



Hua Medicine
华领医药



**2022 Annual Results
Presentation**

March 2023

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2022 Company Overview

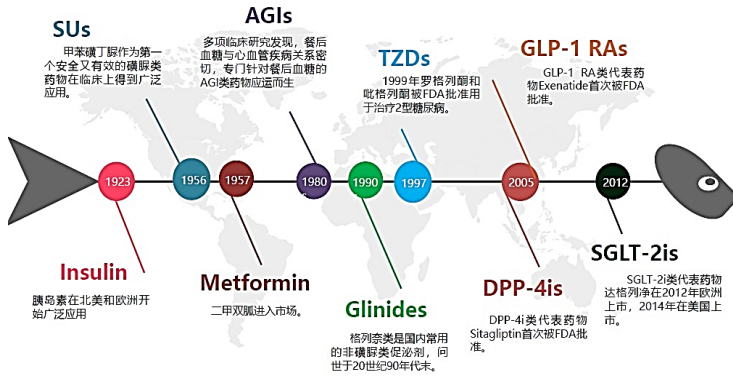
Hua Medicine: A Roadmap to Global First-In-Class



- **Apr. 2021:** NDA for dorzagliatin for the treatment of Type 2 diabetes was accepted by the China NMPA
- **May 2021:** Shanghai Hua Medicine Biotechnology Ltd. established
- **June 2021:** Presentation at 2021 ADA: dorzagliatin can regulate GLP-1 release in T2D patients
- **Sep. 2021:** Signed a supply chain strategic cooperation agreement with Sinopharm
- **Sep. 2021:** Announced positive results for DREAM study: remission rate reached 65.2% within 1 year after drug withdrawal
- **Feb. 2022:** Announced supply agreement with WuXi STA for commercial manufacturing of dorzagliatin
- **May 2022:** Published two peer-reviewed papers in *Nature Medicine* on the results of the Phase III trials of dorzagliatin
- **June 2022:** 2022 ADA conference 3 presentations on DREAM, SENSITIZE, and early phase insulin secretion of dorzagliatin
- **June 2022:** Dorzagliatin is incorporated into Expert Consensus on the assessment and protection of pancreatic islet β -cell function in patients with type 2 diabetes mellitus
- **Oct. 2022:** HuaTangNing was approved for two indications and three allowances, and officially launched in China
- **Dec.2022:** Acquired 100% equity interest in Nanjing AscendRare Pharmaceutical Technology Co., Ltd for approximately RMB1 million
- **Jan.2023:** Received an aggregate milestone payment of RMB400 million from Bayer for approval and commercialization of HuaTangNing
- **Jan.2023:** Receipt of approved production batches, HuaTangNing sales officially resumed
- **Jan.2023:**For the period from the first commercial sales at end of October 2022 through the end of January 2023, approximately generating net sales revenues of approximately RMB 49 million (unaudited) of HuaTangNing

Global Unmet Medical Needs in Glycemic Control

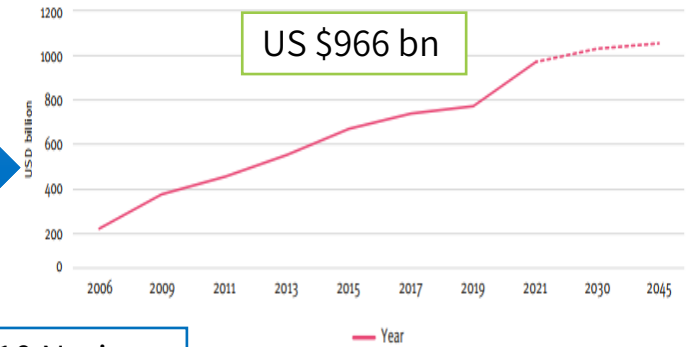
9 Classes of Drugs



IDF 2021

537 Mn Diabetes
Many Complications

Figure 3.14 Total diabetes-related health expenditure for adults (20-79 years) with diabetes from 2006 to 2045

