximately a total of five million doses of CU-10101, CU-40103, CU-40104, CU-10401 and CU-30101. The flow and control of the entire manufacturing process are designed to be compliant with the latest GMP requirements so that our production can meet the clinical and marketing approval requirements of various drug regulatory authorities, including the NMPA, FDA and European Medicines Agency. We believe the production capacity of this factory can support our clinical trials and near-term commercialization plans for our drug candidates.

KEY EVENTS AFTER THE REPORTING PERIOD

Subsequent to the Reporting Period, some of our drug candidates have made encouraging progress. For CU-40101, all enrolled patients have completed the Phase I clinical trial in Mainland China in July 2023 and the clinical trial has completed database lock in August 2023. For CU-10201, we have been granted priority review designation by the CDE in August 2023. For CU-30101, all enrolled patients have completed the Phase III clinical trial in Mainland China in August 2023. For more information, please refer to the announcements of the Company dated 18 July 2023, 10 August 2023, 23 August 2023 and 28 August 2023, respectively.

We are delighted with the advancements we have made. Our R&D, medical and regulatory affairs teams will continue to work closely together to advance the clinical development of our product portfolio to prepare for the commercialization of our pipeline products.

Furthermore, based on the results of the quarterly review of the Hang Seng Family of Indexes announced by Hang Seng Indexes Company Limited on 18 August 2023, the Company has been selected and will be included as a constituent stock of the following index series, with effect from 4 September 2023:

- 1. Hang Seng Composite Index;
- 2. Hang Seng Healthcare Index;
- 3. Hang Seng Innovative Drug Index;
- 4. Hang Seng SCHK Innovative Drug Index;
- 5. Hang Seng SCHK Pharmaceuticals & Biotechnology Index; and
- 6. Hang Seng SCHK Pharmaceuticals & Biotechnology (Investable) Index.

For more information, please refer to the announcement of the Company dated 18 August 2023.

FUTURE DEVELOPMENT

We are dedicated to providing consumers and patients with safe and comprehensive dermatology treatment and care solutions. Looking forward to the second half of 2023, we will accelerate the clinical development of CU-40102, CU-40101, CU-20401, CU-30101 as well as other products in our pipeline.

We have also further upgraded the Group's organization structure to better integrate functions of the Group's various platforms, anticipating to efficiently covering end users' needs and improving operational efficiency. Among which, we are building a medical commercialization and marketing platform to nurture strong strategic cooperative relationships with top hospitals for better preparation for our upcoming commercialized products. We will also continue to expand our external collaboration network, strengthen our sales and marketing capabilities, and work closely with renowned physicians to conduct product demonstrations and provide training to them.

Leveraging on our CATAME[®] technology platform, our integrated commercialization model and the determination of the team, we believe we can seize the opportunities arising from the rapid expansion of China's sales network, provide innovative solutions for patients and generate higher returns to our Shareholders.

FINANCIAL REVIEW

Revenue

Our revenue was generated from the sale of our in-licensed and distributed scalp diseases and care products (CU-40102, CUP-MNDE and CUP-SFJH), skin diseases and care products (CU-10201), certain scalp diseases and care products and certain skin care products.

Revenue of the Group increased by 5,119.3% from RMB0.7 million for the six months ended 30 June 2022 to RMB34.3 million for the six months ended 30 June 2023, which was primarily due to an increase in sales of scalp diseases and care products, certain scalp diseases and care products and certain skin care products.

Cost of Sales

Our cost of sales primarily consisted of purchase costs and logistics costs related to our scalp diseases and care products, skin diseases and care products and certain skin care products. For the six months ended 30 June 2023, we recorded cost of sales of RMB13.1 million, representing an increase of RMB12.9 million from RMB0.2 million for the six months ended 30 June 2022, primarily due to an increase in the sales of our products for the six months ended 30 June 2023.

Gross Profit and Gross Profit Margin

Gross profit represents our revenue less our cost of sales. Gross profit margin represents our gross profit as a percentage of our revenue. Our gross profit amounted to RMB21.3 million for the six months ended 30 June 2023, representing an increase of 4,593.2% from RMB0.5 million for the six months ended 30 June 2022. Our gross profit margin decreased from 68.8% for the six months ended 30 June 2022 to 61.9% for the corresponding period of 2023. The decrease in gross profit margin was primarily due to an increase in the discount promotion activities on e-commerce platforms.

