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2022 半年度报告

2022 Semi-Annual Report



甘李药业股份有限公司
GAN & LEE PHARMACEUTICALS.
股票代码：603087
STOCK CODE: 603087

科学 极致

SCIENCE
EXCELLENCE



CEO 致辞



心怀患者初心不变，脚踏实地探索高质量发展之路

尊敬的各位投资者和朋友们：

今年是实施“十四五”规划的关键一年，工信部等九部门联合印发《“十四五”医药工业发展规划》，提出了未来5年的发展目标和15年远景目标。纵观整个医药行业巨大的市场空间，机遇和挑战并存，如何打破行业挑战，促进企业转型升级，是值得深入探讨的问题。

正所谓“企者不立，跨者不行”，甘李药业始终跟随国家政策的步伐，稳健积极地探索前进之路。2022年是公司在集采中战略选择的落地执行年，也是公司长远市场规划的布局之年。公司积极响应国家为民降费的号召，在集采中全产品高顺位中标，旨在用更普惠的价格惠及更多的患者。胰岛素集采中选结果刚开始执行，鉴于医生的处方习惯与糖尿病患者对产品的认知需要时间转换，本公司产品销量的增长尚不能对冲价格下降的影响给公司业绩带来了短期阵痛。2022年上半年，公司实现营业收入8.35亿元，同比下降43.42%，实现归属于上市公司股东的净利润-1.98亿元。然而，公司与员工对未来充满信心，希望借助集采高顺位中标优势，在第一个集采年度迅速提升市场份额。

Message from the CEO

Keep patients in mind and remain true to our original aspiration, spare no efforts to explore the road of high-quality developments

Dear investors and friends:

This year is a crucial year for the implementation of the "14th Five-Year Plan". The Ministry of Industry and Information Technology and the other eight departments jointly issued the "14th Five-Year Plan" for the development of the pharmaceutical industry, which put forward the development goals for the next five years and the long-term goals for the next 15 years. Looking at the broad market space of the entire pharmaceutical industry, opportunities and challenges coexist. How enterprises break the industry challenges, promote the transformation and upgrading is a question worth further discussion.

Like the old saying, "Those who stand on tiptoe are not steady. Those who strain their strides cannot long keep up the pace". Gan & Lee Pharmaceuticals has always followed the pace of the national policy, and explored the way forward in a steady and positive manner. 2022 is the year that the Company implements the strategic choice in the central volume-based procurement (VBP), as well as the year of layout the long-term market planning. The Company actively responded to the call of the state to reduce medical cost for the people, and all products won the bidding in the VBP, aiming to benefit more patients with a more inclusive price. Given that it takes time for both doctors and diabetic patients to know the products. The increased product volume still cannot hedge the impact of price decline, inevitably the Company's performance has a short-term decline. In the first half of 2022, the Company achieved operating income of RMB 835 million, a year-on-year decrease of 43.42%, and realized net profit attributable to shareholders of the listed company of RMB -198 million. Nevertheless, the Company and employees are full of confidence in the future and hope to increase the market share in the first year of the VBP rapidly.

本次胰岛素集采中选结果从 2022 年 5 月开始陆续在各地落地执行，公司最终获得首年协议采购量 3,533.77 万支（首次报量 1,664.18 万支、获得分量 1,869.59 万支），共计覆盖医疗机构数量 21,000 多家，其中公司新准入医疗机构近万家。凭借公司产品在此次集采中获得的优势，仅在今年上半年，公司在集采报量医疗机构之外新获得准入的医疗机构就达 3,200 多家，远高于以往年度的拓展速度。随着带量采购在全国各省（自治区、直辖市）陆续落地执行，公司医疗机构覆盖数量有望进一步上升，为公司后续销量增长与未来新产品快速进入市场奠定了坚实基础。公司自今年年初就开始扩增专业学术代表团队，希望更全面地服务报量医疗机构，更好地覆盖自由市场，扩大学术宣传范围。尤其在集采执行的大背景下，公司更加鼓励学术代表团队的工作向基层市场下沉。公司在 2022 年上半年扩招近千位专业学术代表，基本完成年初制定的扩充团队目标，从人才储备方面做好了下半年发力实现国内销量大幅增长的准备。

创新研发一直是我们的不懈的追求。为了保障公司未来的长足发展，我们持续加大对研发方面的投入。今年上半年，公司研发投入达 31,951.09 万元，占销售收入的 38.27%，同比增长 28.36%，我们始终秉持着“科学 极致”的企业文化，期望可以不断突破自我为患者提供更多、更好的治疗方案。公司持续发挥国内胰岛素领先优势，积极拓展糖尿病治疗药物的全品类布局。今年上半年，公司自主研发的创新型 GLP-1 类似物 GZR18 完成美国 I 期临床试验首次人体给药，并于 2022 年 7 月完成中国 Ib/Ila 期临床试验首例受试者给药，GZR18 适应症包括 2 型糖尿病和肥胖 / 超重体重管理，是公司在 GLP-1 类似物领域迈向双适应症探索的重要一步；公司创新型预混胰岛素 GZR101 完成中国 I 期临床试验首例受试者给药，该药物是公司在研的超长效胰岛素 GZR33 与速效门冬胰岛素（锐秀霖®）混合制成的预混双胰岛素复方制剂，进一步丰富了产品管线；同时公司首个自主研发的口服降糖药以及首个化学仿制药——磷酸西格列汀片，也已获得上市批准，有望丰富公司产品线并提高学术推广团队的效率。

The selected results of this VBP (insulin) have been implemented in various regions since May 2022. The Company finally obtained the agreed purchase quantity of 35.338 million units in the first year (the first reported quantity of 16.642 million units and the obtained quantity of 18.696 million units), covering more than 21,000 medical institutions, of which nearly 10,000 medical institutions are newly accessed. With the advantages of the Company's products obtained in this procurement, more than 3,200 medical institutions besides reported medical institutions were newly accessed in the first half of this year alone, far higher the expansion speed than before. With the implementation of VBP in various provinces (autonomous region, municipality) across the country, the number of medical institutions covered by the Company is expected to rise further, laying a solid foundation for the Company's subsequent sales growth and rapid entry of new products into the market in the future. We have been expanding our professional academic representative team since the beginning of this year, hoping to provide more services to medical institutions, better cover the free competitive market, and expand the scope of academic publicity. Especially against the background of the VBP, the Company encourages the work of the academic representative team to sink into the primary tier market. In the first half of 2022, we expanded the enrollment of nearly 1,000 professional academic representatives, not only met the goal of team expansion that set at the beginning of the year, but also prepared the reserve of sales talents for the second half of 2022.

R&D innovation has always been our consistent pursuit. To ensure the future long-term development, the Company will continue to increase the investment in R&D. In the first half of this year, we invested RMB 319.51 million in R&D, accounting for 38.27% of sales revenue, with a year-on-year increase of 28.36%. With the corporate culture of "Science & Excellence", we expect to continuously break through and provide more and better treatment solutions for patients. The Company continues to play a leading role in the domestic insulin market and actively explores the layout of the comprehensive portfolio of diabetes treatment drugs. The Company's self-developed innovative GLP-1 analog GZR18 completed the first subject dosing in Phase I clinical trial in the e U.S and then completed the first subject dosing in the Phase Ib/Ila clinical trial in China in July 2022. The approved indications of GZR18 include type 2 diabetes and obesity/overweight management, which is an important milestone in the Company's exploration of dual indications in the GLP-1 analogs. The Company's innovative premixed insulin GZR101 completed the first subject dosing in phase I clinical trial. The drug is a premixed dual insulin compound preparation made by mixing the Company's ultra-long-acting insulin GZR33 and fast-acting insulin aspart(Rapilin®), which further enriches the product pipeline. At the same time, the Company's first self-developed oral glucose-lowering drug and the first chemical generic drug, sitagliptin phosphate tablets, was approved for marketing, which is expected to enrich the Company's product line and improve the efficiency of the academic promotion team.

此外，公司在建项目“甘李临沂生产基地”正在有序推进，目前，该工程已完成土建主体施工、外立面建造和相关配套工程建设，进入全面精装阶段。我们计划将其打造成甘李又一座世界一流的现代化工厂，通过不断扩大产能为公司全球化策略以及生物药、化药、医疗器械等产品的商业化提供强劲保障。

糖尿病是一个全球性疾病，胰岛素产品受益者遍布世界各国。公司始终坚持实行国际化战略部署，并将其作为企业发展的重点任务。目前，公司自主研发的甘精、赖脯以及门冬胰岛素注射液均已分别进入即将向美国食品药品监督管理局 (FDA) 以及欧洲药品管理局 (EMA) 提交上市许可申请前的最后关键节点，相关资料正按计划积极准备中。

康德说：“世界上只有两样东西能永远让我们心怀敬畏，一是头顶灿烂的星空，二是内心崇高的道德律。” 努力打造高质量发展新模式，坚持研发驱动、成本领先、国际化和人才高地战略就是我们“头顶灿烂的星空”，而以糖尿病患者为中心，为世界各国患者提供更为优质的产品和服务则是我们“心中的道德律”。甘李人坚信，我们不负初心，未来必不负我们。

甘李药业 CEO
都凯

In addition, the Company's ongoing project "Gan & Lee Linyi Production Base" is progressing in an orderly manner, which has completed the construction of the main civil building, facade construction and related supporting works and is now entering the full-scale finishing stage. We plan to turn it into another world-class modern factory of Gan & Lee, which will provide a strong guarantee for the Company's globalization strategy and commercialization of biologics, chemicals, medical devices and other products through continuous expansion of production capacity.

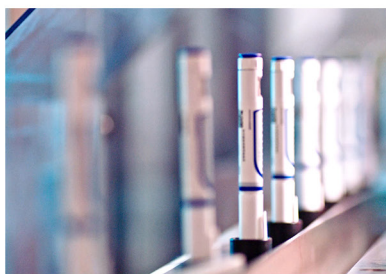
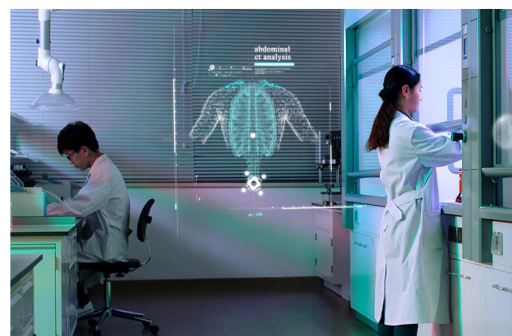
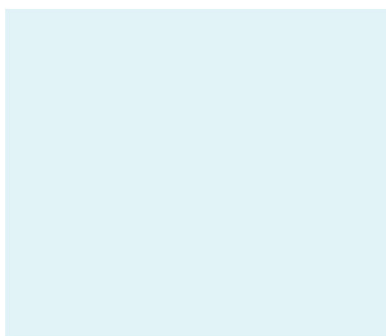
Diabetes is a global disease, and the beneficiaries of insulin products are all over the world. We focus on the internationalization strategy and make it a key task in the Company's development. As of now, the Company has entered the final critical stage before submitting the marketing authorization applications to the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) for its self-developed insulin glargine, insulin lispro and insulin aspart injections, respectively, and the relevant documentation is being prepared according to the plan.

Kant said, "Two things fill the mind with ever new and increasing admiration and awe, the more often and steadily we reflect upon them: the starry heavens above me and the moral law within me." Striving to build a new model of high-quality development, insisting on R&D-driven, cost leading, internationalization and talent highland strategies is our "the starry heavens above me", while providing better products and services to patients all over the world is our "the moral law within me". We believe that we are worthy of our promise. All of Gan & Lee colleagues believe that if we live up to our original intention, the future will live up to us.

CEO of Gan & Lee Pharmaceuticals.
Kai Du

QUALITY FIRST
INNOVATION FOREVER

质量第一 永远创新



重要提示

一、 本公司董事会、监事会及董事、监事、高级管理人员保证半年度报告内容的真实、准确性、完整性，不存在虚假记载、误导性陈述或重大遗漏，并承担个别和连带的法律责任。

二、 公司全体董事出席董事会会议。

三、 本半年度报告未经审计。

四、 公司负责人甘忠如、主管会计工作负责人孙程及会计机构负责人(会计主管人员)周丽声明：保证半年度报告中财务报告的真实、准确、完整。

五、 董事会决议通过的本报告期利润分配预案或公积金转增股本预案

无

六、 前瞻性陈述的风险声明

适用 不适用

报告中所涉及的未来计划、发展战略等前瞻性描述不构成公司对投资者的实质承诺，投资者及相关人士均应当对此保持足够的风险认识，并且应当理解计划、预测与承诺之间的差异，敬请广大投资者注意投资风险。

七、 是否存在被控股股东及其关联方非经营性占用资金情况

否

Important Notes

I The Board of Directors, the Board of Supervisors, directors, supervisors and senior management of Gan & Lee Pharmaceuticals. ('the Company') hereby assure that the content set out in the semi-annual report is true, accurate, and complete, and free from any false record, misleading statements or material omission, and are individually and collectively responsible for the content set out therein.

II All Directors of the Company have attended the board meetings.

III This semi-annual report has not been audited.

IV Gan Zhongru (Legal Representative), Sun Cheng (Chief Accountant) and Zhou Li (Account in charge) hereby certify that the financial report set out in the semi-annual report is true, accurate and complete.

V Proposal of profit distribution or proposal of converting capital reserves into share capital for the reporting period examined and reviewed by the Board

No

VI Disclaimer in respect of forward-looking statements

Applicable Not Applicable

The forward-looking descriptions of plans and development strategies contained in the report do not constitute substantial commitments by the Company to investors. Investors and related parties should be aware of the risks involved and should understand the differences between plans, forecasts and commitments. Investors should pay attention to investment risks.

VII Whether there is any fund occupation by controlling shareholders and their related parties for non-operational purposes.

No

八、是否存在违反规定决策程序对外提供担保的情况？	VIII	Whether there is any provision of external guarantee in violation of prescribed decision-making procedures.
否		No
九、是否存在半数以上董事无法保证公司所披露半年度报告的真实性和准确性、完整性。	IX	Whether more than half of the directors are unable to guarantee the truthfulness, accuracy and completeness of the semi-annual report disclosed by the Company.
否		No
十、重大风险提示	X	Important risk warnings
报告期内，不存在对公司生产经营产生实质性影响的特别重大风险。公司已在本报告中详细阐述在生产经营过程中可能面临的各种风险，详见“第三节管理层讨论与分析/五、其他披露事项/(一)可能面对的风险”。		During the reporting period, there were no particularly significant risks that would materially affect the production and operation of the Company. The Company has detailed the various risks it may face during production and operation in this report, as described in “Section III Management’s Discussion and Analysis/ V The Company’s discussion and analysis on the Company’s future development/(I) Possible risks”.
十一、其他	XI	Others
<input type="checkbox"/> 适用 <input checked="" type="checkbox"/> 不适用		<input type="checkbox"/> Applicable <input checked="" type="checkbox"/> Not Applicable

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载有法定代表人、主管会计工作负责人、会计机构负责人签名并盖章的会计报表；

备查文件目录

Documents Available for Inspection

I Financial statements with signatures and seals of the person in charge of the entity, chief accountant, and person in charge of the accounting department;

报告期内公司在《中国证券报》《上海证券报》公开披露过的文件正本及公告原稿

II The original announcements and original documents publicly disclosed by the Company in the "China Securities Journal", "Shanghai Securities News" during the reporting period.