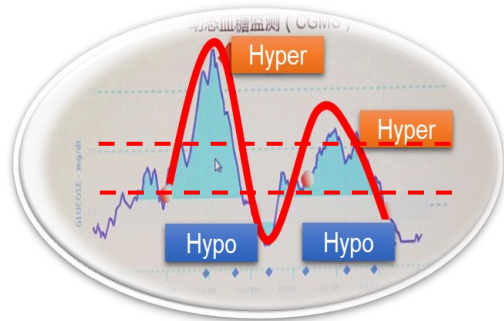


新近 2型糖尿病的药物治疗(1) 临床药物治疗杂志 2015, 13(3): 18-22.
Bae E J. DPP-4 inhibitors in diabetic complications: role of DPP-4 beyond glucose control[J]. Archives of pharmaceutical research, 2016, 39(8): 1114-1128.
Knop F K, Branden A, Vilsbøll T. Exenatide: pharmacokinetics, clinical use, and future directions[J]. Expert opinion on pharmacotherapy, 2012, 18(6): 555-571.

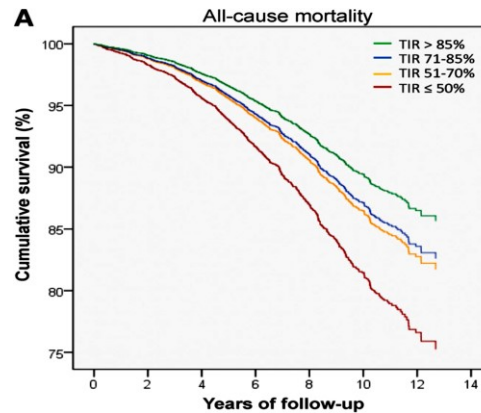
Top 10 Nations

Rank	Country or territory	Total diabetes-related health expenditure in 2021 (USD billion) in adults (20-79 years)
1	United States of America	379.5
2	China	165.3
3	Brazil	42.9
4	Germany	41.3
5	Japan	35.6
6	United Kingdom	23.4
7	France	22.7
8	Mexico	19.9
9	Spain	15.5
10	Italy	14.7

Economic Burden



Lost Glucose Homeostasis



TIR in Diabetes Survival

Source: Cheng YY, Chen L. Global J Obesity, Diabetes and Metabolic Syndrome 2020, 7: 018-023

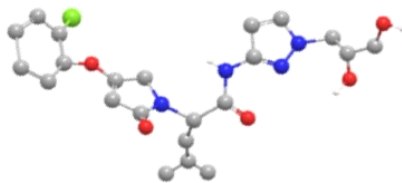
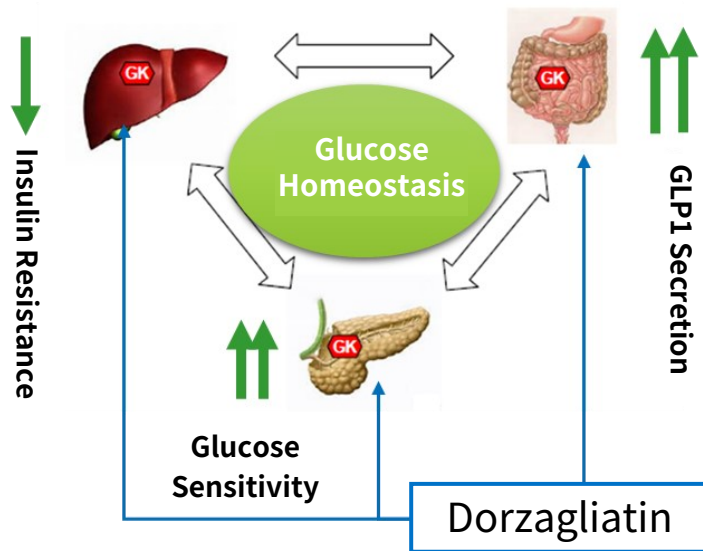
Source: IDF DIABETES ATLAS Tenth edition 2021

Dorzagliatin – A Differentiated First-In-Class Antidiabetic Drug Advance Diabetes Care Globally



Glucokinase (GK) as glucose sensor plays central role in glucose homeostasis
Loss of GK sensor function leads to impaired glucose sensitivity and diabetes