Other Income and Gains

Our other income primarily consisted of interest income and government grants. The government grants mainly represent subsidies received from local government authorities for the purpose of compensation for operating activities. Our interest income comprises (i) bank interest income; (ii) deemed interest income from loans to employees and related parties and (iii) imputed interest income on rental and other deposits. Other income of the Group increased by 493.2% from RMB3.6 million for the six months ended 30 June 2022 to RMB21.5 million for the six months ended 30 June 2023, which was primarily due to (i) the government grants received from the PRC local government authorities to support certain operating activities; and (ii) an increase in the bank interest income in connection with the increase of our cash and cash equivalents and time deposits over three months.

Our gains primarily consisted of net foreign exchange gains in connection with our cash and cash equivalents and time deposits over three months denominated in the U.S. dollars, as a result of the appreciation of the U.S. dollar against RMB and fair value gains on financial assets at FVTPL. Other gains of the Group decreased by 41.0% from RMB54.8 million for the six months ended 30 June 2022 to RMB32.3 million for the six months ended 30 June 2023, which was primarily due to the decrease of the foreign exchange gains resulting from the decrease of our cash and cash equivalents and time deposits over three months denominated in the U.S. dollars.

Research and Development Costs

Our research and development costs consisted of staff costs, share-based payment expenses, acquisition/licensing-in expenses, third-party contracting costs, depreciation and amortization and others. During the six months ended 30 June 2023, we recorded research and development costs of RMB90.1 million, representing an increase of approximately 8.0% as compared to RMB83.5 million for the corresponding period of 2022, primarily due to (i) an increase in the number of our research and development personnel in line with the progress of the development of our product candidates, and (ii) an increase in share-based payment expenses from new grants under the Pre-IPO Equity Incentive Plan in November 2022.

Set out below are the components of research and development costs for the periods indicated:

	For the six months ended 30 June		
	2023		
	<i>RMB'000</i>	RMB'000	
	(unaudited)	(unaudited)	
Staff costs	23,668	16,031	
Share-based payment expenses	22,536	20,973	
Acquisition/licensing-in expenses	943	12,644	
Third-party contracting costs	26,641	27,076	
Depreciation and amortization	11,930	5,094	
Others	4,421	1,646	
Total	90,139	83,464	

Administrative Expenses

Our administrative expenses consisted of staff costs, share-based payment expenses, consulting fees, depreciation and amortization and others.

Administrative expenses of the Group increased by 113.7% from RMB41.1 million for the six months ended 30 June 2022 to RMB87.9 million for the six months ended 30 June 2023, which was primarily due to an increase in our total headcount of administrative staff in line with our business expansion and the increase in the share-based payment expenses resulted from the new grant of Pre-IPO Equity Incentive Plan in November 2022.

Set out below are the components of administrative expenses for the periods indicated:

	For the six months ended 30 June		
	2023 20		
	<i>RMB'000</i>	RMB '000	
	(unaudited)	(unaudited)	
Staff costs	24,596	18,230	
Share-based payment expenses	39,849	16,902	
Consulting fees	4,380	1,889	
Depreciation and amortization	8,089	2,202	
Others	11,020	1,924	
Total	87,934	41,147	

Selling and Distribution Expenses

Our selling and distribution expenses consisted of staff costs, share-based payments expenses, marketing expenses and others. Our selling and distribution expenses increased by 871.1% from RMB6.0 million for the six months ended 30 June 2022 to RMB58.0 million for the six months ended 30 June 2023, primarily due to the increase in staff costs and marketing expenses from the expansion in online marketing activities on e-commerce and social media platforms to further drive online direct sales.

Finance Costs

The Group's finance costs mainly include interests on bank loans and lease liabilities. Finance costs of the Group increased by 182.2% from RMB0.6 million for the six months ended 30 June 2022 to RMB1.7 million for the six months ended 30 June 2023, which was primarily due to the increase of interest on lease liabilities as a result of the increase of new lease contracts and the increase of interest on bank loans in relation to the bank loans of RMB69.4 million obtained by the Group to finance the daily operation during the Reporting Period.

Listing Expenses

Listing expenses of the Group increased by 400.4% from RMB4.7 million for the six months ended 30 June 2022 to RMB23.3 million for the six months ended 30 June 2023 in line with the progress of the global offering.

Income Tax Expenses

Our income tax expense for the six months ended 30 June 2023 was nil (six months ended 30 June 2022: nil).