释义

DEFINITIONS



第一节 释义

SECTION I DEFINITIONS

在本报告书中，除非文义另有所指，下列词语具有如下含义： Unless otherwise stated in context, the following terms should have the following meanings in this report:

常用词语释义 Definition of frequently used terms

公司、本公司、甘李药业 Gan & Lee, the Company	指 indicates	甘李药业股份有限公司 Gan & Lee Pharmaceuticals
北京启明 Beijing Qiming	指 indicates	北京启明创科创业投资中心(有限合伙)，公司股东 Beijing Qiming Chuangke Venture Capital Investment Center(Partnership), Company Shareholder
景林投资 Greenwoods Investment	指 indicates	上海景林景麒投资中心(有限合伙)，公司股东 Shanghai Greenwoods Jingqi Investment Center(L.P.), Company Shareholder
宽街博华 Kuanjie Bohua	指 indicates	北京宽街博华投资中心(有限合伙)，公司股东 Beijing Kuanjie Bohua Investment Center(L.P.), Company Shareholder
明华创新 MING HUA TECHNOLOGY	指 indicates	明华创新技术投资(香港)有限公司，公司股东 MING HUA TECHNOLOGY INVESTMENT (HK) LIMITED, Company Shareholder
苏州启明 Suzhou Qiming	指 indicates	苏州启明创智股权投资合伙企业(有限合伙)，公司股东 Suzhou Qiming Chuangzhi Equity Investment Partnership (limited Partnership), Company Shareholder
天津启明 Tianjin Qiming	指 indicates	天津启明创智股权投资基金合伙企业(有限合伙)，公司股东 Tianjin Qiming Chuangzhi Equity Investment Fund Partnership (L.P.), Company Shareholder
旭特宏达 Xute Hongda	指 indicates	北京旭特宏达科技有限公司，公司股东 Beijing Xute Hongda Technology Co.,Ltd, Company Shareholder
铸成顺康 Zhucheng Shunkang	指 indicates	南京铸成顺康创业投资合伙企业(有限合伙)，曾用名马鞍山铸成长企业管理咨询合伙企业(有限合伙)，公司股东 Nanjing Zhucheng Shunkang Venture Capital Partnership (Limited Partnership), formerly known as Ma'anshan Casting Growth Enterprise Management Consulting Partnership (L.P.), Company Shareholder
GS Direct	指 indicates	GS Direct, L.L.C.，公司股东 GS Direct, L.L.C, Company Shareholder
Hillhouse	指 indicates	HillHouse G&L Holdings(HK) Limited，公司股东 HillHouse G&L Holdings(HK) Limited, Company Shareholder
STRONG LINK	指 indicates	STRONG LINK INTERNATIONAL LIMITED，公司股东 STRONG LINK INTERNATIONAL LIMITED, Company Shareholder
Wintersweet	指 indicates	Vast Wintersweet Limited，公司股东 Vast Wintersweet Limited, Company Shareholder
山德士 Sandoz	指 indicates	山德士公司 Sandoz AG

工信部 MIIT	指 indicates	中华人民共和国工业和信息化部 Ministry of Industry and Information Technology
国家药监局 NMPA	指 indicates	国家药品监督管理局 National Medical Products Administration
国家医保局 NHSA	指 indicates	国家医疗保障局 National Healthcare Security Administration
中国证监会 CSRC	指 indicates	中国证券监督管理委员会 China Securities Regulatory Commission
带量采购、集采 Volume-based procurement, centralized procurement	指 indicates	2021年11月，国家组织药品集中采购办公室发布《全国药品集中采购文件(胰岛素专项)(GY-YD2021-3)》，开展第六批国家组织药品集中带量采购(胰岛素专项)工作。国家组织药品集中采购办公室2022年1月通知要求“本次胰岛素专项集采中选结果于2022年5月开始实施，具体执行日期以各地发布通知为准。”本次集采周期为2年，自各地中选结果实际执行日起计算。除上海等个别省市受疫情影响，均5月份开始执行 In November 2021, the state organized joint drug procurement office issued “The national centralized drug procurement document (insulin special) (gy-yd2021-3)” to carry out the Sixth Batch of national organized centralized drug procurement (insulin special). The notice of the joint procurement office of the state organization for drugs in January 2022 requires that “the results of the special volume-based procurement of insulin will be implemented in May 2022, and the specific implementation date shall be subject to the notice issued by various localities.” The centralized procurement period is 2 years, calculated from the actual implementation date of the selection results in various places. In addition to Shanghai and other provinces and cities affected by the epidemic, the implementation began in May
非长秀霖系列产品 Non- Basalin series products	指 indicates	长秀霖系列产品包括长秀霖®及长秀霖®预填充注射笔，非长秀霖系列产品包括速秀霖®、速秀霖®25、速秀霖®预填充、锐秀霖®、锐秀霖®30和普秀霖®30 Basalin series products include Basalin®and Basalin® ElasPen. Non- Basalin series products include Prandilin®, Prandilin®25, Prandilin®ElasPen, Rapilin®, Rapilin®30and Similin®30
ADA	指 indicates	美国糖尿病协会 American Diabetes Association
EMA	指 indicates	欧洲药品管理局 The European Medicines Agency
FDA	指 indicates	美国食品药品监督管理局 US Food and Drug Administration
GMP	指 indicates	药品生产质量管理规范 Good Manufacturing Practice of drugs
GZR33	指 indicates	公司在研的长效基础胰岛素类似物 The Company's long-acting basal insulin analogues under research
GZR101	指 indicate	公司在研的I类创新型治疗用生物制品，是一种新型预混双胰岛素复方制剂，由公司在研的长效基础胰岛素GZR33 (50%)与速效门冬胰岛素(50%)混合制成，拟用于治疗糖尿病 The class I innovative therapeutic biological product under research by the Company is a new type of premixed dual insulin compound preparation. It is made by mixing the long-acting basal insulin GZR33 (50%) and fast acting insulin aspart (50%) under development by the Company, which is intended to be used to treat diabetes

GZR18	指indicates	公司在研的I类创新型治疗用生物制品，是一种预期每周注射一次的长效胰高血糖素样肽-1 (GLP-1) 受体激动剂类药物，已获批准临床的适应症为2型糖尿病、肥胖/超重体重管理 The class I innovative therapeutic biological products under research by the Company is a long-acting glucagon like peptide-1 (GLP-1) receptor agonists which is expected to be injected once a week. The approved clinical indications are type 2 diabetes and, obesity / overweight management
GZR4	指indicates	公司在研的I类创新型治疗用生物制品，预期每周皮下注射给药一次的超长效胰岛素周制剂，拟用于治疗糖尿病 The class I innovative therapeutic biological products under research by the Company, is expected to be injected subcutaneously into the human body once a week to be used to treat diabetes
IDF	指indicates	国际糖尿病联盟 International Diabetes Federation
IND	指indicates	新药临床试验申请 Investigational New Drug Application
Me Better 新药 Me Better new drug	指indicates	与原研药相比在药物作用机理、有效性、安全性等方面更有优势的创新药 Compared with the original drug, it is an innovative drug with more advantages in drug acting mechanism, effectiveness and safety
Me Too 新药 Me Too new drug	指indicates	与原研药相比在药物作用机理、有效性、安全性等方面高度类似的创新药 Compared with the original drug, it is a highly similar innovative drug in terms of drug acting mechanism, effectiveness and safety
PROTAC 技术 PROTAC Technology	指indicates	PROTAC (Proteolysis Targeting Chimeras)，蛋白降解靶向联合体技术是一种利用泛素-蛋白酶体系统(人体自身的活性系统，是细胞内蛋白质降解的主要途径)对靶蛋白进行降解的药物开发技术 Protac (proteolysis targeting chimeras) technology is a drug development technology that uses ubiquitin proteasome system (the active system of human body, which is the main pathway of protein degradation in cells) to degrade target proteins
报告期、本期 Reporting period, current period	指indicates	2022年1月1日至2022年6月30日 From January 1, 2022 to June 30, 2022

公司简介和主要财务指标

GENERAL INFORMATION OF THE COMPANY AND
KEY FINANCIAL INDICATORS



第二节 公司简介和主要财务指标

SECTION II GENERAL INFORMATION OF COMPANY AND KEY FINANCIAL INDICATORS

一、 公司信息

I Information of the Company

公司的中文名称	Name in Chinese	甘李药业股份有限公司
公司的中文简称	Name Abbreviation in Chinese	甘李药业
公司的外文名称	Name in English	Gan & Lee Pharmaceuticals.
公司的外文名称缩写	Name Abbreviation in English	Gan & Lee
公司的法定代表人	Legal representative	甘忠如 Gan Zhongru

二、 联系人和联系方式

II Contact person and contact information

		董事会秘书	Secretary to the Board
姓名	Name	邹蓉	Zou Rong
联系地址	Address	北京市通州区潮县镇南凤西一路8号	No. 8, Nanfeng West 1st Road, Huoxian Town, Tongzhou District, Beijing
电话	Tel	010-80593699	010-80593699
传真	Fax	010-80593678	010-80593678
电子信箱	Email	IR@ganlee.com	IR@ganlee.com

三、 基本情况变更简介

III Summary of the changes in general information

公司注册地址	Registered address	北京市通州区潮县镇南凤西一路8号No. 8, Nanfeng West 1st Road, Huoxian Town, Tongzhou District, Beijing
公司注册地址的历史变更情况	The historical change of the Company's registered address	北京市通州区中关村科技园区通州园金桥科技产业基地景盛北三街8号 No. 8, Jingsheng North Third Street, Jinqiao Science and Technology Industrial Base, Tongzhou Park, Zhongguancun Science Park, Tongzhou District, Beijing
公司办公地址	Business address	北京市通州区潮县镇南凤西一路8号 No. 8, Nanfeng West 1st Road, Huoxian Town, Tongzhou District, Beijing
公司办公地址的邮政编码	Postal code of the business address	101109
公司网址	Website	http://www.ganlee.com
电子信箱	Email	IR@ganlee.com

四、信息披露及备置地点变更情况简介

IV Information disclosure and storage location change

公司选定的信息披露报纸名称	Name of the newspaper selected by the Company for information disclosure	《上海证券报》、《中国证券报》、 《证券时报》、《证券日报》 "Shanghai Securities News", "China Securities Journal", "Securities Times", "Securities Daily"
登载半年度报告的网站地址	The Website address of semi-annual report	http://www.sse.com.cn
公司半年度报告备置地点	Location of the Company's semi-annual report	甘李药业证券投资部、上海证券交易所 Department of Securities of Gan & Lee, Shanghai Stock Exchange

五、公司股票简况

V Summarized information of Company Share

股票种类	Type of Shares	A股 A share
股票上市交易所	Stock exchange	上海证券交易所 Shanghai Stock Exchange
股票简称	Stock abbreviation	甘李药业 Gan & Lee
股票代码	Stock code	603087
变更前股票简称	Stock abbreviation before variation	无 N/A

六、其他有关资料

VI Other related information

适用 不适用

Applicable Not Applicable

七、公司主要会计数据和财务指标

VII Key accounting data and financial indicators of the Company

(一) 主要会计数据

(I) Key accounting data

单位：元 币种：人民币
Unit: RMB

主要会计数据	Key accounting data	本报告期(1-6月) Reporting period (January-June)	上年同期 In the same period last year	本报告期比上年同期增减 (%) Increase/Decrease over the previous year (%)
营业收入	Operating income	834,799,215.95	1,475,429,759.92	-43.42
归属于上市公司股东的净利润	Net profits attributable to shareholders of the listed company	-197,607,134.96	372,769,630.83	-153.01
归属于上市公司股东的扣除非经常性损益的净利润	Net profits attributable to shareholders of the listed company after deduction of non-recurring profits or losses	-208,858,516.23	339,870,808.38	-161.45
经营活动产生的现金流量净额	Net cash flow from Operating activities	281,247,985.16	445,995,750.73	-36.94
		本报告期末 At the end of this reporting period	上年度末 At the end of last year	本报告期末比上年度末增 (%) Increase or decrease at the end of this reporting period compared with the end of the previous year (%)
归属于上市公司股东的净资产	Net assets attributable to shareholders of the listed company	9,815,812,129.97	10,167,304,894.99	-3.46
总资产	Total assets	10,417,968,523.96	10,853,163,478.10	-4.01

(二) 主要财务指标

(II) Key financial indicators

单位：元 币种：人民币
Unit: Yuan Currency: RMB

主要财务指标	Key financial indicators	本报告期(1-6月) Reporting period (January-June)	上年同期 Same period of previous year	本报告期比上年同期增减 (%) Increase/Decrease over the previous year (%)
基本每股收益(元/股)	Basic earnings per share (RMB / share)	-0.35	0.66	-153.03
稀释每股收益(元/股)	Diluted earnings per share (RMB / share)	-0.35	0.66	-153.03
扣除非经常性损益后的基本每股收益(元/股)	Basic earnings per share after deducting non-recurring profit or loss (RMB / share)	-0.37	0.61	-160.66
加权平均净资产收益率(%)	Weighted average return on net assets (%)	-1.97	4.10	减少6.07百分点 Decrease by 6.07%
扣除非经常性损益后的加权平均净资产收益率(%)	Weighted average return on net assets after deducting non-recurring profit or loss(%)	-2.08	3.74	减少5.82百分点 Decrease by 5.82%

公司主要会计数据和财务指标的说明

√适用 □不适用

营业收入变动原因:

(1) 2022年5月, 第六批国家药品集采(胰岛素专项)中选结果开始在全国各省(自治区、直辖市)正式执行。本次带量采购, 本公司六款胰岛素产品全部高顺位中标, 产品价格下降, 其中占公司营业收入比重最大的产品——甘精胰岛素注射液(长秀霖®)的价格下降幅度在60%以上。公司最终获得首年协议采购3,533.77万支(首次报量1,664.18万支、获得分量1,869.59万支), 共计覆盖医疗机构数量21,000多家, 其中公司新准入医疗机构近万家。本报告期制剂销量同比增长23.20%, 其中非长秀霖系列产品销量同比增长123.01%。虽然公司在此次带量采购中获得了较好的协议采购量, 且本报告期产品销量增长, 但由于带量采购执行时间较短, 公司产品销量的增长尚不能对冲价格下降的影响, 产品价格下降依然是公司收入大幅下降的主要影响因素。

(2) 2022年第二季度作为带量采购后胰岛素价格的转换期, 一方面, 商业公司以及终端医疗机构陆续开始集采备货, 控制高价产品购进, 一定程度上影响了本公司当期产品销售; 另一方面, 为保障集采产品的良性供应, 经与商业公司友好协商, 决定采用价格补差的形式协助商业公司进行集采前库存产品价格的调整。

(3) 受全球疫情及国际政局变动等因素的影响, 本报告期国际订单数量下降, 国际销售收入下降。

归属于上市公司股东的净利润变动原因:

本报告期归属于上市公司股东的净利润为-1.98亿元, 主要系报告期内营业收入下降所致。

Description of the Company's main accounting data and financial indicators

√ Applicable □ Not Applicable

Reasons for changes in operating income:

(1) In May 2022, the sixth national centralized volume-based procurement (insulin special) began to be formally implemented in all provinces and cities across the country. In the volume-based procurement, all the six insulin products of the Company won the bidding in high ranking, and the price decreased. Among them, the price of insulin glargine injection ("Basalin®"), which accounts for the largest share of the Company's revenue, has dropped by more than 60%. The Company finally obtained the agreed purchase quantity of 35.338 million units in the first year (the initial reported quantity of 16.642 million units and the reallocated quantity of 18.696 million units), covering more than 21,000 medical institutions, of which nearly 10,000 medical institutions are newly accessed. The sales volume of the products in this reporting period increased by 23.20% year-on-year, among which the sales volume of non-basalin series of products increased by 123.01% year-on-year. Although the Company obtained a better agreed purchase volume in this volume-based procurement, and the sales volume of products increased during the reporting period, the growth of the Company's product sales can not yet offset the impact of the price decline due to the short implementation time of the procurement, product price decline is still the main impact of the Company's significant decline in revenue.

(2) In the second quarter of 2022, as the conversion period of insulin prices after volume-based procurement, on the one hand, commercial companies and terminal medical institutions started to collect and stock up gradually, controlling the purchase of high-priced products, which affected the Company's product sales in the current period to a certain extent. On the other hand, in order to ensure the benign supply of products in the centralized procurement, after friendly negotiation with those commercial companies, it is decided to assist those companies to adjust the price of inventory products by means of price compensation before volume-based procurement.

(3) Due to the influence of the global epidemic and changes in the international political situation, the number of international orders has decreased, and international sales have declined during the report period.

The reasons for the change in net profit attributable to the shareholder:

The net profit attributable to shareholders during the reporting period was RMB -198 million, mainly due to the decline in operating income during the reporting period.

归属于上市公司股东的扣除非经常性损益的净利润变动原因：

本报告期归属于上市公司股东的扣除非经常性损益的净利润为-2.09亿元，主要系报告期内营业收入下降所致。

经营活动产生的现金流量净额变动原因：

本报告期经营活动现金流量净额较上年同期减少1.65亿元，同比减少36.94%，主要系本报告期销售商品、提供劳务收到的现金减少所致。

The reasons for the change in net profit attributable to shareholders after deducting non-recurring profit and loss:

The net profit after deduction of non-recurring profit or loss attributable to shareholders of the listed company for the reporting period was RMB -209 million, which was mainly due to the decrease in operating income during the reporting period.

Reasons for the change in net cash flow from operating activities:

The net cash flow from operating activities for the reporting period decreased by RMB 165 million, 36.94% year on year, mainly due to the decrease in cash received from the sale of goods and provision of services for the reporting period.