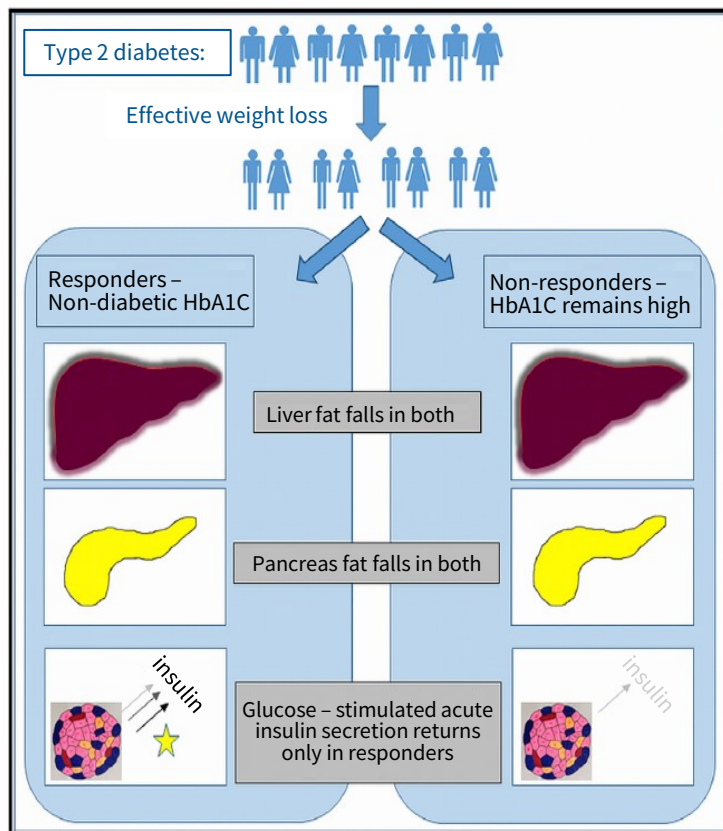
Dorzagliatin improves glucose sensitivity and beta cell function as novel mechanism to treat diabetes



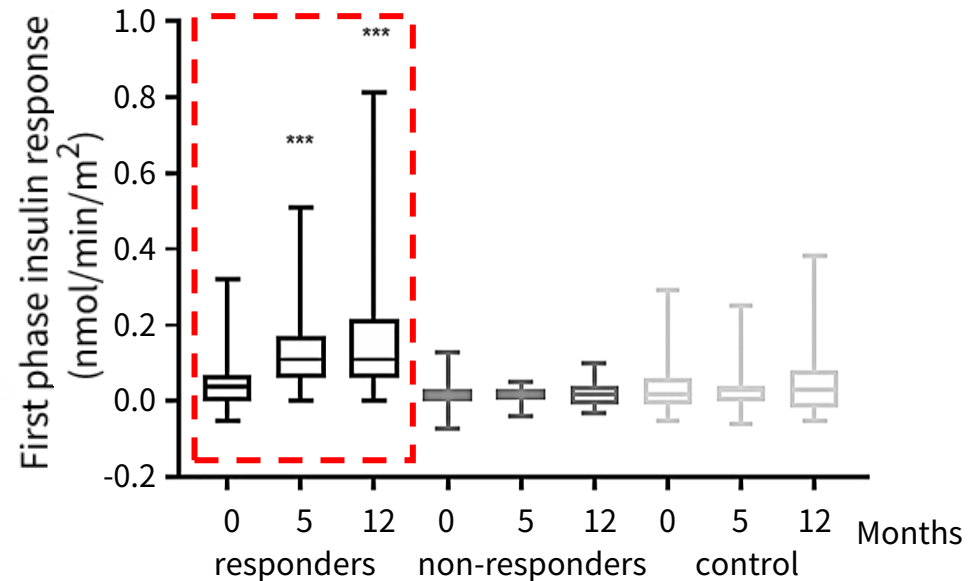
- In clinical trials - Dorzagliatin improves β -cell function in T2D in China, and repairs GLP-1 secretion in obese T2D patients in US
- Phase 3 SEED, DAWN studies demonstrated the potential for best homeostasis control for drug naïve and metformin-tolerant T2D patients in China
- Diabetes remission achieved in Dorzagliatin treated drug naïve T2D patients in the DREAM study

Improving early-phase insulin secretion is a key factor in glycemic remission in T2D

DiRECT Study: For patients with diabetes remission driven by weight loss, weight loss of 15 kg to reduce liver and islet organ fat can contribute to a certain proportion of diabetes remission, but glucose-stimulated early insulin secretion have to be improved.