Fair Value Losses on Convertible Redeemable Preferred Shares

Our fair value losses on convertible redeemable preferred shares increased from RMB174.7 million for the six months ended 30 June 2022 to RMB1,454.3 million for the corresponding period of 2023. This increase was primarily due to the increase in our Company's valuation and it is expected that no such fair value losses will be incurred in the future as all convertible redeemable preferred shares were automatically converted into ordinary shares upon the completion of the global offering on 12 June 2023.

Loss for the Period

As a result of the above factors, for the six months ended 30 June 2023, our loss was RMB1,640.3 million, representing an increase of RMB1,388.7 million from RMB251.6 million for the six months ended 30 June 2022.

Liquidity and Financial Resources

As of 30 June 2023, the Group's total cash and cash equivalents amounted to approximately RMB693.6 million, representing an increase of approximately 48.9% as compared to approximately RMB465.9 million as of 31 December 2022. Such increase was primarily due to the proceeds from the global offering.

As of 30 June 2023, the Group's time deposits over three months amounted to approximately RMB243.8 million, representing a decrease of approximately 57.0% as compared to approximately RMB567.1 million as of 31 December 2022. Such decrease was primarily due to the maturity of our time deposits.

As of 30 June 2023, the Group's financial assets at fair value through profit or loss amounted to approximately RMB461.6 million, representing an increase of approximately 961.2% as compared to approximately RMB43.5 million as of 31 December 2022. We believe that making such investments is in the best interest of the Company and conducive to enhancing the utilization efficiency of capital and increasing income from idle funds of the Company without causing any adverse impact on the operation and liquidity of the Company.

As of 30 June 2023, current assets of the Group amounted to approximately RMB1,480.0 million, including cash and cash equivalents of approximately RMB693.6 million. Current liabilities of the Group amounted to approximately RMB131.3 million, including interest-bearing bank borrowings of approximately RMB69.4 million.

Indebtedness

The following table sets forth the breakdown of our lease liabilities, interest-bearing bank borrowings and convertible redeemable preferred shares as of the dates indicated:

	As of	As of
	30 June	31 December
	2023	2022
	RMB'000	RMB'000
	(unaudited)	(audited)
Lease liabilities	48,820	54,128
Interest-bearing bank borrowings	69,416	_
Convertible redeemable preferred shares	-	2,570,021

Except as discussed above, we did not have any other material mortgages, charges, debentures, loan capital, debt securities, loans, bank overdrafts or other similar indebtedness, finance lease or hire purchase commitments, liabilities under acceptance (other than normal trade bills), acceptance credits, which are either guaranteed, unguaranteed, secured or unsecured, or guarantees or other contingent liabilities as of 30 June 2023.

Gearing Ratio

As of 30 June 2023, the gearing ratio, calculated by dividing total liabilities by total assets and multiplied by 100%, decreased to approximately 9.6%, as compared with approximately 186.1% as of 31 December 2022, due to the automatic conversion of all convertible redeemable preferred shares into ordinary shares upon the global offering on 12 June 2023.

Significant Investments, Material Acquisitions and Disposal

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

Capital Commitments

As of 30 June 2023, we had capital commitment of RMB7.0 million for the contracts in relation to acquisition of property, plant and equipment and other intangible assets (as of 31 December 2022: RMB6.5 million).

Contingent Liabilities

As of 30 June 2023, we did not have any material contingent liabilities, guarantees or any litigation against us (as of 31 December 2022: nil).

Pledge of Assets

As of 30 June 2023, the Group has not pledged or charged any assets (as of 31 December 2022: nil).

Foreign Exchange Exposure

Foreign currency risk refers to the risk of loss resulting from changes in foreign currency exchange rates. Fluctuations in exchange rates between RMB and other currencies in which our Group conducts business may affect our financial condition and results of operation. The Group mainly operates in the PRC and is exposed to foreign exchange risk arising from various currency exposures, primarily with respect to Hong Kong dollars and the U.S. dollars. The conversion of foreign currencies into RMB, including Hong Kong dollars and the U.S. dollars, has been based on rates set by the People's Bank of China. The Group primarily limits our exposure to foreign currency risk by closely monitoring the foreign exchange market. During the six months ended 30 June 2023, the Group did not enter into any currency hedging transactions.