八、境内外会计准则下会计数据差异

适用 不适用

VIII Differences in accounting data under domestic and overseas accounting standards

Applicable Not Applicable

九、非经常性损益项目和金额

适用 不适用

IX Non-recurring profit or loss items and amount

Applicable Not Applicable

单位：元 币种：人民币
Unit:RMB

非经常性损益项目	Non-recurring profit or loss items	金额 Amount	附注(如适用) Note (if applicable)
非流动资产处置损益	Profit or loss from disposal of non-current assets	-1,521.66	
计入当期损益的政府补助，但与公司正常经营业务密切相关，符合国家政策规定、按照一定标准定额或定量持续享受的政府补助除外	Government grants recognized in profit or loss other than grants which are closely related to the Company's business and are either in fixed amounts or determined under quantitative methods in accordance with the national standard	10,562,126.24	
除同公司正常经营业务相关的有效套期保值业务外，持有交易性金融资产、衍生金融资产、交易性金融负债、衍生金融负债产生的公允价值变动损益，以及处置交易性金融资产、衍生金融资产、交易性金融负债、衍生金融负债和其他债权投资取得的投资收益	Profit or loss on changes in the fair value of financial assets held for trading, derivative financial assets, held for trading financial liabilities and derivative financial liabilities and investment income on disposal of financial assets held for trading, derivative financial assets, held for trading financial liabilities, derivative financial liabilities and other debt investments, other than those used in the effective hedging activities relating to normal operating business	4,501,793.97	
除上述各项之外的其他营业外收入和支出	Other non-operating income or expenses than the above items	-2,267,875.22	
其他符合非经常性损益定义的损益项目	Other losses and profits conforming to the definition of non-recurring profit and loss	584,528.40	
减：所得税影响额	Deduct: Amount affected by income tax	2,127,670.46	
合计	Total	11,251,381.27	

将《公开发行证券的公司信息披露解释性公告第1号——非经常性损益》中列举的非经常性损益项目界定为经常性损益项目的情况说明

适用 不适用

Explanation on defining the non-recurring profit and loss items listed in the "Explanatory Announcement No. 1 on Information Disclosure of Companies Offering Securities to the Public - Non-recurring Profit and Loss" as recurring profit and loss items.

Applicable Not Applicable

十、其他

适用 不适用

X Others

Applicable Not Applicable

管理层讨论与分析

MANAGEMENT DISCUSSION AND ANALYSIS



第三节 管理层讨论与分析

SECTION III MANAGEMENT DISCUSSION AND ANALYSIS

一、报告期内公司所属行业及主营业务情况说明

(一) 公司主要业务

本公司是一家主要从事胰岛素类似物原料药及注射剂研发、生产和销售的高新技术企业。本公司作为国内领先掌握产业化生产胰岛素类似物技术的高科技生物制药企业，具备完整胰岛素研发管线。公司主要产品包括甘精胰岛素注射液(长秀霖®)、赖脯胰岛素注射液(速秀霖®)、精蛋白锌重组赖脯胰岛素混合注射液(25R)(速秀霖®25)、门冬胰岛素注射液(锐秀霖®)、门冬胰岛素30注射液(锐秀霖®30)、精蛋白人胰岛素混合注射液(30R)(普秀霖®30)多个胰岛素类似物和人胰岛素品种，产品覆盖长效、速效、预混三个胰岛素功能细分市场；其中公司明星产品——“长秀霖®”的面世使得我国成为世界上少数能进行胰岛素类似物产业化生产的国家之一，具有里程碑意义。同时，公司产品覆盖相关医疗器械领域，包括可重复使用的胰岛素注射笔(秀霖笔®)和一次性使用注射笔用针头(秀霖针®)等。

I Description of the Company's industry and main business during the reporting period

(I) Main business of the Company

Gan & Lee is a high and new technology enterprise (HNTE) mainly engaged in the research and development (R&D), production, and sales of active pharmaceutical ingredients (APIs) and injections of insulin analogs. As China's leading high-tech biopharmaceutical enterprise with the commercialized production technology of insulin analogs, the Company has a comprehensive insulin R&D pipeline. The Company's main products include insulin glargine injection (Basalin®), insulin lispro injection (Prandilin™), mixed protamine zinc recombinant human insulin lispro injection (25R) (Prandilin™25), insulin aspart injection (Rapilin®), insulin aspart 30 injection (Rapilin®30), and mixed protamine human insulin injection (30R) (Similin®30). Our products cover three functional market segments of insulin: long-acting, fast-acting, and premixed insulins. Among them, the launch of the Company's star product, Basalin®, has made China one of the few countries worldwide that can produce insulin analogs on an industrial scale, which symbolizes a milestone. At the same time, the Company's products cover related medical device fields, including reusable insulin injection pens (GanleePen™) and disposable needles for injection pens (GanleeFine®), etc.



在未来，公司将实现在糖尿病诊断和治疗领域产品线全面覆盖，进一步提升公司在糖尿病治疗领域的市场竞争力。公司还将积极投入到化学药、真核及原核蛋白质工程、肿瘤和心血管及代谢病等研究领域。

In the future, the Company will achieve complete product line coverage in the field of diabetes diagnosis and treatment to further enhance the Company's market competitiveness in the diabetes therapeutic area. In addition, the Company will also actively invest in research fields such as chemical drugs, eukaryotic and prokaryotic protein engineering, oncology, and cardiovascular and metabolic diseases.

(二) 公司经营模式

1. 采购模式



采购部按照公司采购制度要求，统一负责对外采购工作，组织制定公司的年度采购计划，根据月度需求指导完成采购任务；并对供应商进行准入、评估和维护管理，深挖优质供应商，不断优化供应商体系。同时，为保证生产安全和原辅料的稳定供应，由质量管理部对原辅料供应商进行审计及资质管理，并在原辅料入库时，由质量管理部门进行严格的质量入库检验。对于工程、设备类货物，根据公司采购管理制度及国家规定，采用议价或招标采购方式，确定最终供应商

2. 生产模式



公司的商业生产计划、工艺管理、生产调度及组织由生产管理部统一管理。生产管理部根据供应链管理制定产销计划，结合原辅料采购及产品库存情况，制定生产车间的滚动生产计划，采用按订单生产(Make-to-Order)和按库存生产(Make-to-Stock)相结合的生产模式，满足多方客户的需求，同时对产品的整个生产过程进行严格的管理。在生产过程中，质量管理部也对生产全过程进行质量监督，对原辅料、中间产品、待包装产品和产成品的质量进行全程检测和监控。

3. 销售模式



(1) 国内销售模式

公司主要采取商业公司和专业化学术推广相结合的销售模式。公司国内产品销售主要采用经销模式，即通过医药商业公司向医院进行药品的销售配送，商业公司并不承担市

(II) Company business model

1. Procurement model



Per the requirements of the Company's procurement system, the Procurement Department oversees and is responsible for external procurement, organizing the Company's annual procurement plan, guiding the completion of procurement tasks based on the monthly demand; and managing the access, evaluation, and maintenance of suppliers, searching for high-quality suppliers and continuously optimizing the supplier system. Meanwhile, to ensure production safety and a stable supply of auxiliary and raw materials, the Quality Control Department audits and manages the qualification of material and accessories suppliers and conducts strict quality inspections by the Quality Control Department when raw materials and accessories are put into storage. Furthermore, for engineering type and equipment type goods, per the Company's procurement management system and national regulations, the bargaining or bidding procurement method is used to determine the final supplier.

2. Production model



The Company's commercial production planning, production process management, and production allocation and organization are unified and managed by the Production Management Department. In line with the production and sales plan made by the Supply Chain Management Department, the Production Management Department will make rolling production plans for the production plants by the model of combining Make-to-Order with Make-to-stock to meet the needs of various customers, at the same time, strictly manage the entire production process of the product. During the process of production, the Quality Management Department supervises the quality of the whole process. In addition, it conducts the overall inspection and monitoring of the quality of raw materials and accessories, intermediate products, products to be packaged, and finished products.

3. Sales model



(1) Domestic sales model

The Company mainly adopts a sales model combining distributors and professional academic promotion. The Company's domestic product sales are primarily based on the distribution model, i.e., the sales and distribution of drugs to hospitals through pharmaceutical distributors, who do not undertake market development and promotion functions but

场开发及推广职能，仅根据其配送区域内医院或药店的临床用药需求，向公司下发需求订单。公司根据年度《经销协议》及具体订单向合作医药商业公司销售药品，由各区域商业公司完成向医院及零售终端的药品销售及物流配送。

根据胰岛素类似物技术壁垒高的特点，国内市场主要由营销系统通过自主专业化学术推广模式对公司及产品进行推广和宣传，其中推广信息包括：产品相关信息(药品适应症、使用方法、安全性以及相关的学术理论和最新临床研究成果)、公司品牌信息等。

only place orders to the Company based on the clinical demand for drugs in hospitals or pharmacies in their distribution areas. The Company sells drugs to the cooperative pharmaceutical distributors according to the annual "Distribution agreement" and specific orders, and the regional distributors complete drug sales and logistics distribution to hospitals and retailers.

According to the characteristics of high technical barriers possessed by insulin analogs, the domestic market is mainly promoted and publicized by independent professional academic promotion mode through the marketing system, in which the promotion information includes product-related information (including drug indications, usage, safety, relevant academic theories, and latest clinical research results), company brand information, etc.



(2) 海外销售模式

根据海外各国政策和市场特点，公司国际销售产品包括胰岛素原料药、胰岛素制剂（笔芯和预填充笔）、笔组件和其他医疗器械。销售模式分为胰岛素制剂授权分销、与进口国当地企业进行原料药制剂灌装合作以及在当地设立子公司进行自主经营。在合作销售模式下，本公司多采取与当地具有较强灌装能力、完整组装线及生物药品生产资质的企业进行合作，由公司出口原料药和笔组件，进口国合作伙伴在当地进行制剂灌装生产、预充笔组装和销售；在授权分销模式下，公司产品由公司授权的国际分销商向海外市场进行销售。

(三) 行业情况说明**1. 行业政策变动**

在“十四五”全民医疗保障规划的政策背景下，2022年上半年，医药行业各类政策频发，机遇和挑战共存。

(1) 胰岛素专项集采落地执行

截至目前，国家层面已经组织了七批药品、两批高值耗材的带量采购，其中第六批是胰岛素专项采购。

2022年4月29日，《国家医保局办公室国家卫生健康委办公厅关于完善国家组织药品（胰岛素专项）集中带量采购和使用配套措施的通知》发布，要求紧密结合胰岛素生产、采购、配送、使用特点，落实好各项配套措施，促进中选产品及时稳定供应、安全顺畅使用，确保改革红利惠及广大患者。重点内容如下：一、要规范胰岛素平台挂网工作；二、要做好医保支付政策衔接；三、要促进医疗机构合理用药；四、要落实医疗机构激励约束政策；五、要强化履约情况监测。

胰岛素专项集采是糖尿病治疗领域的重要事件，其产生的影响十分深远。政策落地将直接降低患者用药成本，逐渐改变糖尿病治疗的用药结构，重塑胰岛素行业竞争格局。2022年5月开始，各省（自治区、直

(2) Overseas sales model

According to overseas national policies and market characteristics, the Company's products sold internationally include insulin APIs, insulin preparations (penfill and pre-filled pens), pen components, and other medical devices. Sales modes are divided into the authorized distribution of insulin preparations, cooperation with local enterprises in importing countries for filling API preparations, and independent management by setting up subsidiaries. Under the cooperative sales mode, the Company mainly cooperates with local enterprises with strong filling capacity, complete assembly lines, and biological medicine production qualifications. The Company exports the API and pen components, and the importing partners carry out local formulation filling production, pre-filled pen assembly and sales. Under the authorized distribution mode, the Company's products are sold to overseas markets by the Company's authorized international distributors.

(III) Industry description**1. Industry policy changes**

Under the policy background of the "14th Five-Year Plan", various policies in the pharmaceutical industry were issued frequently in the first half of 2022, which brings both opportunities and challenges.

(1) Implementation of special insulin collection

Up to now, seven rounds of drugs and two rounds of high-value consumables have been organized at the national level for volume-based procurement, of which the sixth round was insulin procurement.

On April 29, 2022, the "Notice of the Office of the National Health Insurance Administration and the General Office of the National Health and Wellness Commission on Improving Supporting Measures for the Centralized Quantity Procurement and Use of Drugs (Insulin Special) of the State Organization" was released, requiring close integration with the characteristics of insulin production, procurement, distribution, and usage to implement the supporting measures to promote timely and stable supply and safe and smooth use of the selected products and ensure that the reform dividends benefit the majority of patients. The key points are as follows: 1. To standardize the insulin platform listing work; 2. To ensure the convergence of health insurance payment policies; 3. To promote the rational use of drugs by medical institutions; 4. To implement the incentive and restraint policies of medical institutions; 5. To strengthen the monitoring of compliance.

The centralized procurement of insulin is an important event in the field of diabetes treatment, and its impact is far-reaching. The policy will directly reduce the medication cost for patients, gradually change the medication structure of diabetes treatment, and reshape the competitive landscape of the insulin industry.

辖市)陆续发布胰岛素专项集采落地执行文件。本公司积极筹备迎接集采中选结果的落地执行,提高本公司药品的患者普及率,让更多的糖尿病患者可以快速用上公司产品。

Starting from May 2022, each province (autonomous region and municipality) has gradually released the implementation documents for centralized procurement of insulin. The Company is actively preparing for the implementation to increase the popularity rate of the Company's drugs and enable more diabetic patients to use the Company's products quickly.

(2) DRG/DIP 付费改革

为加快建立管用高效的医保支付机制,推进DRG/DIP支付方式改革全覆盖,在国家医疗保障局发布关于印发《DRG/DIP支付方式改革三年行动计划》的通知后,各省(自治区、直辖市)在2022年上半年陆续发布了本省的DRG/DIP支付方式改革三年行动方案。

(2) DRG/DIP payment reform

To accelerate the establishment of a managed and efficient health insurance payment mechanism and promote full coverage of Diagnosis Related Groups (DRG)/ Diagnosis-Intervention Packet (DIP) payment reform, following the issuance of a notice by the National Health Insurance Administration on the issuance of the "Three-Year Action Plan for DRG/DIP Payment Reform," provinces (autonomous regions and municipalities) have released their own three-year action plans for DRG/DIP payment reform in the first half of 2022.

DRG/DIP支付方式改革是一项系统工程和战略任务,是为了建立医保对医疗机构管用高效的支付管理和激励约束机制从而进行的医保支付方式改革。DRG/DIP付费方式相当于给医院预设了成本天花板。

DRG/DIP payment reform is a systematic project and a strategic task, which is carried out to establish an efficient payment management and incentive and restraint mechanism for medical insurance to medical institutions. The DRG/DIP payment is equivalent to setting a cost ceiling for the hospital.

随着各省(自治区、直辖市)改革的持续推进,公立医院的诊疗方式和药品耗材的使用方式都将发生改变,部分医疗机构的定位和业务范围也将进行重大调整,这些都将对药品、耗材生产企业产生较大的影响。此改革将进一步推进医院在药品和器械的选择上更倾向于质优价廉的产品,也会引导更多的医院在胰岛素用药的选择上更多地考虑集采中标价格低的产品。

As provinces (autonomous regions and municipalities) advance their reforms one after another, public hospitals will change their treatment and the usage of drugs consumables, and the positioning and business content of some medical institutions will also be adjusted significantly, which will have a greater impact on drug and drug consumable manufacturers. This reform will further promote the hospital in the choice of drugs and equipment more inclined to quality and inexpensive products but also guide more hospitals to use insulin with more consideration in the choice of the low price of the centralized procurement products.

本公司在胰岛素专项集采中全线六款产品以普惠的高降幅、低价格获得了高顺位中标,与DRG/DIP支付方式改革政策引导方向一致,也将吸引更多的医疗机构选用本公司产品。

The Company's six products in the centralized procurement of insulin have won the bidding with a high rate of reduction and better price, which is consistent with the direction of DRG/DIP payment reform policy and will attract more medical institutions to choose the Company's products.

(3) 家庭医生签约服务

2022年3月3日,国家医保局等多部委发布《关于推进家庭医生签约服务高质量发展的指导意见》(以下简称“《指导意见》”)。

(3) Family doctor contract service

On March 3, 2022, the National Health Insurance Bureau and other ministries and commissions issued the "Guidance on Promoting the High-Quality Development of Family Physicians Contracted Services" (the "Guidance").