Patients who achieved blood sugar target in the trial
Glucose-stimulated early-phase insulin secretion was significantly improved



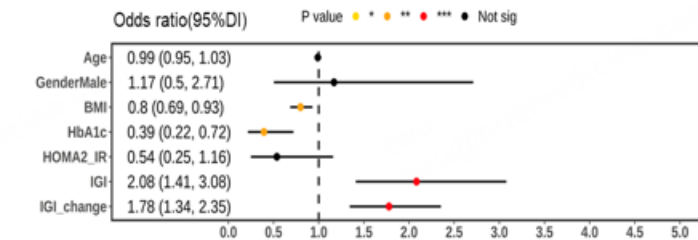
Improvement of GSIS by Dorzagliatin Drives Glycemic Control



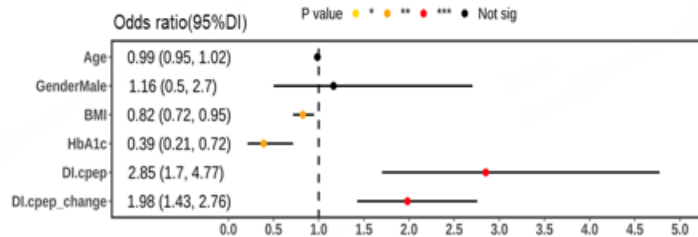
- Patients in SEED and DAWN achieved effective glycemic control in 43-45%
- Glycemic control (HbA1c < 7%) in SEED and DAWN is dependent on the early phase insulin secretion (IGI & DI) baseline status and improvement from baseline by Dorzagliatin treatment
- Improvement of disposition index (DI) and IGI are validated in large Ph III registration trials

SEED: Drug Naïve T2D

IGI model

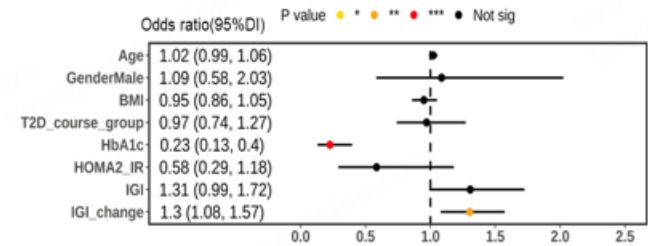


DI.Cpep model

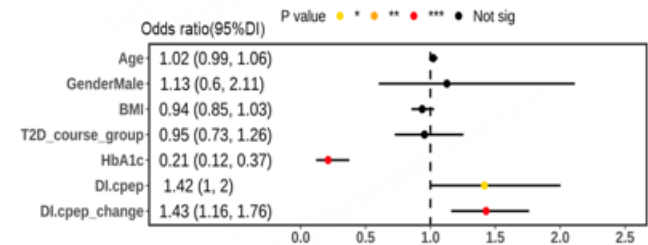


DAWN: Metformin Failed T2D

IGI model



DI.Cpep model



Source: LG Feng, L Chen, WY Yang, 2022 ADA 117-LB; Diabetes 2022;71(Supplement_1):117-LB

HuaTangNing (华堂宁®) Approved by NMPA



1. One Breakthrough: restores the impaired glucose homeostasis in T2D patients
2. Two Indications: with dietary and exercise to treat
 1. Drug naïve T2D
 2. Metformin tolerated T2D
3. Three Allowances
 1. No dose adjustment for DKD
 2. Combination with sitagliptin (DPP-IV) allowed
 3. Combination with empagliflozin (SGLT-2) allowed



Retail Launch Price: 420 RMB / 28 Tablet Pack

2 Key Takeaways:
(1) Improves β -cell function
(2) Restores impaired glucose homeostasis

HuaTangNing(华堂宁®) – Commercialization Progress



31 Jan. 2023 – Approximately 148,000 packs (unaudited) of HuaTangNing (华堂宁®) have been sold, generating net sales revenues of approximately RMB49 million (unaudited) – for a period of approximately 100 days of sales

Beginning of Jan. 2023 –After being approved, the first batch of approx. 90,000 packs of HuaTangNing produced has been introduced into the market, and the supply chain has fully resumed

31 Dec. 2022 –Total revenue generated was approximately RMB17.6 million, approximately 53,000 packs of HuaTangNing was sold since launch

Mid-Nov. 2022 –Voluntarily restricted sales within the two months after the first week of launch to ensure adequate continuous supply was available for patients who successfully secured HuaTangNing prescriptions due to significant demand and initial launch supply constraints