Use of Proceeds

The Group received net proceeds (after deduction of underwriting commissions and related costs and expenses) from the global offering of approximately HK\$392.7 million (equivalent to approximately RMB356.8 million). As at the date of this announcement, the Company had not used any of the proceeds. The Company intends to apply such net proceeds in accordance with the purposes as set out in the Prospectus.

Employees and Remuneration

As of 30 June 2023, the Group had a total of 236 employees. The total remuneration cost of the Group for the six months ended 30 June 2023 was RMB134.4 million, as compared to RMB75.8 million for the six months ended 30 June 2022, primarily due to an increase in headcount. The following table sets forth the total number of employees by function as of 30 June 2023:

Function	Number	Percentage of total
R&D	43	18.2%
Manufacturing and Quality Control	48	20.3%
Medical and Regulatory Affairs	37	15.7%
Sales, Marketing and Administration	108	45.8%
Total	236	100.0%

The remuneration of the employees of our Group comprises salaries, bonuses, employees' provident fund, share-based payment, and social security contributions and other welfare payments. In accordance with applicable laws and regulations, we made contributions to social security insurance funds (including pension plans, medical insurance, work-related injury insurance, unemployment insurance and maternity insurance) and housing funds for the Group's employees.

OTHER INFORMATION

Compliance with the Corporate Governance Code

The Company has adopted the principles and code provisions in the Corporate Governance Code and has complied with all applicable code provisions from the Listing Date to 30 June 2023.

Model Code for Securities Transactions

The Company has adopted the Model Code as its own code of conduct regarding securities transactions by the Directors. Having made specific enquiries with all Directors, each of them has confirmed that he/she has complied with the Model Code from the Listing Date to 30 June 2023. No incident of non-compliance of the Model Code by the employees who are likely to be in possession of inside information of the Company was noted by the Company.

Purchase, Sale or Redemption of Listed Securities

Neither the Company nor any of its subsidiaries purchased, sold or redeemed any of the Company's listed securities from the Listing Date to 30 June 2023.

REVIEW OF FINANCIAL INFORMATION

Audit Committee

The Board has established the Audit Committee which comprises Mr. Chung Ming Kit (chairman), Mr. Tao Tak Yan Dennis and Mr. Ye Xiaoxiang, who are all our independent non-executive Directors. The primary duties of the Audit Committee are to review and supervise the Company's financial reporting process and internal controls.

The Audit Committee, together with the management of the Company, has reviewed the unaudited interim condensed consolidated financial information of the Group for the six months ended 30 June 2023.

Scope of Work of Ernst & Young

The Company's external auditor, Ernst & Young, has performed an independent review of the Group's interim financial information for the Reporting Period in accordance with Hong Kong Standard on Review Engagement 2410, "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" issued by the Hong Kong Institute of Certified Public Accountants.

Interim Dividend

The Board does not recommend the payment of an interim dividend for the six months ended 30 June 2023 (30 June 2022: nil).

PUBLICATION OF INTERIM RESULTS ANNOUNCEMENT AND INTERIM REPORT

This announcement is published on the websites of the Stock Exchange (www.hkexnews.hk) and the Company (www.cutiatx.com).

The interim report of the Company for the six months ended 30 June 2023 containing all the information required by the Listing Rules will be dispatched to the Shareholders and will be published on the respective websites of the Stock Exchange and the Company in due course.

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

For the six months ended 30 June 2023

	Notes	2023 <i>RMB'000</i> (Unaudited)	2022 <i>RMB'000</i> (Unaudited)
Revenue Cost of sales	4	34,343 (13,083)	658 (205)
Gross profit Other income and gains Selling and distribution expenses Research and development costs Administrative expenses Fair value losses on convertible redeemable preferred shares Finance costs Listing expenses	4	21,260 53,844 (58,032) (90,139) (87,934) (1,454,280) (1,716) (23,342)	$453 \\ 58,446 \\ (5,976) \\ (83,464) \\ (41,147) \\ (174,652) \\ (608) \\ (4,665) \\ (4,665)$
LOSS BEFORE TAX Income tax expense	5	(1,640,339)	(251,613)
LOSS AND TOTAL COMPREHENSIVE LOSS FOR THE PERIOD		(1,640,339)	(251,613)
Attributable to: Owners of the parent		(1,640,339)	(251,613)
LOSS PER SHARE ATTRIBUTABLE TO ORDINARY EQUITY HOLDERS OF THE PARENT			
Basic and diluted (RMB)	7	(15.84)	(3.14)