《指导意见》提出要进一步提升家庭医生开展常见病、多发病诊疗及慢性病管理能力，并通过依规范拓展切实符合群众需求的服务项目，如康复、医养结合、安宁疗护、智慧诊疗等服务，进一步强化基层医疗卫生机构的基本医疗服务功能。《指导意见》针对长期处方服务提出了阶段性目标，即到2025年全部乡镇卫生院和社区卫生服务中心均应提供长期处方服务，同时进一步强调了长处方的用药周期为4-12周。

此外，《指导意见》从开展上门服务、提供优先转诊以及中医药服务等方面对家庭医生的医疗服务功能进行了诠释。强调了基层医疗卫生机构从预约就诊和智能分诊方面与签约工作做好功能连接，注重强化家庭医生与签约居民的联系，引导签约居民逐步形成到基层医疗卫生机构首诊的就医习惯。并通过向签约居民个人开放电子健康档案等方式优化基本公共卫生和健康管理服务效果。

可以预见，未来慢性病的预防、诊断(首诊)及用药场景将更多的发生在签约家庭医生所在的基层医疗机构。本公司作为慢性病药品生产销售企业，积极布局基层医疗机构市场，树立本公司药品在家庭医生中的良好品牌形象，进一步提升本公司药品在基层首诊的用药占比。

(4) 2022年国家医保目录调整

2022年6月13日，国家医保局发布《2022年国家基本医疗保险、工伤保险和生育保险药品目录调整工作方案(征求意见稿)》(以下简称“《工作方案》”)及相关文件公开征求意见。

《工作方案》指出，2022年的药品目录调整将统筹疫情防控、参保人员需求和基金支付能力等工作，努

The “Guidance” proposes to further enhance the ability of family physicians to carry out common and multi-morbidity treatment and chronic disease management and to further strengthen the basic medical service functions of primary health care institutions by expanding services that actually meet the needs of the public, such as rehabilitation, medical and health care integration, hospice care, and intelligent diagnosis and treatment services, following regulations. The “Guidance” puts forward a milestone for long-term prescription services; by 2025, all township health centers and grassroots health service centers and primary hospital should provide long-term prescription services while further emphasizing that the long prescription medication cycle should be 4-12 weeks.

In addition, the “Guidance” interprets the medical service functions of family physicians in terms of conducting onsite services, providing priority referrals, and providing traditional Chinese medicine services. It emphasizes the function of primary hospital to connect well with the contracted work in terms of appointment consultation and intelligent triage, focuses on strengthening the connection between family physicians and contracted residents, and guides contracted residents to gradually form the habit of visiting primary hospital for the first visit. It also optimizes the effect of basic public health and health management services by opening up electronic health records to contracted residents individually, etc.

It is expected that in the future, the prevention, diagnosis (first visit), and medication scenarios of chronic diseases will occur more often in the primary hospitals where the contracted family physicians are located. As a manufacturer and sales company of chronic disease drugs, the Company is actively laying out the market of primary hospital to establish a good brand image of the Company's drugs among family physicians and further increase the proportion of the Company's drugs used in primary hospitals.

(4) National health insurance catalog adjustment in 2022

On June 13, 2022, the National Health Insurance Administration (NHA) released the “2022 National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug Catalog Adjustment Work Plan (Draft for Public Comments)” (the “Work Plan”) and related documents for public comments.

The “Work Plan” points out that the adjustment of the drug catalog in 2022 will coordinate the work of epidemic prevention and control, the needs of participants, and the fund's ability to

力使药品目录结构更加合理优化、管理更加科学规范、支付更加管用高效、保障更加公平可及，助力解决人民群众看病就医后顾之忧。

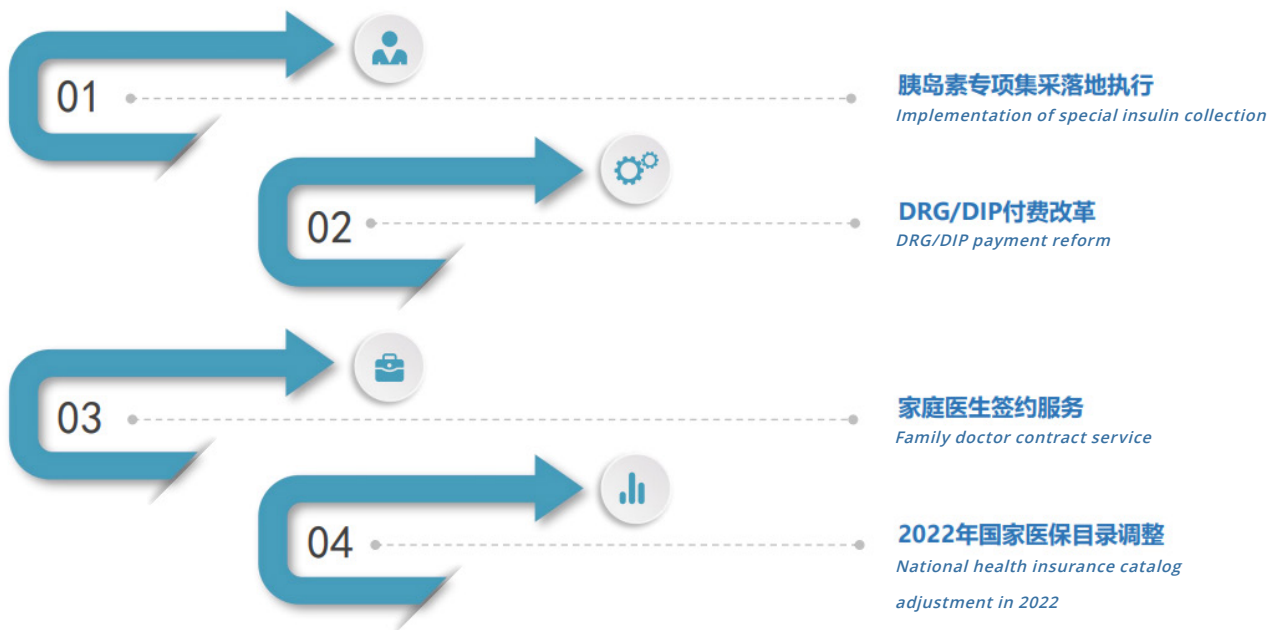
《工作方案》显示，2022年医保目录调整工作将持续5个月左右。2022年7月到8月为企业申报阶段，符合条件企业可以申报，并进行形式审查。2022年8月，专家将根据企业申报情况，建立评审药品数据库，形成拟直接调入、拟谈判/竞价调入、拟直接调出、拟按续约规则处理等4方面药品的建议名单。随后，医保谈判将于2022年9月至10月进行，通过谈判，确定全国统一的医保支付标准，同步明确管理要求。2022年11月公布医保目录调整结果。

《工作方案》首次公开“谈判药品续约规则”和“非独家药品竞价规则”，进一步明确了不同类型品种药品的目录准入规则。同时，明确鼓励儿童药和罕见病药两个较薄弱领域药品纳入，预计医保覆盖面进一步扩大。公司高度关注国家医保目录的调整情况，合理规划和布局公司研发产品管线。

pay. It strives to make a more reasonable and optimized drug catalog structure, more scientific and standardized management, more effective and efficient payment, and more fair and accessible protection, which help solve people's worries about medical care.

The "Work Plan" shows that the adjustment of the medical insurance catalog in 2022 will last about five months. From July to August 2022 is the enterprise declaration phase; eligible enterprises can declare and conduct a formal review. In August 2022, experts will establish a database of reviewed drugs based on enterprise declarations, and form a proposed list of drugs to be transferred directly, negotiated/competitive transferred, transferred directly out, and handled according to renewal rules in 4 areas. Subsequently, medical insurance negotiations will be conducted from September to October 2022, through which the national unified medical insurance payment standards will be determined, and the management requirements will be clarified simultaneously. Finally, the medical insurance catalog adjustment results will be announced in November 2022.

The "Work Plan" discloses "the rules for the renewal of negotiated drugs" and "the rules for bidding on non-exclusive drugs" for the first time, further clarifying the rules for access to the catalog for different types of drugs. At the same time, it encourages the inclusion of children's and rare disease drugs, which is expected to expand medical insurance coverage further. The Company pays close attention to adjusting the national medical insurance catalog and rationalizes the planning and layout of the Company's R&D product pipeline.



2. 公司所处的行业地位情况

(1) 行业基本信息

糖尿病是一组以高血糖为特征的代谢性疾病，根据发病机制，糖尿病可分为1型糖尿病、2型糖尿病、妊娠糖尿病和特殊类型糖尿病，其中2型糖尿病是临床上最常见的类型，占总体糖尿病人群的90%以上。2型糖尿病是胰岛素抵抗(即机体对胰岛素不敏感)和胰岛β细胞功能缺陷(即机体胰岛素分泌不足)共同作用的结果。临床上常用的降糖药物还包括口服药物(包括二甲双胍、磺脲类促泌剂、格列奈类促泌剂、噻唑烷二酮(TZD)、α-糖苷酶抑制剂、DPP-4抑制剂、SGLT-2抑制剂等)、GLP-1受体激动剂和胰岛素。根据患者患病程度的不同，用药策略也不同。在糖尿病诊断的早期，胰岛素水平正常或偏高，血糖水平稍高于正常，一般选择口服降糖药控制血糖。当胰岛β细胞功能近乎衰竭时，可采用口服药物和胰岛素的联合治疗，有利于残存胰岛功能的保护和血糖水平的稳定控制。而当胰岛β细胞功能完全衰竭时则只能采用胰岛素替代治疗。

胰岛素的发展经历过动物胰岛素(一代，已基本被淘汰)、人胰岛素(二代)和胰岛素类似物(三代)。自上世纪90年代末期胰岛素类似物上市以来，其在全球范围内的销售规模迅速增长。相比于人胰岛素，胰岛素类似物在起效时间、峰值表现、作用持续时间等方面有较大优势，可更好地模拟生理胰岛素分泌，具有显著降低低血糖风险等优势；胰岛素类似物在发达国家市场已较大程度取代了人胰岛素产品。虽然胰岛素类似物比人胰岛素已有进步，但是仍不能完全模拟人体胰岛素生理分泌模式。被称为第四代胰岛素的超长效胰岛素周制剂具有半衰期更长、给药频率低、血药浓度与药效更加平稳，血糖日间变异小，低血糖风险更小等特点，成为糖尿病药物研发企业目前新药研发的重要方向之一。本公司在研的超长效胰岛素周制剂GZR4，预期每周只需注射一次，实现一周基础血糖的平稳控制，在提高用药依从性的同时，有望大幅降低患者的注射频率，减轻患者身心负担，从整体上改善糖尿病患者的生活质量。

2. Position of the Company in the industry

(1) Basic industry information

Diabetes is a group of metabolic diseases characterized by hyperglycemia. According to pathogenesis, diabetes can be divided into type 1 diabetes, type 2 diabetes, gestational diabetes, and specific types of diabetes. Type 2 diabetes is the most common type clinically, accounting for more than 90% of the overall diabetic population. Type 2 diabetes occurs due to a combination of insulin resistance (i.e., the body is insensitive to insulin) and impaired pancreatic β-cell function (i.e., the body does not secrete enough insulin). Commonly used clinical glucose-lowering drugs include oral drugs (including metformin, sulfonylureas, glinides, thiazolidinediones (TZD), alpha-glucosidase inhibitors, DPP-4 inhibitors, SGLT-2 inhibitors, etc.), GLP-1 receptor agonists, and insulin. The treatment strategy differs depending on the course of the patient's disease. In the early stage of diabetes diagnosis, when insulin levels are normal or high and blood glucose levels are slightly above standard, oral hypoglycemic drugs are generally chosen to control blood glucose. When the function of pancreatic islet β-cells is near in failure, the combination of oral medication and insulin can be used, which is conducive to the protection of residual islet function and the stable control of blood glucose levels. When the function of pancreatic islet β-cells completely fails, only insulin replacement therapy can be used.

The development of insulin has gone through animal insulin (first generation, which is basically out of use), human insulin (second generation), and insulin analogs (third generation). Since the launch of insulin analogs in the late 1990s, the scale of sales has grown rapidly worldwide. Compared with human insulin, insulin analogs have greater advantages in onset time, peak performance, duration of action, etc. In addition, insulin analogs can better mimic physiological insulin secretion patterns and significantly reduce the risk of hypoglycemia; thereby, insulin analogs have widely replaced human insulin products in developed markets. Although insulin analogs have been improved over human insulins, they still cannot fully mimic human pancreatic insulin's natural physiological secretion pattern. The ultra-long-acting insulin weekly formulations, known as the fourth generation of insulin, have become one of the important directions of new drug development for diabetes drug developers given their relatively longer half-life, lower dosing frequency, more stable blood concentration and efficacy, less interday blood glucose variation, and less risk of hypoglycemia. The Company's ultra-long-acting weekly insulin formulation under development, GZR4, is expected to be injected once a week to achieve smooth control of basal blood glucose over a week, which is expected to significantly reduce the frequency of injections for patients while improving medication compliance, alleviating the physical and mental burden of patients and improving the overall quality of life for diabetic patients.

部分常用胰岛素及其作用特点 (小时)
Commonly used insulins and characteristics (hour)

	种类 Type of commitments	产品(举例) Covenanter	起效时间 Contents of	峰值时间 Date and term of	作用持续时间 Any deadline for
人胰岛素(二代) Human insulin (2nd gen)	速效 Mealttime	人胰岛素 Regular insulin	0.25-1.00	2-4	5-8
	基础 Basal	精蛋白锌胰岛素 Protamine zinc insulin	1.50	4-12	24
	预混 Premixed	人30/70 Premixed human insulin 30/70	0.50	2-12	14-24
人胰岛素(二代) Insulin analogs (3rd gen)	速效 Mealttime	门冬胰岛素 Insulin aspart	0.17-0.25	1-2	4-6
	基础 Basal	甘精胰岛素U300 Insulin glargine u300	6.00	无峰 NA	36
	预混 Premixed	门冬胰岛素30 Insulin aspart 30	0.17-0.33	1-4	14-24

注释: 上图数据中起效时间、峰值时间和作用持续时间来源为中国2型糖尿病防治指南(2020年版)下, 种类来源为公司整理

Note: The sources of onset time, peak time, and duration of action in the data above are under China's Type 2 Diabetes Prevention and Control Guidelines (2020 Edition), and the Company collates the category sources.

目前, 市面上常见的口服降糖药共有7大类, 不同的降糖药其特点各有不同。其中双胍类药物——二甲双胍被称为2型糖尿病药物治疗的基石, 其主要药理作用是通过减少肝糖输出、增加肌肉糖摄取、改善外周胰岛素抵抗等机制起到降糖作用。无论是中华医学会糖尿病学分会推出的《中国2型糖尿病防治指南(2020版)》, 还是美国糖尿病协会发布的《糖尿病诊疗路径2021版》, 都将二甲双胍推荐为2型糖尿病的首选初始治疗药物。

DPP-4抑制剂是最近几年上市的新型糖尿病口服药物。这类药物具有一天服用一次(某些药物一天服用两次, 餐前和餐后服用均可)、不增加低血糖风险、没有胃肠道反应等优点。SGLT-2抑制剂和GLP-1受体激动剂不显著增加低血糖风险, 可降低体重, 还对降低心血管主要事件风险有显著作用, 在国内外指南中的地位不断提升, 逐渐成为2型糖尿病的标准治疗之一, 市场渗透率将显著提升。随着DPP-4抑制剂、SGLT-2抑制剂等全球热销的降糖药专利相继到期, 国内仿制药产品即将陆续上市销售, 将迎来收获期, 有望加速国产替代进程。本公司自主研发的首个口服降糖药——磷酸西格列汀片产品获批上市, 将有利于公司积极参与到DPP-4抑制剂国产替代进程提升在糖尿病用药领域的市场综合竞争力。

So far, there are seven major classes of common oral glucose-lowering drugs on the market, with different characteristics. Among them, metformin is the cornerstone of type 2 diabetes pharmacotherapy. Its primary pharmacological effect is to lower glucose by reducing hepatic glucose output, increasing muscle glucose uptake, and improving peripheral insulin resistance and other mechanisms. Both the "Guidelines for the Prevention and Treatment of Type 2 Diabetes in China (2020 Edition)" released by the Chinese Medical Association Diabetes Branch and the "Diabetes Care and Treatment Pathway 2021 Edition" released by the American Diabetes Association recommend metformin as the initial therapy option for type 2 diabetes.

DPP-4 (dipeptidyl peptidase-4) inhibitors are new oral diabetes medications that have come to market in the last few years. These drugs have the advantages of being taken once a day (some can be taken twice a day, both before and after meals), not increasing the risk of hypoglycemia, and having no gastrointestinal reactions. SGLT-2 inhibitors and GLP-1 receptor agonists do not significantly increase the risk of hypoglycemia, can reduce body weight, and considerably reduce the risk of major cardiovascular events. Their status in domestic and international guidelines continues to rise and has gradually become one of the standard treatments for type 2 diabetes. In addition, the market penetration of these two therapies will be significantly increased. With the patent expiration of those global hits hypoglycemic medicines such as DPP-4 inhibitors and SGLT-2 inhibitors, domestic generic products will be marketed and sold, which is expected to accelerate the process of domestic substitution. The Company's self-developed first oral hypoglycemic drug, sitagliptin phosphate tablet, has been approved for marketing, which will help the Company to actively participate in the process of domestic substitution of DPP-4 inhibitors and enhance the comprehensive market competition in the field of diabetes drugs force.