2 Nov. 2022– HuaTangNing ranked first in the sales list of type 2 diabetes prescription drugs on JD.com during Double Eleven, and ranked in the top three in the list of metabolic drugs

1 Nov. 2022 – Officially launched regulated sales online

28 Oct. 2022 – The first prescription of HuaTangNing was issued, priced at RMB 420/per pack

8 Oct. 2022 – HuaTangNing (华堂宁®) NMPA approval notification officially published

30 Sep. 2022– NDA approved by NMPA

Hua Medicine R&D Pipeline



Product Name	Indication	Development phase	Development phase							
			Pre-clinical	IND	Phase I	Phase II	Phase III	NDA	Launched	
HuaTangNing (华堂宁®)	T2D - monotherapy	Launched (China)	[Blue arrow from Pre-clinical to Launched]							
	T2D - combination therapy with metformin	Launched (China)	[Blue arrow from Pre-clinical to Launched]							
HuaTangNing (华堂宁®)	DKD	Launched (China) - Allowances	[Green arrow from Pre-clinical to Launched]							
	Combination therapy with DPP4i	Launched (China) - Allowances	[Green arrow from Pre-clinical to Launched]							
	Combination therapy with SGLT2i	Launched (China) - Allowances	[Green arrow from Pre-clinical to Launched]							
Fixed dose combinations - dorzagliatin and OADs	T2D	Phase I ready	[Grey arrow from Pre-clinical to Phase I]							
★ Next GKA	Metabolic Diseases	Pre-clinical	[Grey arrow from Pre-clinical to Pre-clinical]							
★ Glucokinase compound	Congenital Hyperinsulinism	Pre-clinical	[Grey arrow from Pre-clinical to Pre-clinical]							
Fructose Kinase Inhibitor	Metabolic Disease	Pre-clinical	[Grey arrow from Pre-clinical to Pre-clinical]							
mGLUR5 NAM- CNS	PD-L1D	Pre-clinical	[Grey arrow from Pre-clinical to Pre-clinical]							



Outlook

After the successful launch of HuaTangNing (华堂宁®), Hua Medicine will continue to develop its product pipeline.

- **The second generation GKA - a key product of Hua Medicine for the next 20 years**
 - To submit an IND application in the U.S. by the end of 2023 or early 2024
 - To complete Phase I clinical research in the U.S. by 2024
 - To identify BD partners for oversea markets
- **Novel glucokinase inhibitor - for congenital hyperinsulinism (rare disease)**
 - Currently in the pre-clinical stage and is stepping up preparations for IND
 - Active communication with regulatory; subject to feedback, would like to initiate both in China and US
- **HuaTangNing (华堂宁®) related studies**
 - The Sensitize II study lead by Professor Juliana Chan and Elaine Chow has begun to enroll
 - Actively preparing for the clinical research of IGT to NGT

Outlook - Commercialization



To secure the supply of HuaTangNing (华堂宁®), while stepping up sales efforts. Higher sales and growth targets for 2023.

- **Stronger sales**

- Cooperation with Bayer to cover more regions and hospitals
- Cooperation with tier-1 distributors to provide better purchasing and after-sales experience for patients

- **Secured supply**

- Capacity increase to cater to growing patient demand
- Optimization of production process for faster throughput and lower cost

- **NRDL entry**

- Proactive preparation for the year-end NRDL negotiation
- More evidence to demonstrate the value of HuaTangNing (华堂宁®)



Financial Review

Financial Summary

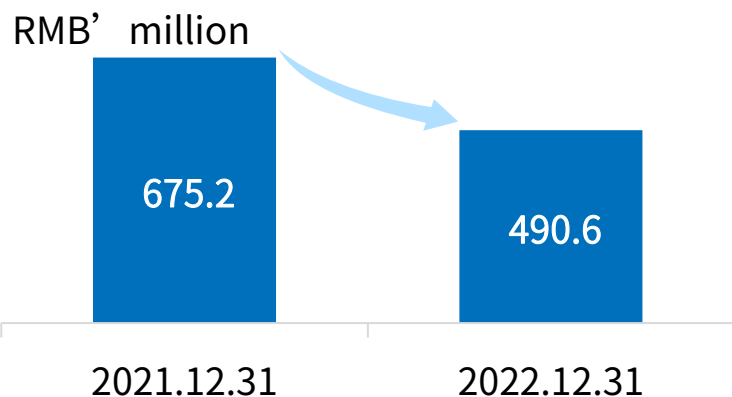


Cash Balance: RMB490.6 million of cash at 12/31/2022 vs. 675.2 million at 12/31/2021.