INTERIM CONDENSED CONSOLIDATED STATEMENT OF FINANCIAL POSITION 30 June 2023

	Notes	30 June 2023 <i>RMB'000</i> (Unaudited)	31 December 2022 <i>RMB'000</i> (Audited)
NON-CURRENT ASSETS			
Property, plant and equipment		173,031	179,398
Right-of-use assets		44,245	49,610
Other intangible assets		8,029	597
Amounts due from related parties		36,522	36,554
Prepayments, other receivables and other assets		46,975	35,221
Total non-current assets		308,802	301,380
CURRENT ASSETS			
Inventories		20,944	19,996
Trade receivables	8	4,048	98
Prepayments, other receivables			
and other assets		54,821	47,584
Amounts due from related parties		1,272	1,240
Financial assets at fair value through			
profit or loss ("FVTPL")	9	461,599	43,496
Time deposits over three months		243,795	567,145
Cash and cash equivalents		693,557	465,866
Total current assets		1,480,036	1,145,425

	Notes	30 June 2023 <i>RMB'000</i> (Unaudited)	31 December 2022 <i>RMB'000</i> (Audited)
CURRENT LIABILITIES			
Trade and other payables	10	53,797	68,572
Lease liabilities Deferred income		7,735 400	8,830
Interest-bearing bank borrowings	11	400 69,416	_
Total current liabilities		131,348	77,402
NET CURRENT ASSETS		1,348,688	1,068,023
TOTAL ASSETS LESS CURRENT LIABILITIES		1,657,490	1,369,403
NON-CURRENT LIABILITIES			
Lease liabilities		41,085	45,298
Deferred income		-	400
Convertible redeemable preferred shares			2,570,021
Total non-current liabilities		41,085	2,615,719
Net assets/(liabilities)		1,616,405	(1,246,316)
EQUITY			
Equity attributable to owners of the parent			
Share capital Reserves/(deficits)		43 1,616,362	11 (1,246,327)
			(1,210,327)
Total equity/(deficits)		1,616,405	(1,246,316)

NOTES TO INTERIM CONDENSED CONSOLIDATED FINANCIAL INFORMATION *30 June 2023*

1. CORPORATE INFORMATION AND BASIS OF PREPARATION

1.1 Corporate information

Cutia Therapeutics (the "**Company**") was incorporated in the Cayman Islands as an exempted company with limited liability on 15 May 2019, and its shares are listed on The Stock Exchange of Hong Kong Limited on 12 June 2023. The registered office address of the Company is 4th Floor, Harbour Place, 103 South Church Street, P.O. Box 10240, Grand Cayman KY1-1002, Cayman Islands.

The Company is an investment holding company. The Company and its subsidiaries (the "**Group**") are principally engaged in developing innovative and comprehensive solutions that are tailored to meet the diverse and evolving needs of patients and consumers in the broader dermatology treatment and care market.

1.2 Basis of preparation

The interim condensed consolidated financial information for the six months ended 30 June 2023 has been prepared in accordance with International Accounting Standard 34 *Interim Financial Reporting*. The interim condensed consolidated financial information does not include all the information and disclosures required for a complete set of financial statements prepared in accordance with the International Financial Reporting Standards ("**IFRSs**"), and should be read in conjunction with the Group's consolidated financial statements for each of the years ended 31 December 2021 and 2022 as set out in the accountants' report (the "Accountants' Report") included in the prospectus of the Company dated on 31 May 2023.

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

2 CHANGES IN ACCOUNTING POLICIES AND DISCLOSURES

The accounting policies adopted in the preparation of the interim condensed consolidated financial information are consistent with those applied in the preparation of the Accountants' Report, except for the adoption of the following new and revised IFRSs for the first time for the current period's financial information.