目前，我国糖尿病呈现知晓率、诊断率、控制率、治疗率“四低”特征。随着医保政策的推动和医患知识的教育程度普及、医疗水平的提高，糖尿病诊出率会持续上升，用药率提高，用药市场规模将继续扩大。作为行业领先掌握产业化生产重组胰岛素技术的中国企业，公司主营降糖产品线全面稳健发力，除已上市、市场成熟的第二、三代胰岛素，正在积极地布局和推进第四代胰岛素以及更前沿的糖尿病治疗相关的药物和疗法，为全球糖尿病患者提供更多的优质胰岛素产品选择。目前，本公司已上市销售的产品包括五个胰岛素类似物品种以及一个人胰岛素品种，产品覆盖长效、速效、预混三个胰岛素功能细分市场，已进入临床阶段的研发项目包括胰岛素复方制剂GZR101、第四代胰岛素类似物GZR4和长效胰高血糖素样肽-1 (GLP-1RA) 受体激动剂类药物GZR18。

Presently, the awareness rate, diagnosis rate, control rate, and treatment rate of diabetes in China are in “four low” characteristics. However, with the promotion of medical insurance policy, the popularization of medical education, and the improvement of medical level, the diagnosis rate of diabetes will continue to rise, the medication rate will increase, and the market scale of medication will continue to expand. As a leading Chinese company in the industry that has mastered the industrialized production of recombinant insulin, the Company’s main glucose-lowering pipeline is making steady and comprehensive progress. In addition to the 2nd and 3rd generation insulins that have been marketed and matured in the market, the Company is actively laying out and promoting the 4th generation insulins and more advanced diabetes treatment-related drugs and therapies to provide more insulin product choices of high quality for global diabetes patients. The Company has now launched and commercialized five insulin analog products and one human insulin product, covering three functional segments: long-acting, fast-acting, and premixed insulins. The Company’s clinical development projects cover insulin analog compound preparation GZR101, fourth-generation insulin analog GZR4, and long-acting glucagon-like peptide-1 receptor agonist (GLP-1 RA) GZR18.

(2) 公司所处行业地位

糖尿病具有患者基数大、增长快和病程长的特点。纵观全球人类社会的发展历史，发展程度较高的国家会更早步入老龄化社会，而中国的老龄化问题也逐渐加深，人口老龄化加快了糖尿病患者人数的增长。同时由于经济和科技的发展，越来越多的人受生活不规律、饮食不规律的影响，糖尿病的发病群体呈现年轻化或儿童化的趋势。

在国内，随着中国经济快速发展，国民收入节节攀升、支付能力不断增强，同时国家多措并举推进医保支付、加速医保结算，进一步释放糖尿病患者的医药消费能力，使更多的人享受医疗保健服务，将进一步提升我国糖尿病患者诊断和治疗市场容量。特别是2021年开展的胰岛素专项带量采购工作，在快速推进第三代胰岛素(胰岛素类似物)替换第二代胰岛素(人胰岛素)进程的同时，也将进一步提升中国胰岛素市场的销量规模。而本公司作为国内领先成功研发、生产胰岛素类似物并实现产业化的中国企业，长期处于国产第三代胰岛素类似物行业领先地位，且在第三代胰岛素类似物的长效、速效、预混三个功能细

(2) Overseas sales model

Diabetes is characterized by a large patient base, rapid growth, and a long disease course. Throughout the global history of human societies, countries with higher development levels would enter an aging society earlier, while China’s aging problem is also gradually emerging, and the aging population has accelerated the growth of the number of people with diabetes. At the same time, due to the development of the economy and technology, more and more people are affected by irregular lifestyles and diets, and the incidence of diabetes tends to be younger generations.

Domestically, with China’s rapid economic development, national income and payment capacity are increasing. At the same time, the country has taken multiple measures to promote medical insurance payment and accelerate medical insurance settlement, further releasing the medical consumption capacity of diabetic patients and enabling more people to enjoy healthcare services, which will further enhance the diagnostic and treatment market capacity of diabetic patients in China. In particular, the special volume-based procurement of insulin to be carried out in 2021 will further enhance the sales scale of China’s insulin market while rapidly promoting replacing the 2nd generation insulin (human insulin) with the 3rd generation insulin (insulin analogs). As the first Chinese company that successfully developed, manufactured, and industrialized insulin analogs in China, the Company has been in the leading position in the domestic 3rd generation insulin industry for a long time. Moreover, the Company has products covering three functional segments of 3rd generation insulin: long-acting, fast-acting, and premixed

分市场均有产品覆盖，能够满足市场上糖尿病患者的不同需求。

近年来，国家多措并举大力推进基层医疗服务能力，不断加强中心卫生院、县级医院和县域医疗服务共同体的建设，推动基层卫生服务水平的提高。基层市场的消费规模也将不断上升。公司在集采前，产品覆盖的医疗机构主要集中在各城市中心医院，在基层市场尚有广阔的发展空间。目前，基层患者的胰岛素用药主要以第二代人胰岛素为主，但随着集采后第三代胰岛素类似物价格的下降，公司基层学术代表人员的扩增以及对基层市场的学术推广宣导，将推动公司产品在基层市场的快速渗透，提升公司在基层市场的品牌影响力。

公司在持续提升原有上市产品市场占有率的同时，不断加码研发投入，报告期内多个在研项目取得突破性进展。GLP-1受体激动剂作为新型减肥药物，因其良好的减重效果和安全性优势，市场前景持续被看好。在应用于超重或肥胖领域的GLP-1RA周制剂，国内尚未有类似产品上市。2022年6月，公司在国内顺利召开了在研药物GZR18 (GLP-1RA)的Ib/IIa期临床试验项目启动会，适应症为肥胖/超重体重管理和2型糖尿病，标志着公司在肥胖和超重治疗领域临床转化和产业化发展道路上又迈出了关键一步，是公司在肥胖和超重治疗领域重要里程碑之一。2022年7月，公司在研的第四代胰岛素类似物GZR4临床试验在中国获得批准，适应症为糖尿病。截至目前，全球范围内尚未有胰岛素周制剂产品开发上市，本公司的GZR4有望为患者提供一种新的治疗选择。2022年7月，公司自主研发的I类新药GZR101的I期临床试验在国内启动并完成首例受试者给药，GZR101是公司在胰岛素复方制剂的一个重要的突破。2022年6月，公司首个口服降糖药磷酸西格列汀片(DPP-4抑制剂)在国内获得产品注册批件。临床研究证实磷酸西格列汀片每日仅需口服一次即可有效控制血糖达到延缓糖尿病进展的目的。且磷酸西格列汀片低血糖发生率低，凭借出色的安全性和有效性列入国内外权威临床指南。多款研发产品不仅拓展了公司主营降糖产品线，丰富了产品结构，也是公司未

insulins, which can meet the different needs of patients with diabetes in the market.

In recent years, the state has taken multiple measures to vigorously promote the capacity of primary healthcare services and continuously strengthen the construction of central health centers, county hospitals, and county medical service communities, to promote the improvement of primary healthcare services. In addition, the primary tier market's consumption scale will continue to rise. Before the procurement, the medical institutions covered by the Company's products were mainly concentrated in the cities' central hospitals. Therefore, there is still a broad space to develop in the primary tier market. At present, the available insulin for primary patients is mainly human insulin. However, with the price drop of insulin analogs after the procurement, the expansion of the Company's primary academic representatives, and the academic promotion and publicity for the primary tier market, the Company will promote the rapid penetration of its products in the primary tier market and enhance the brand influence of the Company in the primary tier market.

The Company continues to enhance the market share of its marketed products, while continuously increasing its investment in research and development, and has made breakthroughs in several projects under development during the reporting period. For example, GLP-1 receptor agonist, a new type of weight-reducing drug, has a favorable market prospect due to its good weight-reducing effect and safety advantage. In the field of GLP-1 RA weekly formulation applied to overweight or obesity management, there are no similar products on the market domestically. In June 2022, the Company successfully held the kick-off meeting of phase Ib/IIa clinical trial project of the novel investigational drug GZR18 (GLP-1 RA) in China for the indications of type 2 diabetes and obesity/overweight management, which marks the Company's progress in obesity and overweight treatment. In July 2022, the Company's investigational fourth-generation insulin GZR4 was cleared to conduct clinical trials in China for the indication of diabetes mellitus. Up to now, no weekly formulation insulin product has been marketed worldwide, and the Company's GZR4 is expected to provide a new treatment option for patients. In June 2022, the Company received product registration approval for its first oral glucose-lowering agent, sitagliptin phosphate tablets (DPP-4 inhibitor), in China. Clinical studies have confirmed that sitagliptin phosphate tablets can be taken orally once a day to effectively control blood glucose and slow down the progression of diabetes. Sitagliptin phosphate tablets have a low incidence of hypoglycemia and are listed in authoritative clinical guidelines both domestically and globally for their excellent safety and efficacy profile. Several products under research and development not only expand the Company's main hypoglycemic product line but also enrich the product structure and guarantee the Company's future

来市场竞争的有力保障。同时，公司积极投入到其他领域的药物研发，在自身免疫类、肿瘤类等药物研发领域均布局了研发管线，也将进一步扩宽公司的发展路径，助力公司未来发展。

在国外，为了给全球糖尿病患者提供优质的药物解决方案，本公司自2005年起开始推进国际化战略布局，在包括美欧、亚太、中东、北非、中南美洲、撒哈拉以南非洲等全球各个国家及地区全面布局甘精胰岛素注射液、赖脯胰岛素注射液、门冬胰岛素注射液、人胰岛素注射液、胰岛素注射笔、胰岛素注射针头等全系列糖尿病治疗产品，通过生产经营本土化和合作商业化运作，积极导入优势资源，推动国际化商业版图的扩张。另外，通过与国际糖尿病联盟(IDF)的合作，助力全球范围内的糖尿病防治工作，提升品牌全球知名度和影响力。截至报告期期末，本公司陆续在全球二十多个国家和地区建立了国际化商业网络。在不断突破糖尿病治疗天花板的同时，本公司还积极投入到相关领域的药物研发工作中。

market competition. At the same time, the Company has actively invested in drug development in other fields and laid out R&D pipelines in autoimmune, oncology and other drug development fields, which will further broaden the Company's development path and boost future development.

Globally, to provide high-quality drug solutions for global patients with diabetes, the Company has been promoting its internationalization strategy since 2005 and has comprehensively laid out the full range of insulin products such as glargine insulin injection, lispro insulin injection, aspart insulin injection, human insulin injection, insulin injection pen and insulin injection needle in various countries and regions around the world, including the United States, Europe, Asia Pacific, Middle East, North Africa, Central and South America, and Sub-Saharan Africa. Through localization of production and operation and commercialization of cooperation, we are actively importing valuable resources and promoting the expansion of our international business territory. In addition, through collaboration with the International Diabetes Federation (IDF), the Company is contributing to the prevention and treatment of diabetes worldwide and enhancing the global awareness and influence of the brand. At the end of the reporting period, the Company has established international business networks in more than 20 countries and regions worldwide. While constantly breaking through the ceiling of diabetes treatment, the Company is also actively engaged in related drug research and development fields.



2022年3月，公司在研药物GZR18在美国启动适应症为2型糖尿病的I期临床试验。2022年6月，GZR18临床前相关研究成果已刊登在权威学术期刊《欧洲药理学杂志》(European Journal of Pharmacology)中。2022

In March 2022, the Company's investigational drug GZR18 initiated a Phase I clinical trial for the indication of type 2 diabetes in the US. In June 2022, the preclinical study results of GZR18 were published in the "European Journal of Pharmacology". In August 2022, GZR4 received IND clearance from the US FDA,

年8月，GZR4获得美国FDA的IND批文，正式批准GZR4用于在美国开展的I期临床试验。

which officially allows GZR4 to conduct Phase I clinical trials in the US.

(四) 主要业绩驱动因素

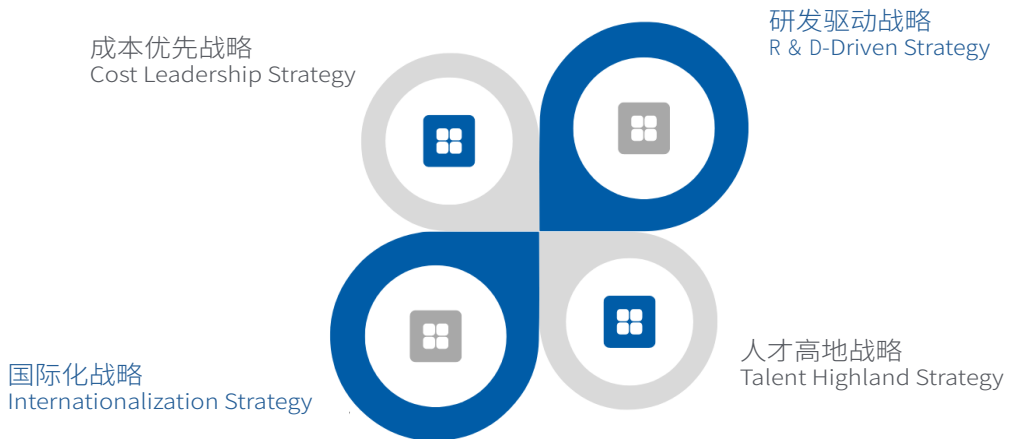
(IV) Key Performance Drivers

公司在研发驱动、成本领先、国际化和人才高地战略的指导下，研发创新成果显著，新产品陆续获批上市，助力公司不断巩固国内行业领先地位。公司在国内市场深耕多年，凭借过硬的产品质量和专业服务赢得了市场的广泛认可并形成国内市场先发优势。公司在深耕国内市场、不断扩宽销售渠道的同时，持续扩张海外市场，提升公司海外品牌影响力。

Under the R&D-driven, cost-leading, internationalization, and talent pool strategy, the Company has achieved remarkable results in R&D innovation. New products have been approved and launched, helping the Company continuously consolidate its leading position in the domestic industry. The Company has been cultivating in the domestic market for many years, has won wide market recognition, and has formed the first-mover advantage in the domestic market by its excellent product quality and professional services. In addition to expanding the domestic market and sales channels, the Company continues to expand overseas markets and enhance its overseas brand influence.

受我国胰岛素专项集采中选结果执行的影响，公司产品价格下降导致本报告期营业收入下降明显。公司将继续践行发展战略，借助带量采购的资源优势，推动中国市场第三代胰岛素类似物替换第二代人胰岛素的进程，进一步加快提高公司各产品下沉基层市场的渗透率，以获得更多的市场份额。同时公司将继续坚持研发创新战略，加速推进研发项目工作，不断丰富研发管线，优化产品结构，推动公司可持续的高质量发展。

Influenced by the implementation of the outbidding results of China’s insulin centralized procurement, the Company’s product price dropped, resulting in a significant decline in operating income in this reporting period. Nevertheless, the Company will continue to practice its development strategy to promote the process of replacing second-generation insulin with third-generation insulin in the Chinese market by taking advantage of the resources from the procurement and further accelerating the penetration rate of each of the Company’s products down to the primary tier market to gain more market share. Meanwhile, the Company will continue to adhere to its R&D innovation strategy, accelerate its research projects, continuously enrich its R&D pipelines, optimize its product structure, and promote sustainable high-quality development.