Total cash decrease of RMB184.6 million, consisted of

- Net cash used in operating activities was RMB230.1 million
- Net cash used in investing activities was RMB4.8 million
- Net cash from financing activities was RMB21.5 million
- Net effect of exchange rate changes was RMB28.8 million

Net cash used in operation activities of RMB230.1 million mainly includes cash payment of RMB 110.4 million for the research and development activities, RMB114.3 million for the administrative activities and of RMB5.4 million for the selling activities.



Note: On January 12, 2023 and January 19, 2023, we received RMB400.0 million in aggregate upon the NDA approval and the achievement of another commercialization milestone.

Financial Summary- continued



Revenue: of RMB17.6 million in the year of 2022.

Our revenue was generated from the sale of our core product – HuaTangNing (华堂宁®). From first commercial launch through December 31, 2022, approximately 53,000 packs of HuaTangNing (华堂宁®) were sold, generating sales of approximately RMB17.6 million.

Gross profit: of RMB7.7 million and a gross profit rate of 43.7% in the year of 2022.

In view of the high unit production cost and high fixed cost ratio due to the sales volume at the early stage of commercialization, the gross profit rate for year 2022 is relatively low. As our commercialization scale increases, our gross profit rate is expected to increase to a more normalized rate.

Loss before tax of RMB203.5 million in the year of 2022 vs. RMB325.7 million in the year of 2021.

Financial Summary- continued



Selling expenses of RMB15.3 million in the year of 2022.

Our selling expenses consisted primarily of RMB5.8 million of employee compensation, RMB8.2 million of promotion expense and RMB1.3 million of meeting expense, logistics expense and other related expenses.

Research and development expenses of RMB129.5 million in the year of 2022 vs. RMB186.8 million in the year of 2021.

- a decrease of RMB17.3 million for dorzagliatin clinical trials from RMB22.2 million for the year ended December 31, 2021 to RMB4.9 million for the year ended December 31, 2022, which was primarily attributable to the data analysis and trial master file report preparation of SEED/HMM0301 and DAWN/HMM0302 conducted in the year 2021. In the year 2022, we primarily focused on our NDA approval and conducted several additional clinical research to support the review by the NMPA;
- a decrease of RMB21.5 million in chemical, manufacturing, and control (CMC) expenses from RMB31.3 million for the year ended December 31, 2021 to RMB9.8 million for the year ended December 31, 2022. We focused on the process validation, drug substance and production for clinical trial which was required by NMPA in the first half of 2022, and transitioned to commercial production after NDA approval. In year of 2021, we focused on the chemical and process research for our fructose kinase inhibitor candidates and manufacture-dynamic process validation batch production to support our NDA approval;
- a decrease of RMB13.8 million in labor cost from RMB98.1 million for the year ended December 31, 2021 to RMB84.3 million for the year ended December 31, 2022, which was primarily attributable to the decrease of share-based payment under the accelerated amortization method; and
- a decrease of RMB5.4 million in other expenses from RMB29.1 million for the year ended December 31, 2021 to RMB23.7 million for the year ended December 31, 2022, which was primarily attributable to decreased travel cost, meeting cost and utility cost due to the impact of COVID-19 in the year 2022.

Financial Summary- continued



Administrative expenses of RMB129.9 million in the year of 2022 vs. RMB134.8 million in the year of 2021.

- decrease in labour costs which was attributable to the decrease of RMB7.5 million in share-based payment under the accelerated amortization method, adjusted for an increase of RMB4.0 million in cash compensation;
- decrease of RMB1.9 million in marketing and public relations costs, mainly due to fewer national and regional meetings conducted in the year of 2022 which was impacted by our marketing strategy and COVID-19;
- decrease of RMB2.0 million in recruitment expense due to our recruitment strategy;
- decrease of RMB0.8 million in entertainment expense and RMB0.7 million in travelling expense due to decreased commercial and travel activities compared to the year 2021, which was impacted by COVID-19;
- adjusted for the increase in consulting fee of RMB7.3 million mainly associated with the NDA approval application and commercialization strategy consulting in the year of 2022 and fewer such activities in the year of 2021.



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