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

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

- (a) Amendments to IAS 1 require entities to disclose their material accounting policy information rather than their significant accounting policies. Accounting policy information is material if, when considered together with other information included in an entity's financial statements, it can reasonably be expected to influence decisions that the primary users of general purpose financial statements make on the basis of those financial statements. Amendments to IFRS Practice Statement 2 provide non-mandatory guidance on how to apply the concept of materiality to accounting policy disclosures. The Group has applied the amendments since 1 January 2023. The amendments did not have any impact on the Group's interim condensed consolidated financial information but are expected to affect the accounting policy disclosures in the Group's annual consolidated financial statements.
- (b) Amendments to IAS 8 clarify the distinction between changes in accounting estimates and changes in accounting policies. Accounting estimates are defined as monetary amounts in financial statements that are subject to measurement uncertainty. The amendments also clarify how entities use measurement techniques and inputs to develop accounting estimates. The Group has applied the amendments to changes in accounting policies and changes in accounting estimates that occur on or after 1 January 2023. Since the Group's policy of determining accounting estimates aligns with the amendments, the amendments did not have any impact on the financial position or performance of the Group.
- (c) Amendments to IAS 12 Deferred Tax related to Assets and Liabilities arising from a Single Transaction narrow the scope of the initial recognition exception in IAS 12 so that it no longer applies to transactions that give rise to equal taxable and deductible temporary differences, such as leases and decommissioning obligations. Therefore, entities are required to recognise a deferred tax asset (provided that sufficient taxable profit is available) and a deferred tax liability for temporary differences arising from these transactions. The Group has applied the amendments on temporary differences related to leases and decommissioning obligations as at 1 January 2022, with no financial effect recognised as an adjustment to the balance of accumulated losses or other component of equity as at that date. In addition, the Group has applied the amendments other than leases and decommissioning obligations that occurred on or after 1 January 2022, if any.

Prior to the initial application of these amendments, the Group applied the initial recognition exception and did not recognise a deferred tax asset and a deferred tax liability for temporary differences for transactions related to leases. Upon initial application of these amendments, the Group recognised (i) a deferred tax asset amounting to RMB6,137,000 (unaudited) for all deductible temporary differences associated with lease liabilities and tax losses (provided that sufficient taxable profit is available), and (ii) a deferred tax liability amounting to RMB6,137,000 (unaudited) for all taxable temporary differences associated with right-of-use assets as at 1 January 2022.

The adoption of amendments to IAS 12 did not have any impact on the financial position or performance of the Group for the six months ended 30 June 2023 and 2022.

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

3. OPERATING SEGMENT INFORMATION

Operating segment information

For management purposes, the Group has only one reportable operating segment, which is developing innovative and comprehensive solutions that are tailored to meet the diverse and evolving needs of patients and consumers in the broader dermatology treatment and care market. Since this is the only reportable operating segment of the Group, no further operating segment analysis thereof is presented.

Geographical information

During the reporting period, all of the Group's revenue was derived from customers located in the People's Republic of China ("**PRC**") and nearly all of the Group's non-current assets were located in the Mainland China, and therefore no geographical segment information is presented in accordance with IFRS 8 *Operation Segments*.

Information about major customers

Revenue derived from sales to customers, which amounted to more than 10% of the Group's revenue during the six months ended 30 June 2023 and 2022, is as follows:

	For the six month	For the six months ended 30 June		
	2023	2022		
	RMB'000	RMB'000		
	(Unaudited)	(Unaudited)		
Customer A	-	139		
Customer B	13,344	_		

4. **REVENUE, OTHER INCOME AND GAINS**

An analysis of revenue is as follows:

	For the six months	For the six months ended 30 June		
	2023	2022		
	RMB'000	RMB'000		
	(Unaudited)	(Unaudited)		
Revenue from contracts with customers				
Sale of products – at a point in time	34,343	658		

An analysis of other income and gains is as follows:

	For the six months ended 30 June		
	2023		
	RMB'000	RMB'000	
	(Unaudited)	(Unaudited)	
Other income			
Government grants*	7,855	_	
Bank interest income	12,057	2,844	
Imputed interest income on rental and other deposits	84	-	
Deemed interest income from loans to employees	114	56	
Deemed interest income from the loans to related parties	610	306	
Others	785	419	
	21,505	3,625	
Gains			
Foreign exchange gains, net	27,680	53,090	
Gain on termination of a lease contract	37	_	
Fair value gains on financial assets at FVTPL	4,622	1,731	
	32,339	54,821	
	53,844	58,446	

* The government grants have been received from the PRC local government authorities to support certain subsidiaries' operating activities. There are no unfulfilled conditions relating to these government grants.

5. INCOME TAX

The Company was incorporated in the Cayman Islands and is exempted from income tax.

No Hong Kong profits tax was provided for as there was no estimated assessable profit of the Group's Hong Kong subsidiary that was subject to Hong Kong profits tax during the periods presented in the interim condensed consolidated financial information.