二、报告期内核心竞争力分析

II Analysis of core competitiveness during the reporting period

适用 不适用

Applicable Not Applicable



(一) 技术创新及研发优势

作为首家取得糖尿病第三代胰岛素类似物生产批文并已实现产业化生产的中国企业，公司自成立以来，一直秉承“质量第一 永远创新”的企业宗旨，先后研发出多款第三代胰岛素类似物产品，覆盖长效、速效、预混三个胰岛素功能细分市场。在不断突破糖尿病治疗天花板的同时，积极投入到肥胖、降脂等糖尿病相关适应症的药物研发工作中，为糖尿病患者带来更好的治疗选择。本公司在不断深耕糖尿病以及相关适应症的新药研发领域的同时，大力支持其他适应症的药物研发，不断丰富化学药、真核及原核蛋白质工程、肿瘤和心血管及代谢病等研发管线，为公司的持续长远发展增加动力。目前，在北京、江苏、美国新泽西等地设有研发中心，未来将进一步开拓欧洲研发中心，通过整合多样的资源，开展密切的国内外交流与合作，进一步提高公司研发实力，为公司长远的持续发展增强动力。

公司持续加强药物研究与开发团队的能力建设，经过多年发展，已形成一支能力全面、规模化的药物研究与开发团队，其中近六成为硕博人才。公司通过设置博士后科研工作站，与北京大学、清华大学等国家重点高校博士后流动站共同培养博士后研究人员，提升公司在药物

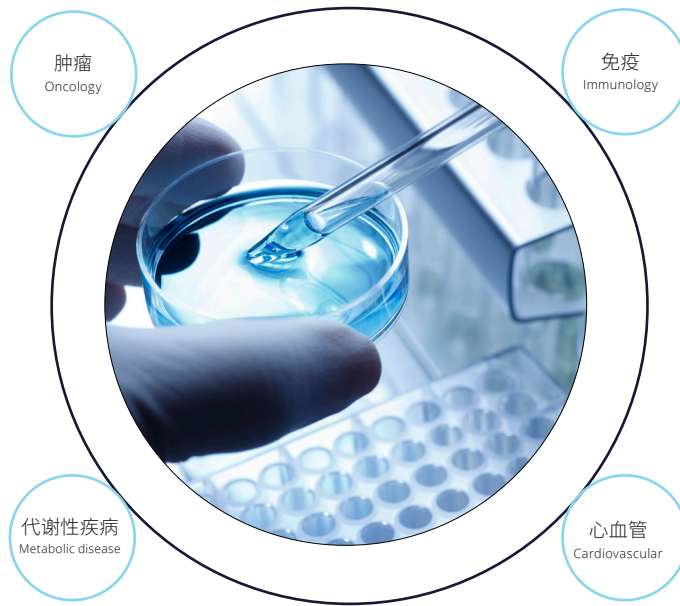
(I) Technological innovation and R&D advantages

As the first Chinese company to obtain the manufacturing approval for third-generation insulin for diabetes and to achieve industrialized production, the Company has been adhering to the corporate motto of “Quality First and Innovation Forever” since its establishment. The company has developed several third-generation insulin analog products covering three functional segments of insulin: long-acting, fast-acting, and premixed insulins. In addition to breaking through the edge of diabetes treatment, we are also actively engaged in researching and developing drugs for diabetes-related indications such as obesity and lipid-lowering to bring better treatment options for diabetes patients. While the Company continues to deepen its R&D efforts in new medicines for diabetes and related indications, it also strongly supports drug development for other indications and continues to enrich its R&D pipeline for chemical drugs, eukaryotic and prokaryotic protein engineering, oncology and cardiovascular and metabolic diseases, adding momentum to the Company’s sustainable long-term development. Currently, the Company has R&D centers in Beijing, Jiangsu, and New Jersey, USA, and will further develop our European R&D center in the future. By integrating diverse resources and conducting close domestic and international communication and cooperation, we will further improve our R&D strength and increase our long-term sustainable development momentum.

The Company continues to strengthen the competence of its R&D team and, after years of development, has formed a comprehensive and large-scale R&D team, of which nearly 60% are talents with master or PhD degrees. Furthermore, by setting up post-doctoral research stations and training post-doctoral researchers with post-doctoral mobile stations at key national universities such as Peking University and Tsinghua University, the Company has enhanced its academic level in the field of

研究领域的学术水平。同时，建立起极具创造力的研发孵化平台，如胰岛素平台、抗体平台、小分子新药平台、PROTAC技术平台、药理毒理平台、分析平台等，使公司在肿瘤、免疫、心血管、代谢性疾病研究领域形成一定的竞争优势。

drug research. Meanwhile, we have established highly creative R&D incubation platforms, such as insulin platform, antibody platform, small molecule new drug platform, PROTAC technology platform, pharmacology, and toxicology platform, and analytical platform, which enable the Company to form certain competitive advantages in the field of oncology, immunology, cardiovascular and metabolic disease research.



凭借专业的研发团队和强大的自主创新研发能力，公司多项研发项目在国内外顺利进入临床阶段。在国内，以适应症为肥胖/超重体重管理和2型糖尿病的公司在研药物GZR18为例，此项目从2021年10月获得开展临床试验批准后，在当前新冠疫情环境下，本公司只用了8个月的时间推动该项目顺利进入Ib/IIa期临床试验阶段；公司在研药物GZR101在2022年5月取得国家药监局批准开展临床试验后，于2022年7月启动了I期临床试验。2022年7月，公司收到国家药监局下发的关于公司在研药品GZR4的《药物临床试验批准通知书》。在国外，多项研发项目也取得了重大进展，例如自主研发的第四代胰岛素药物周制剂GZR4在2022年8月获得美国FDA的IND批文，正式批准GZR4用于在美国开展的I期临床试验；截至目前，公司自主研发的甘精、赖脯以及门冬胰岛素注射液均已分别进入即将向美国食品药品监督管理局

With a professional R&D team and independent solid innovation R&D capabilities, many of the Company's R&D projects have successfully entered the clinical stage domestically and abroad. In China, for example, under the current environment of the COVID-19, the Company's investigational drug GZR18, which has indications of obesity/overweight management and type 2 diabetes mellitus, took only eight months to enter into Phase Ib/IIa clinical trials after obtaining approval to start clinical trials in October 2021; the Company's investigational drug GZR101 began Phase I clinical trials in July 2022 after getting approval to start clinical trials from the National Medical Products Administration in May 2022. In July 2022, the Company received the "Notice of Approval of Drug Clinical Trial" from the National Medical Products Administration for the Company's investigational drug GZR4. Overseas, several R&D projects have also made significant progress; for example, GZR4, the self-developed fourth-generation insulin drug weekly formulation, received IND clearance from the FDA in August 2022, approving GZR4 to enter into Phase I clinical trials in the US. In addition, the Company's self-developed insulin glargine, insulin lispro, and insulin aspart injections have entered the final critical stage before submitting their biologic license application to the US Food and Drug Administration (FDA) and marketing authorization applications to

(FDA) 以及欧洲药品管理局 (EMA) 提交上市许可申请前的最后关键节点，相关资料正按计划积极准备中。

凭借专业的研发团队和强大的自主创新研发能力，自2011年起，本公司连续获得《高新技术企业证书》，且本公司的子公司甘甘医疗科技江苏有限公司于2020年获得《高新技术企业证书》。自公司成立以来，持续提升创新能力并得到多个权威机构和专家的广泛认可，其中报告期内取得的多项荣誉认证有：2022年1月获得“2021常春奖年度创新医药企业”称号；2022年2月获得“北京市新技术新产品”荣誉认定；2022年7月公司荣誉登“2021年度中国生物医药企业Top20”排行榜，其中企业创新驱动动力是本次榜单核心考察维度之一。

the European Medicines Agency (EMA), respectively.

With its professional R&D team and solid independent innovation and R&D capability, the Company has continuously obtained the “High and New Technology Enterprise Certificate” since 2011. Its subsidiary, Gan Gan Medical Technology Jiangsu Co. since its establishment, has continued to improve its innovation capability and received extensive recognition from various authorities and experts. Among them, a number of honorary certifications obtained during the reporting period include: the Company won the title of “2021 evergreen award of annual innovative pharmaceutical enterprise” in January 2022; the Company won the honorary recognition of “Beijing new technology and new products” in January 2022. the Company was ranked among the “Top 20 Biopharmaceutical Enterprises in China in 2021” in July 2022, in which corporate innovation's driving force is one of this list's core dimensions.

(二) 全产品线布局优势

胰岛素的发展经历过动物胰岛素(一代，已基本被淘汰)、人胰岛素(二代)和胰岛素类似物(三代)。自上世纪90年代末期胰岛素类似物上市以来，其在全球范围内的销售规模迅速增长。相比于人胰岛素，胰岛素类似物可更好地模拟生理胰岛素分泌，具有显著降低低血糖风险等优势；胰岛素类似物在发达国家市场已较大程度取代了人胰岛素产品。作为行业领先掌握重组胰岛素技术的中国企业，本公司具备完整胰岛素研发管线，拥有五个胰岛素类似物品种以及一个人胰岛素品种，产品覆盖长效、速效、预混三个胰岛素功能细分市场，为全球糖尿病患者提供更全面优质的胰岛素产品选择。

公司主营降糖产品线全面稳健发力，除已上市、市场成熟的第二、三代胰岛素，正在积极地布局和推进第四代胰岛素以及更前沿的糖尿病治疗相关的药物和疗法。目前，已进入临床阶段的研发项目包括胰岛素复方制剂GZR101、第四代胰岛素类似物

(II) Advantages of full product line layout

The development of insulin has gone through animal insulin (first generation, basically obsolete), human insulin (second generation), and insulin analogs (third generation). Since the launch of insulin analogs in the late 1990s, their sales scale has grown rapidly worldwide. Compared with human insulin, insulin analogs can better simulate physiological insulin secretion pattern and significantly reduce the risk of hypoglycemia; insulin analogs have replaced human insulin products to a large extent in developed markets. As the leading company with recombinant insulin technology in the industry from China, the Company has a complete insulin R&D pipeline with five insulin analogs and one human insulin product, covering three insulin functional segments: long-acting, fast-acting, and premixed insulins, providing a more comprehensive and high-quality choice of insulin products for global diabetes patients.

In addition to the second and third-generation insulins that have been marketed and matured in the market, the Company is actively promoting the fourth-generation insulins and more cutting-edge drugs and therapies related to diabetes treatment. Currently, the development projects that have entered the clinical stage include the insulin compound formulation GZR101, the fourth-generation insulin analog GZR4, and the long-

GZR4和长效胰高血糖素样肽-1 (GLP-1) 受体激动剂类药物GZR18。2022年6月，公司在研创新药GZR101的I期临床试验已启动并完成首例受试者给药，这是公司在胰岛素复方制剂的一个重要突破，我们期待GZR101能给全球患者带来更多的用药选择。2022年7月，公司收到国家药监局下发的关于公司在研药品GZR4的《药物临床试验批准通知书》，下一阶段将按国家药品注册相关规定开展糖尿病适应症临床试验；2022年8月，GZR4获得美国FDA的IND批文，正式批准GZR4用于在美国开展的I期临床试验，有望进一步丰富和拓展公司的产品管线，为全球糖尿病患者带来革新性的治疗选择。2021年，本公司在研创新生物药GZR18(GLP-1RA)在中国和美国获得2型糖尿病适应症临床试验的批准，均展现出公司在糖尿病相关领域突出的创新能力以及成长性。此外，GZR18还具有治疗肥胖/超重体重管理的潜力。2022年6月，GZR18在中国顺利召开了Ib/IIa期临床试验项目启动会，适应症为2型糖尿病和肥胖/超重体重管理，为公司在肥胖和超重治疗领域形成商业化先发优势提供良好的开端。

除上述产品外，磷酸西格列汀片是本公司自主研发的首个口服降糖药。2022年6月，磷酸西格列汀片在国内获批上市，拓展了公司降糖产品线，有利于提升公司在糖尿病用药领域的市场综合竞争力，巩固公司在国内糖尿病治疗领域的市场领先地位。

我们在丰富产品线的同时积极推进产能建设，公司在建产能扩增项目正在同步有序推进，投产后将为公司产品商业化生产提供强劲保障，助力公司在糖尿病治疗领域的全产品线布局。

acting glucagon-like peptide-1 (GLP-1) receptor agonist drug GZR18. In June 2022, the Phase I clinical trial of the Company's investigational innovative drug GZR101 was initiated, and the first subject administration was completed, which is an essential breakthrough in the Company's insulin compound formulation. In July 2022, the Company received the "Notice of Drug Clinical Trial Approval" from the National Medical Products Administration for the Company's investigational drug GZR4, and the next stage will be to conduct clinical trials for diabetes indications in accordance with the relevant provisions of the national drug registration; In August 2022, GZR4 received IND clearance from the US FDA for a Phase I clinical trial in the US, which is expected to enrich further and expand the Company's product pipeline and will bring innovative treatment options to diabetes patients worldwide. 2021, the Company's investigational innovative biologic drug GZR18 (GLP-1 RA) received approval in both China and the US for Type 2 diabetes GZR18 (GLP-1 RA) was approved for clinical trials in China and the US for type 2 diabetes, both demonstrating the Company's outstanding innovation and growth in diabetes-related areas. In addition, GZR18 has the potential to treat obesity/overweight management. In June 2022, GZR18 successfully held a Phase Ib/IIa clinical trial kick-off meeting in China for the indications of type 2 diabetes and obesity/overweight management. It provides a good start for the Company to develop a commercial first-mover advantage in the obesity and overweight treatment.

In addition to the mentioned products, sitagliptin phosphate tablet is the first oral hypoglycemic drug independently developed by the Company. In June 2022, the sitagliptin phosphate tablet was approved for launch in China, expanding the Company's hypoglycemic product line, which is conducive to enhancing the Company's comprehensive market competitiveness in the field of diabetes medication and consolidating the Company's leading market position in the domestic diabetes treatment field.

We are actively promoting production capacity construction while enriching our product line. The Company's under-construction capacity expansion project is progressing in an organized manner, which will provide a strong guarantee for the commercial production of the Company's products and help the Company's complete product line layout in the field of diabetes treatment when it comes into operation.

(三) 成本领先优势

公司拥有经验丰富的研发和产业化团队，有利于实验室成果快速实现产业化。公司凭借多年的研发及生产经验，打造了技术先进、工艺科学的生产工厂，并持续进行工艺优化，在保证公司产品质量安全的同时加强产品成本控制，践行公司的成本领先战略，旨在为全球糖尿病患者提供更多可及可负担的药品。

本公司采用全过程控制的策略，将成本控制融入到公司经营活动的各个环节中，从产品研发、材料采购、产品制造到产品销售及售后服务整个链条都得到有效的成本控制。同时，不断完善全链条精益化管控体系，增强了各链条间的黏性，有助于实现公司降本增效的目的。

在带量采购执行后，公司有望凭借此次带量采购的优势不断提高产品销量，进而提升产能利用率，发挥规模效应，摊薄生产成本，进一步保持并提升成本领先优势。同时公司通过扩大生产规模、加强生产管理和优化资源配置等有效措施，进一步保证药品质量，提高生产效率，多举措确保集采量的供应。同时，随着产量的增加，公司单位产品所分摊的固定成本下降，规模效应将会进一步凸显。本公司将凭借成本优势以及规模优势支持公司在市场以及研发方面的持续投入，以保障公司的可持续发展。

(四) 国际化战略优势

公司的一次性使用注射笔用针头(秀霖针®)作为甘李药业首个获得美国FDA注册批准的产品，为实现“布局全球市场”这一愿景起到了积极的推动作用。目前，公司海外获批产品的类别包括各类胰岛素原料药、卡式瓶注射液、预填充注射液、胰岛素笔和针头等产品。

国际化战略是公司实现“布局全球市场”愿景的重要着力点。本公司自2005年开始推进国际化战略布局，

(III) Cost Leadership

The Company has an experienced R&D team and an industrialization team, which facilitates the rapid industrialization of experimental achievements. With years of experience in R&D and manufacturing, the Company has built a technologically advanced and scientifically efficient manufacturing plant. It continues to optimize its processes to ensure the quality and safety of the Company's products while strengthening the control of product costs, in line with the Company's cost leadership strategy, to provide more accessible and affordable medicines to diabetes patients worldwide.

The Company uses a whole process control strategy. It integrates cost control into all aspects of the Company's business activities so that the entire chain from product development, material procurement, and product manufacturing to product sales and after-sales service is controlled effectively. At the same time, the continuous improvement of the lean control system of the whole business chain has enhanced the adhesion between the chains and helped to achieve the Company's goal of cost reduction and efficiency increase.

After the implementation of the volume-based procurement, the Company is expected to continuously increase the scale of product sales with the advantage of this procurement, which will, in turn, enhance the capacity utilization rate, bring into play the scale effect, dilute the production cost and further maintain and enhance the advantages of cost leadership. At the same time, the Company will further ensure the quality of drugs and improve production efficiency through effective measures such as expanding production scale, strengthening production management, and optimizing resource allocation to ensure the supply of volume-based procurement. At the same time, with the increase in production volume, the fixed cost apportioned per unit of product will decrease, and the scale effect will be further highlighted. The Company will rely on the cost advantage and the scale advantage to support the Company's continuous investment in marketing as well as R&D to ensure the sustainable development of the Company.

(IV) International strategic advantages

The Company's disposable needle for injection pen (GanleeFine®), the first product of Gan & Lee Pharmaceuticals. to be registered and approved by the US FDA, has played a positive role in realizing the vision of "laying out the global market." the Company's overseas approved product categories include various insulin APIs, cartridge injections, pre-filled injections, insulin pens, and needles.