No PRC Enterprise Income tax was provided for as there was no estimated assessable profit of the Group's PRC subsidiaries during the periods presented in the interim condensed consolidated financial information.

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

6. **DIVIDENDS**

No dividend was paid or proposed for ordinary shareholders of the Company during the six months ended 30 June 2023, nor has any dividend been proposed since the end of the reporting period (during the six months ended 30 June 2022: nil).

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

The calculation of the basic loss per share amounts for the six months ended 30 June 2023 and 2022 is based on the loss for the period attributable to ordinary equity holders of the parent and the weighted average numbers of ordinary shares in issue after taking into account the retrospective adjustments on the assumption that the share subdivision had been in effect on 1 January 2022.

No adjustment has been made to the basic loss per share amounts presented for the six months ended 30 June 2023 and 2022 in respect of a dilution as the impact of convertible redeemable preferred shares, over-allocation option, share options and restricted share units had an anti-dilutive effect on the basic loss per share amounts presented.

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

	For the six months ended 30 June	
	2023	2022
	RMB'000	RMB'000
	(Unaudited)	(Unaudited)
Loss		
Loss attributable to ordinary equity holders		
of the parent for the purpose of calculating basic and		
diluted loss per share (RMB'000)	(1,640,339)	(251,613)
Shares Weighted average number of ordinary shares in issue during		
the period used in the basic and diluted loss per share calculation	103,557,292	80,045,710
Loss per share (basic and diluted) (RMB per share)	(15.84)	(3.14)

8. TRADE RECEIVABLES

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

	30 June	31 December
	2023	2022
	RMB'000	RMB'000
	(Unaudited)	(Audited)
Within 3 months	4,048	98

9. FINANCIAL ASSETS AT FVTPL

	30 June 2023	31 December 2022
	<i>RMB'000</i> (Unaudited)	<i>RMB</i> '000 (Audited)
Financial products	461,599	43,496

The financial assets measured at FVTPL represented financial products with no predetermined return which are principal protected investments. The financial products are with expected yield rates, depending on the market prices of underlying financial instruments, including bonds, debentures and other financial assets. Hence their contractual cash flows do not qualify for solely payments of principal and interest. The expected yield rates ranged from 1.5% to 4.5% per annum as at 30 June 2023 (31 December 2022: 2.86%~3.05% per annum).

10. TRADE AND OTHER PAYABLES

	30 June 2023 <i>RMB'000</i> (Unaudited)	31 December 2022 <i>RMB'000</i> (Audited)
Trade payables	239	_
Accrued expenses for research and development services	2,676	6,021
Payables for purchase of items of property, plant and equipment	9,606	28,176
Other payables	8,251	2,943
Salary and bonus payables	11,596	11,859
Other taxes payable	921	960
Accrued listing expenses	20,508	18,613
	53,797	68,572

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

	30 June 2023 <i>RMB'000</i> (Unaudited)	31 December 2022 <i>RMB'000</i> (Audited)
Within 3 months	239	

11. INTEREST-BEARING BANK BORROWINGS

		30 June 2023		31	December 2022	
	Effective interest			Effective interest		
	rate (%) Maturity	Amount <i>RMB'000</i> (Unaudited)	rate (%)	Maturity	Amount <i>RMB'000</i> (Audited)	
Current: Bank loans						
 unsecured 	One-year LPR	2024	69,416	-	-	_

DEFINITIONS AND GLOSSARY OF TECHNICAL TERMS

"androgenetic alopecia"	a common form of hair loss in both men and women
"Audit Committee"	the audit committee of the Board
"ANDA"	abbreviated new drug application
"Board"	the board of Directors of our Company
"CDE"	Center for Drug Evaluation of the NMPA (國家藥品監督管理局藥品 審評中心), a division of the NMPA to review applications for clinical trials and drug marketing authorization
"China", "Mainland China", or "PRC"	the People's Republic of China, but for the purpose of this announcement and for geographical reference only and except where the context requires, excluding Taiwan, the Macao Special Administrative Region and Hong Kong
"clinical trial"	a research study for validating or finding the therapeutic effects and side effects of test drugs in order to determine the therapeutic value and safety of such drugs
"Company"	Cutia Therapeutics (科笛集团), an exempted company with limited liability incorporated under the laws of the Cayman Islands on 15 May 2019
"Corporate Governance Code"	the Corporate Governance Code contained in Appendix 14 to the Listing Rules
"Core Product"	has the meaning ascribed to it under Chapter 18A of the Listing Rules; for the purpose of this announcement, our Core Product refers to CU- 20401
"dermatology"	the branch of medicine that deals with the diagnosis and treatment of skin related disorders
"DHT"	dihydrotestosterone, a male sex hormone which is the active form of testosterone, formed from testosterone in bodily tissue
"Director(s)"	the director(s) of the Company
"FDA"	Food and Drug Administration of the United States
"GMV"	gross merchandise value