The internationalization strategy is important for the Company to realize the vision of "laying out the global market." Therefore, the Company has been promoting its internationalization strategy

现阶段公司国际化战略为：

since 2005. Right now, the Company's internationalization strategy is as follows:

1. 占领注册标准高地

本公司立足于生物制剂的研发优势，加速推进研发项目进展。2021年12月，本公司在研预期每周注射一次的GZR18 (GLP-1RA) 制剂获准在美国开展适应症为2型糖尿病的I期临床试验，并于2022年3月完成了首例受试者给药。2022年6月，GZR18的临床前相关研究成果在全球性权威学术期刊《欧洲药理学杂志》(European Journal of Pharmacology) 上进行了发表。目前，本公司自主研发的甘精、赖脯以及门冬胰岛素注射液均已分别进入即将向美国食品药品监督管理局 (FDA) 以及欧洲药品管理局 (EMA) 提交上市许可申请前的最后关键节点，相关资料正按计划积极准备中，希望将来这三款产品的获批上市能为更多的糖尿病患者带来福音。

凭借新兴市场本土企业拥有的优势资源，公司持续推进药品和医疗器械在新兴市场的注册工作，新兴市场也逐渐成为公司布局全球化的重要舞台。截至本报告期末，公司胰岛素产品已在18个国家累计取得39份药品注册批件。

2. 全球市场同步开拓

(1) 欧美等发达国家市场：甘李药业与诺华集团 (Novartis) 旗下子公司山德士 (Sandoz) 于2018年签订商业和供货协议。协议约定，在三款生物类似药获得批准后，山德士将进行药品在美国、欧洲及其他特定区域的商业运作，由甘李药业负责药物开发 (包括临床研究) 及供货等事宜。

(2) 新兴市场：甘李药业通过制剂生产本土化和经营本土化这两大战略，积极将优势资源导入新兴国家市场，推动国际业务的快速发展，实现国际化商业版图的扩张。一方面，公司利用各国对药品本土化生产的优惠政策，与当地大型医药企业合作，签订原料药供货协议，通过技术转移实现制剂生产本土化，进一步降低成本，提高产品竞争力。另一方面，

1. Occupation of Registered Standard Heights

Based on the research and development advantages of biological preparations, the Company accelerates the progress of research and development projects. In December 2021, The Company's GZR18 (GLP-1 RA) preparation, which is expected to be injected once a week, was cleared for Phase I clinical trials in the United States for the indication of type 2 diabetes, and the first-in-human administration was completed in March 2022. In June 2022, the related preclinical study results of GZR18 were published in the "European Journal of Pharmacology" a global authoritative academic journal. In addition, the Company's self-developed insulin glargine, insulin lispro, and insulin aspart injections have entered the final critical stage before submitting their biologic license application to the US Food and Drug Administration (FDA) and marketing authorization applications to the European Medicines Agency (EMA), respectively. Relevant documentation is being actively prepared as planned. Hopefully, the approval of these three products will bring great benefits to more patients with diabetes in the future.

Relying on the advantageous resources of local companies in emerging markets, the Company continues to promote the registration of drugs and medical devices in emerging markets, and emerging markets have gradually become an important stage for the Company's globalization. At the end of the reporting period, the Company's insulin products had obtained a total of 39 drug registration certificates accumulatively in 18 countries.

2. Simultaneous expansion of the global market

(1) Developed markets such as Europe and the United States: In 2018, Gan & Lee signed commercialization and supply agreements with Sandoz, division of the international pharmaceutical company Novartis. Under the terms of the agreement, Sandoz will conduct commercial operations of these three drugs in the US, Europe, and other specified regions, with Gan & Lee being responsible for drug development (including clinical studies) and supply.

(2) Emerging markets: Gan & Lee has been actively importing its valuable resources into emerging countries' needs through the two strategies of localized production and localized operation to promote the rapid development of its international business and realize the expansion of its international business territory. On the one hand, the Company takes advantage of preferential policies for localized drug production in each country, cooperates with large local pharmaceutical companies, signs API supply agreements, and localizes preparation production through technology transfer to further reduce costs and

公司拟在多地设立子公司或授权当地企业，搭建当地商业分销渠道网络，实现经营本土化，深入挖掘当地市场潜力，提升产品销量，抢占更多的全球市场份额。

improve product competitiveness. On the other hand, by setting up subsidiaries in many places or authorizing local enterprises, the Company has built up local distribution channels and localized its operation to deeply explore the potential of local markets, increase product sales, and seize more global market shares.

三、经营情况的讨论与分析

III Discussion and analysis of business conditions

(一) 经营概览：

(I) Business overview:

2022年是公司在集采中战略选择的落地执行年，也是公司长远市场规划的布局之年。公司积极响应国家为民降费的号召，在集采中全线六款产品高顺位中标，旨在用更普惠的价格惠及更多的患者，力争更多的市场份额。鉴于医生的处方习惯与糖尿病患者对产品的认知需要时间转换，短期内销量的增长尚不能对冲价格下降的影响，给公司业绩带来短期阵痛。但从长远来看，公司扩增营销团队，全面覆盖各级市场，并积极进行基层市场深耕细作，扩大学术推广宣传范围，深入宣传公司产品价格优势，在提升对现有患者专业化服务水平的同时，加速第三代胰岛素类似物对第二代人胰岛素的市場替换。

2022 is the implementation year of the Company's strategic choice in volume-based procurement, and it is also the year of the Company's long-term market planning. The Company actively responded to the national call to reduce fees for the people. As a result, six products have won the bidding with a high ranking in the volume-based procurement, aiming to benefit more patients with better prices and strive for more market shares. Because doctors' prescription habits and diabetic patients' perception of products take time to change, the increase in sales volume in the short term cannot offset the impact of falling prices, which will bring short-term pain to the Company's performance. However, in the long-term, the Company will expand its marketing team to cover all levels of the market, actively cultivate the primary tier market, and expand the scope of academic promotion and publicity. In-depth publicize the price advantage of the Company's products and accelerate the market replacement of third-generation insulin analogs for second-generation human insulin while enhancing the level of specialized services for existing patients.

研发创新是公司可持续发展的基本保障，继续发挥国内胰岛素领先优势，积极发展胰岛素全产品线布局。目前，在研的超长效的第四代胰岛素类似物、双适应症(包括2型糖尿病和肥胖/超重体重管理)的胰高血糖素样肽1(GLP-1)受体激动剂周制剂、胰岛素复方制剂等领先产品均取得可喜进展，也将为全球糖尿病患者带来革新性的治疗选择。

R&D innovation is the fundamental guarantee for the Company's sustainable development. Therefore, the Company will continue to perform the leading advantages of domestic insulin and actively develop the composition of the entire insulin product line. Currently, there are ultra-long-acting fourth-generation insulin analogs under development, glucagon-like peptide 1 (GLP-1) receptor agonist weekly preparations for dual indications (including type 2 diabetes and obesity/overweight management), insulin compound preparations as well as other leading products have made gratifying progress. We hope to bring innovative treatment options for diabetes patients around the world.

虽然2022年国际局势动荡，全球疫情不断反复加剧，国际航运紧张，运输费用上涨，影响公司国际业务合作的开展，但公司依然紧抓国际化战略不动摇，加大新品海外宣传力度，巩固原有客户合作关系，踏实推进潜在客户开发和新老客户合作，稳步开拓国际市场。

In 2022, although with the impact of the turbulent international situation, the intensified global epidemic, international shipping tension, and transportation costs rise, which will affect the Company's international business cooperation, the Company will continue to grasp the internationalization strategy firmly, increase overseas promotion of new products, consolidate the existing customer cooperation relationship, steadily promote the development of potential customers and cooperation with new customers, and steadily develop the international market.

(二) 报告期内，公司主要完成和重点工作开展了以下工作：**1. 研发创新持续加码：**

2022年上半年，公司研发项目累计投入31,951.09万元，较上年同期增长28.36%，占销售收入比重为38.27%。其中，费用化研发投入24,442.90万元，较上年同期增加9.49%；资本化研发投入7,508.19万元，占研发总投入的23.50%，较上年同期增加192.44%。

研发与创新始终是甘李药业的立身之本，我们在产品开发、技术创新的道路上从未停止前进与探索的步伐。为进一步提高患者的生活质量，公司每一位研发人员始终如一地秉持着“科学 极致”的企业文化，不断创新，尝试挑战人类认知的极限，找寻下一个更佳解决方案。报告期内，公司坚持自主创新研发，以内生性发展为主要驱动力，在糖尿病治疗领域取得突破性进展的同时，积极投入到其他领域的药物研发，自身免疫类、肿瘤类等药物研发均布局了研发管线，并取得了可喜进展。

(1) GLP-1受体激动剂：GZR18

本公司在研I类新生物药GZR18注射液是一种预期每周注射一次的长效胰高血糖素样肽-1 (GLP-1) 受体激动剂类药物，与人体内源性GLP-1同源性高达94%。GLP-1是一种肠促胰岛素，在血糖升高时，其能够促进胰岛素分泌，并同时抑制胰高血糖素(胰高血糖素促进肝糖原分解和糖异生的作用很强，会使血糖明显升高)分泌，从而发挥降血糖作用。

2022年6月，GZR18临床前相关研究成果已在权威学术期刊《欧洲药理学杂志》(European Journal of Pharmacology)上进行发表。从目前的研究数据可以明确地看到GZR18在糖尿病动物模型上具有良好的降糖和减重作用，显示出了较好的糖尿病治疗前景。2022年6月，GZR18在国内召开针对2型糖尿病和肥胖/超重体重管理两种适应症的Ib/IIa期临床试验项目研究启动会。公司于

(II) During the reporting period, the Company mainly completed and focused on the following tasks:**1. R&D and innovation continue to increase:**

During the first half of 2022, the Company's accumulated investment in R&D projects was RMB 319.51 million, representing an increase of 28.36% over the same period of the previous year and accounting for 38.27% of the sales revenue. Among them, the expensed R&D investment was RMB 244.43 million, representing an increase of 9.49% compared with the same period of the previous year; the capitalized R&D investment was RMB 75.08 million, accounting for 23.50% of the total R&D investment, representing an increase of 192.44% compared with the same period of the previous year.

R&D and innovation have always been the foundation of Gan & Lee. We have never stopped advancing and exploring on the road of product development and technological innovation. To further improve patients' quality of life, every R&D member of Gan & Lee has consistently adhered to the corporate culture of "Science & Excellence", constantly innovating, trying to challenge the limits of human cognition, and looking for the next better solution. During the reporting period, the Company insisted on independent innovation, research, and development, with endogenous development as the main driving force. While making breakthroughs in the field of diabetes treatment, the Company actively invested in the research and development of diabetic drugs, autoimmune, tumor, and other drugs, which made gratifying progress.

(1) GZR18 GLP-1 receptor agonist: GZR18

GZR18 injection, an innovative class 1 biological drug under development by the Company, is a long-acting glucagon-like peptide-1 (GLP-1) receptor agonist with 94% homology in human endogenous GLP-1 expected to be injected once a week. GLP-1 is an incretin, which can promote insulin secretion and inhibit glucagon secretion at the same time to exert hypoglycemic effects when blood glucose rises. Glucagon has a strong role in promoting hepatic glycogenolysis and gluconeogenesis, which can significantly increase blood glucose.

In June 2022, the preclinical study results related to GZR18 were published in the authoritative academic journal "European Journal of Pharmacology". The current research data shows that GZR18 has good hypoglycemic and weight loss effects in diabetic animal models, indicating a good prospect for diabetes treatment. In June 2022, GZR18 held a kick-off meeting for Phase Ib/IIa clinical trial projects for both indications of type 2 diabetes and obesity/overweight management in China. In addition, the Company initiated a Phase Ib/IIa clinical trial in patients with type 2 diabetes and obesity/overweight management in July 2022 and

2022年7月在国内启动了适应症为2型糖尿病和肥胖/超重体重管理Ib/IIa期临床试验并已完成首例受试者给药。

在应用于超重或肥胖领域的GLP-1RA周制剂，尚处于市场初期阶段。目前，在全球范围内，仅有一款GLP-1RA周制剂在美国被批准应用于肥胖或超重成人体重管理，而在中国，还未有相关产品获批上市。GZR18在中国的临床试验获批，标志着公司在肥胖和超重治疗领域临床转化和产业化发展道路上又迈出了关键一步，是公司在肥胖和超重治疗领域重要里程碑之一。

has completed the first-in-human administration in China.

The weekly formulation of GLP-1 RA for overweight or obesity is still in the early stages of the market. Currently, only one GLP-1 RA weekly preparation has been approved for weight management in obese or overweight adults in the United States. In contrast, no related products have been approved for marketing in China. The approval of the clinical trial of GZR18 in China marks another critical step for the Company on the road to clinical transformation and industrialization in the field of obesity and overweight treatment. It is one of the important milestones for the Company in the field of obesity and overweight treatment.

(2) 第四代胰岛素类似物：GZR4

GZR4是本公司在研的I类创新型治疗用生物制品，属于第四代胰岛素类似物，预期在人体每周皮下注射给药一次，实现平稳控制基础血糖。GZR4预计每周注射一次的超长效胰岛素有望大幅减少患者的注射频率，降低注射恐惧，减轻患者身心负担；在提高用药依从性的同时，提升患者的治疗效果，从整体上改善糖尿病患者患者的生活质量。

2022年7月，公司收到国家药监局下发有关GZR4的《药物临床试验批准通知书》，获批适应症为糖尿病。2022年8月，GZR4获得美国FDA的IND批文，正式批准GZR4用于在美国开展的I期临床试验。截至目前，全球范围内尚未有胰岛素周制剂产品获批上市，本公司在研药物GZR4临床试验获批，有望进一步丰富和拓展公司的产品管线，为糖尿病患者提供更多的用药选择。

(3) 新型预混双胰岛素复方制剂：GRZ101

GRZ101注射液是本公司自主研发的新型预混双胰岛素复方制剂，由本公司在研的长效基础胰岛素GZR33 (50%)与速效门冬胰岛素(50%)混合制成，拟用于治疗糖尿病。预期GRZ101注射液在每日一次给药的情

(2) Fourth generation insulin analogs: GZR4

GZR4 is a Class I innovative therapeutic biological product under development by the Company, belonging to the fourth generation of insulin. It is expected to be administered by subcutaneous injection once a week into the human body to achieve stable control of basal blood glucose. GZR4 is expected to be administered once a week by subcutaneous injection to achieve stable control of basal blood glucose for one week. In addition, it can potentially reduce the pain of injection, improve patients' compliance with insulin therapy, and optimize long-term treatment management, with high clinical benefits.

In July 2022, the Company received the "Notice of Drug Clinical Trial Approval" issued by the National Medical Products Administration for GZR4, and the approved indication is diabetes. In August 2022, GZR4 received IND clearance from the US FDA, officially approving GZR4 for Phase I clinical trials in the US. Up to now, no insulin weekly preparation product has been approved for marketing globally. The Company's drug GZR4 has been approved for clinical trials, which is expected to enrich further and expand the Company's product pipeline and provide more medication options for diabetic patients.

(3) Novel premixed dual insulin compound preparation: GRZ101

GRZ101 injection is a new premixed dual insulin compound preparation independently developed by the Company. It is made by mixing the Company's under research long-acting basal insulin GZR33 (50%) and fast-acting insulin aspart (50%) and is intended to be used for treating diabetes. It is expected that GZR101 can simulate the biphasic pattern of physiological

况下能模拟生理性胰岛素分泌的双相模式，兼顾空腹和餐后血糖控制，平稳降糖，提高血糖控制达标率，同时简化治疗，提高患者依从性和降低治疗负担，优化糖尿病长期管理，有利于降低或延缓并发症的发生。

2022年5月，GZR101已收到国家药监局下发的《药物临床试验批准通知书》，获批适应症为糖尿病。GZR101药物临床试验批准是公司在胰岛素复方制剂的一个重要的突破，将进一步丰富本公司的产品管线。于2022年7月在国内启动了GZR101的I期临床试验并已完成首例受试者给药。本试验也是GZR101在中国的首次人体试验(FIH)，将评估GZR101注射液及其组成成分GZR33在受试者中安全性、耐受性、药效动力学和药代动力学指标。

(4) 口服降糖药：磷酸西格列汀片

磷酸西格列汀片是全球首个获批的口服二肽基肽酶-4 (DPP-4) 抑制剂，通过增加肠促胰素水平，增加胰岛素分泌、抑制胰高血糖素，减缓胃排空，降低血糖水平，配合饮食控制和运动，用于改善2型糖尿病患者的血糖控制。临床研究证实磷酸西格列汀片每日仅需口服一次即可有效控制血糖达到延缓糖尿病进展的目的。磷酸西格列汀片低血糖发生率低，凭借出色的安全性和有效性列入国内外权威临床指南。(参考文献Scott L. J. (2017). *Sitagliptin: A Review in Type 2 Diabetes. Drugs*, 77(2), 209-224. <https://doi.org/10.1007/s40265-016-0686-9>)

本公司自主研发的磷酸西格列汀片(甘唐维®)是公司首个获批的小分子化药仿制药。2022年6月，本公司之全资子公司甘李药业江苏有限公司收到国家药品监督管理局(NMPA)下发的磷酸西格列汀片产品注册批件，该药物适应症为2型糖尿病。磷酸西格列汀片的获批上市拓展了公司主营降糖产品线，有利于提升公司在糖尿病用药领域的市场综合竞争力，巩固公司在国内糖尿病治疗领域的市场领先地位，为患者提供更多的治疗选择。

insulin secretion under once-daily administration, take into account both fasting and postprandial blood glucose control, stabilize blood sugar steadily, and improve the rate of glycemic control rate. GZR101 is also expected to simplify treatment, improve patient compliance, and reduce treatment burden to optimize long-term diabetes management and help reduce or delay the onset of complications.