"GMP"	good manufacturing practice, the practices required in order to conform to the guidelines recommended by agencies that control the authorization and licensing of the manufacture and sale of products
"Group", "our Group", "our", "we", or "us"	our Company and our subsidiaries
"Hong Kong"	the Hong Kong Special Administrative Region of the PRC
"IND"	investigational new drug, an application in the drug review process required by an regulatory authority to decide whether a new drug is permitted to initiate clinical trials; also known as clinical trial application, or CTA, in China
"indication"	a valid reason to use a specific test, drug, device, procedure or surgery
"Key Product"	for the purpose of this announcement, our Key Products refer to CU-40102 and CU-10201
"Listing Date"	12 June 2023
"Listing Rules"	the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited, as amended, supplemented or otherwise modified from time to time
"mechanism of action"	the specific biochemical interaction through which a drug substance produces its pharmacological effect
"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, a process required by an regulatory authority to approve a new drug for sale and marketing
"NMPA"	the National Medical Products Administration of China (國家藥品監督 管理局)
"OTC"	over-the-counter, a kind of drug that may be sold over the counter upon receiving the competent authority's approval at dispensers, pharmacies or retail outlets without requiring a prescription by a medical practitioner
"PK"	pharmacokinetics, the study of the bodily absorption, distribution, metabolism, and excretion of drugs, which, together with pharmacodynamics, influences dosing, benefit, and adverse effects of the drug

- "Phase I clinical trial" a study in which a drug is introduced into healthy human subjects or patients with the target disease or condition and tested for safety, dosage tolerance, absorption, metabolism, distribution, excretion, and if possible, to gain an early indication of its efficacy
- "Phase II clinical trial" a study in which a drug is administered to a limited patient population to preliminarily evaluate the efficacy of the product for specific targeted diseases, to identify possible adverse effects and safety risks, and to determine optimal dosage
- "Phase III clinical trial" a study in which a drug is administered to an expanded patient population generally at geographically dispersed clinical trial sites, in well-controlled clinical trials to generate enough data to statistically evaluate the efficacy and safety of the product for approval, to provide adequate information for the labeling of the product
- "pre-clinical study" a study testing a drug on non-human subjects, to gather efficacy, toxicity, pharmacokinetic and safety information and to decide whether the drug is ready for clinical trials

"prescription drug" a drug which may only be prescribed by qualified medical practitioners

"Pre-IPO Equity the equity incentive plan adopted by the Company that took effect on 23 August 2019

- "primary endpoint" a main or most important outcome at the end of a study to determine whether a new drug or treatment worked
- "Prospectus" the prospectus issued by the Company dated 31 May 2023
- "registrational clinical a clinical trial or study to demonstrate clinical efficacy and safety evidence required before submission for drug marketing approval
- "Reporting Period" the six months ended 30 June 2023
- "RMB" the lawful currency of the PRC
- "Shares" ordinary share(s) with nominal value of US\$0.00002 each in the share capital of the Company
- "Shareholders" holder(s) of the Shares
- "SKU" stock keeping unit
- "Stock Exchange" The Stock Exchange of Hong Kong Limited

"subsidiary(ies)" has the meaning ascribed to it in section 15 of the Companies Ordinance
"US" or "United States" the United States of America, its territories and possessions, any State of the U.S." the United States, and the District of Columbia
"U.S. dollars" the lawful currency of the U.S.

By order of the Board **Cutia Therapeutics Zhang Lele** *Chief Executive Officer and Executive Director*

Hong Kong, 29 August 2023

As at the date of this announcement, the Board comprises (i) Ms. Zhang Lele and Mr. Huang Yuqing as executive Directors; (ii) Dr. Chen Lian Yong, Dr. Xie Qin, Dr. Huang Xiao, Ms. Yang Yunxia as non-executive Directors; and (iii) Mr. Chung Ming Kit, Mr. Tao Tak Yan Dennis and Mr. Ye Xiaoxiang as independent non-executive Directors.