In May 2022, GZR101 received the "Drug Clinical Trial Approval Notice" issued by the National Medical Products Administration, and the approved indication is diabetes. The clinical trial approval of GZR101 is an important breakthrough for the Company in insulin compound preparation, which will further enrich the Company's product pipeline. In addition, the Phase I clinical trial of GZR101 was launched in China in July 2022, and the first subject has been administered. This trial is also the first human trial (FIH) of GZR101 in China and will evaluate the safety, tolerability, pharmacodynamics, and pharmacokinetic indicators of GZR101 injection and its constituent GZR33 in subjects.

(4) Oral hypoglycemic drugs: Sitagliptin Phosphate Tablets

Sitagliptin Phosphate is the world's first approved oral dipeptidyl peptidase-4 (DPP-4) inhibitor. It can increase the level of incretin, increase insulin secretion, inhibit glucagon, slow gastric emptying, and lower blood sugar levels, combined with diet control and exercise, to improve blood sugar control in patients with type 2 diabetes. Clinical studies have confirmed that sitagliptin phosphate tablets only need to be taken orally once a day to control blood sugar and delay the progression of diabetes effectively. Sitagliptin Phosphate has a low incidence of hypoglycemia and is listed in authoritative clinical guidelines at home and abroad with its excellent safety and efficacy. (Reference: Scott L. J. (2017). *Sitagliptin: A Review in Type 2 Diabetes. Drugs*, 77(2), 209-224. <https://doi.org/10.1007/s40265-016-0686-9>)

The Company's self-developed sitagliptin phosphate tablet is the Company's first approved small-molecule generic drug. In June 2022, Gan & Lee Pharmaceutical Jiangsu Co, Ltd, a wholly-owned subsidiary of the Company, received the registration approval for sitagliptin phosphate tablets issued by the National Medical Products Administration (NMPA). The indication of the drug is type 2 diabetes. The approval and listing of sitagliptin phosphate tablets expand the Company's main hypoglycemic product line, which is conducive to enhancing the Company's comprehensive market competitiveness in the field of diabetes drugs, consolidating the Company's market-leading position in the domestic diabetes treatment field, and providing patients with better treatment options.

2006年，磷酸西格列汀片于美国获批后在全球口服降糖市场增速迅猛。据药融云全球药物研发数据库预估，磷酸西格列汀片近几年全球年销售额稳定在35-40亿美元左右。2009年，磷酸西格列汀片正式进入中国；2017年，该药物纳入国家医保(乙类)实现快速放量；2021年，全国二级及以上医院的磷酸西格列汀片销售额达15.12亿元，市场前景广阔。磷酸西格列汀片在国内的磷酸结晶单水合物原研专利将于2024年6月到期，届时公司将正式投入生产和销售，将会优化公司产品结构，开辟新的利润增长点。

In 2006, after the approval of sitagliptin phosphate tablets in the United States, the global oral hypoglycemic market grew rapidly. According to the estimates of Pharnexcloud's global drug research and development database, the global annual sales of sitagliptin phosphate tablets have stabilized at about 3.5-4.0 billion US dollars in recent years. In 2009, sitagliptin phosphate tablets officially entered China; In 2017, the drug was included in the national medical insurance (Class B) to achieve rapid volume growth; In 2021, the sales of sitagliptin phosphate tablets in second-class and above hospitals nationwide reached RMB 1.512 billion which means the market prospect is broad. The original research patent of phosphate crystal monohydrate in China for sitagliptin phosphate tablets will expire in June 2024. At that time, the Company will officially put into production and sales, which will optimize the Company's product structure and create new profit growth points.

2. 迎接集采落地，扩增学术团队

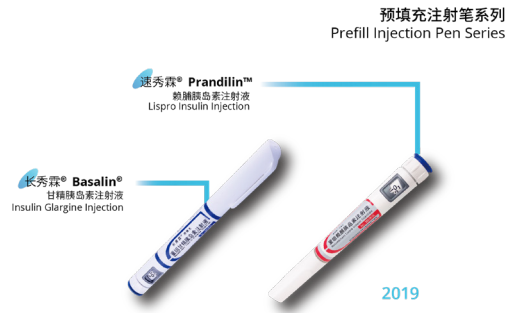
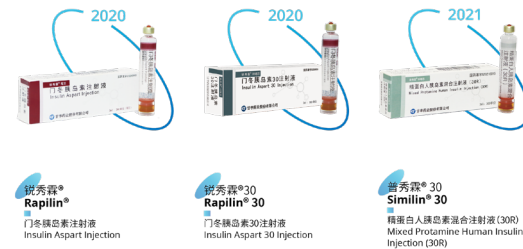
胰岛素产品作为糖尿病患者控制血糖的重要药品，在糖尿病治疗中具有不可替代的地位。由于胰岛素需要长期使用，患者承受较高的费用负担。2021年11月，国家组织了第六批胰岛素药品集中带量采购工作，涵盖临床常用的第二代人胰岛素和第三代胰岛素类似物，而第三代胰岛素类似物在降血糖的效果、控制低血糖的风险和使用便携程度方面更具优势。本次集采后，第三代胰岛素类似物在价格上与第二代人胰岛素持平、甚至低于第二代人胰岛素产品，第三代胰岛素类似物已经具备了替换第二代人胰岛素的有利价格条件，将会进一步推进中国第三代胰岛素类似物替代第二代人胰岛素的进程，让更多的糖尿病患者可以更快享受到疗效更佳、安全性更高的胰岛素产品。

本公司作为生产供应第三代胰岛素类似物产品的主要国产企业，覆盖长效、速效、预混三个胰岛素功能细分市场，为患者提供了多样化的产品选择，具体包括长效胰岛素中的长秀霖®产品，速效胰岛素中的速秀霖®、锐秀霖®产品，预混胰岛素中的速秀霖®25、锐秀霖®30产品。同时，公司在第二代人胰岛素也布局有预混产品普秀霖®30。

2. Welcome the landing of the collection Promote the upgrading and transformation of the sales team

As an essential drug for diabetic patients to control blood sugar, insulin products have an irreplaceable position in diabetes treatment. However, patients bear a high-cost burden due to their long-term needs. In November 2021, the nation organized the sixth batch of volume-based procurement of insulin drugs, covering the second-generation human insulin and third-generation insulin analogs commonly used in clinical practice. Third-generation insulin analogs have more advantages in lowering blood sugar, controlling hypoglycemia risk, and using portability. After the centralized procurement, the price of the third-generation insulin analogs is the same or even lower than the second-generation human insulin products. The third-generation insulin analogs already have the advantage of replacing second-generation human insulin. The price conditions will further promote replacing second-generation human insulin with third-generation insulin analogs in China so that more diabetic patients can enjoy insulin products with better efficacy and higher safety.

As the leading domestic enterprise producing and supplying third-generation insulin products, the Company covers the three functional segments of insulin: long-acting, rapid-acting, and premixed insulins, so that patients have a variety of product choices, including long-acting insulin Basalin® products, rapid-acting insulin Prandilin® and Rapilin®, premixed insulin Prandilin® 25 and Rapilin®30. At the same time, in the second generation insulin (human insulin), the Company also has a premixed product, Similin®30.



在2021年集采中，本公司全产品高顺位中标，最终获得协议采购量3,533.77万支(基础量1,664.18万支、获得分量1,869.59万支)，超过上年度胰岛素制剂销售总量，共计覆盖医疗机构数量21,000多家，其中公司新准入医疗机构近万家。本次公司通过集采获得的协议采购量及医疗机构的资源，将有助于公司加速市场渗透，特别有助于公司近两年新上市的三款主流胰岛素产品(锐秀霖®、锐秀霖®30及普秀霖®30)快速进行市场覆盖和上量。

In the 2021 centralized procurement, the Company won the bidding for all products in high ranking and finally obtained 35.338 million pcs of agreed procurement volume (basic volume is 16.642 million pcs and reallocated volume is 18.696 million pcs), exceeding the total sales volume of insulin preparations in the previous year. A total of more than 21,000 medical institutions are covered, of which nearly 10,000 medical institutions are newly entered. The agreed procurement volume and the resources of medical institutions obtained by the Company through volume-based procurement will help the Company to accelerate market penetration, especially for the Company's three mainstream insulin products listed in the past two years (Rapilin®, Rapilin®30 and Similin®30) quickly achieved market coverage and volume.

按照本次集采规则，除协议采购量外，院外及非集采市场仍有约一半的市场份额，公司凭借价格优势，在本报告期新准入(未在本公司协议采购清单内)的医疗机构达3,200多家。随着带量采购政策的陆续落地执行，公司医疗机构覆盖数量有望进一步上升，为公司后续销量增长和市场覆盖的扩宽奠定了基础。

According to the rules of this volume-based procurement, except for the agreed procurement volume, the out-of-hospital and non-centralized procurement market still occupied nearly half of the market share. The Company's new access medical institutions (not included in the agreed procurement volume list) reached more than 3,200 medical institutions in this reporting period by the price advantage. With the implementation of the volume-based procurement policy, the number of medical institutions covered by the Company is expected to increase further, laying a foundation for the Company's subsequent sales growth and market coverage expansion.

面对集采后的市场需求增长，公司强化推进产能升级及供应保障工作。一方面，公司生产、质量、供应链等核心部门以集采产品供应为第一要务，确保高效生产、质量第一、供应稳定；另一方面，公司加速推进产能增量项目建设，提升公司产能规模。

Facing the increase in market demand after volume-based procurement, the Company has strengthened the promotion of production capacity upgrades and supply guarantees. On the one hand, the Company's core departments, such as production, quality, and supply chain, take centralized product supply as the first priority to ensure efficient production, quality first, and stable supply; on the other hand, the Company accelerates the construction of capacity increment projects to increase the Company's production capacity and scale.

在市场推广方面，为更好的借助集采中选结果的价格和资源优势，公司加速深化基层市场的团队建设，在2022年上半年新招募专业学术代表近千人。公司的学术推广团队，覆盖全国31个省(自治区、直辖市)，是公司产品知识推广和糖尿病学术知识推广的生力军。本次学术代表的扩张，不仅可以进一步提升公司市场推广的终端覆盖率，为更多的医疗机构和患者提供更加优质全面的学术服务，让更多的基层患者知道和了解第三代胰岛素类似物产品，加速推进中国市场的第三代胰岛素类似物替换第二代人胰岛素的进程。

3. 加大海外宣发力度

近年来，公司持续拓展海外市场，加快全球化布局，借助海外市场打造新的利润增长点。截至本报告期末，公司胰岛素产品已在18个国家累计取得39份药品注册批件，在14个国家形成正式商业销售。

公司利用海内外媒体平台形成宣发矩阵，持续对外释放公司重要信息，不断提高信息透明度，并为海内外潜在客户了解本公司信息提供了新的渠道。通过公司全球官网向潜在国际合作伙伴推送公司最新的研发临床进展和新产品获批等信息。长期以来，公司与IDF(国际糖尿病联盟)共同开展了多个海外项目的合作，涵盖患者关怀、药物科普、国际学术交流会议等方面，并于2022年上半年，双方达成了战略合作伙伴关系，此次合作还将促进公司参与相关领域的活动宣传，例如世界糖尿病日以及发现胰岛素百年纪念活动，这将进一步提升公司品牌全球知名度和影响力。2022年6月，本公司参加了美国糖尿病协会(ADA)第82届科学年会，以展台的形式亮相，在世界糖尿病治疗领域提升了企业品牌知名度，为后期糖尿病相关产品在欧美市场上做出了积极有效的市场铺垫。

公司将持续发力海外品牌建设，拓宽海外市场销售渠道，推进公司产品的海外销售覆盖，让世界更多的糖尿病患者可以享受疗效更佳、可负担的胰岛素产品。

In terms of market promotion, the Company has accelerated and deepened the team building in the primary tier market to better use the price and resource advantages resulting from volume-based procurement. It will recruit nearly 1,000 professional academic representatives in the first half of 2022. The Company's academic promotion team, covering 31 provinces (autonomous regions and municipalities), is a new force for the Company's product knowledge promotion and diabetes academic knowledge promotion. The expansion of academic representatives can not only further improve the terminal coverage of the Company's marketing but also provide more high-quality and comprehensive academic services for more medical institutions and patients and let more primary patients know and understand the third-generation insulin analogs product to accelerate the process of replacing second-generation insulin with third-generation insulin in the Chinese market.

3. Increase overseas publicity efforts

In recent years, the Company has continued to expand overseas markets, accelerated its globalization, and created new profit growth points with the help of overseas markets. At the end of the reporting period, the Company's insulin products obtained 39 drug market approvals in 18 countries and established official commercial sales in 14 countries.

The Company uses domestic and overseas media platforms to form a publicity matrix, continuously releases important company information to the outside world, constantly improves information transparency, and provides new channels for potential customers at home and abroad to understand the Company's information. Published the Company's latest clinical progress and new product approvals news to potential international partners through the Company's official website. For a long time, the Company and International Diabetes Federation (IDF) have jointly carried out many overseas projects, covering patient care, drug science, international academic exchange conferences, etc. In the first half of 2022, the two parties reached a strategic partnership. The partnership will also facilitate the Company's participation in events in related areas, such as World Diabetes Day and the Centennial of the Discovery of Insulin, further enhancing the Company's global brand awareness and influence. In June 2022, the Company participated in the 82nd Scientific Annual Meeting of the American Diabetes Association (ADA) and appeared in the form of an exhibition booth, which enhanced the brand awareness of the Company in the field of diabetes treatment in the world, and made a positive and effective market foreshadowing to the late-stage diabetes-related products listed in the European and American markets.

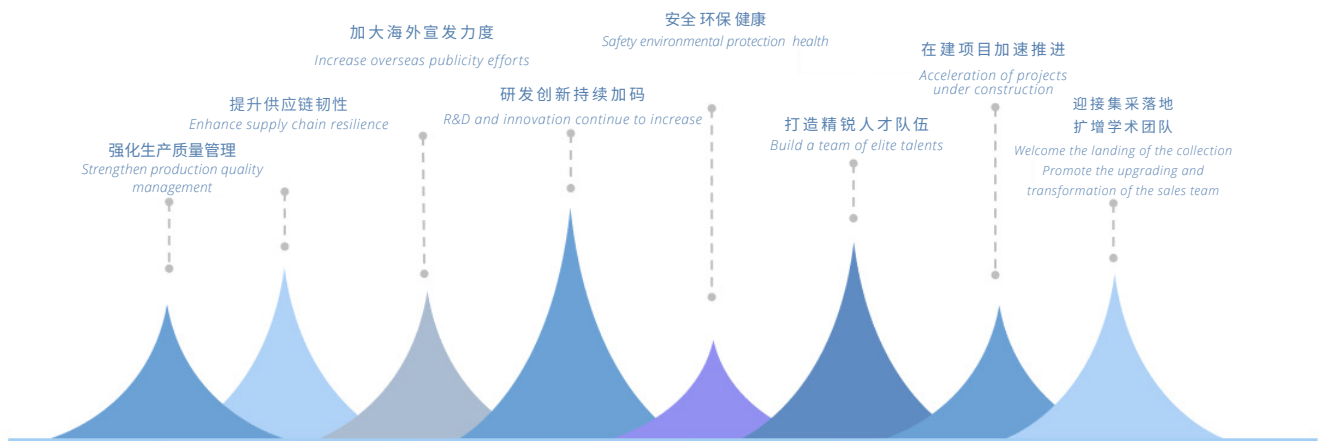
The Company will continue to build overseas brands, expand sales channels in overseas markets, and promote the overseas sales coverage of the Company's products so that more diabetic patients worldwide can enjoy better and more affordable insulin products.

4. 在建项目加速推进

本公司自成立以来利用自身竞争优势深耕于糖尿病治疗领域，积极致力于将创新的科学发现转化为高可及性的医疗保健解决方案。随着本公司胰岛素研发管线的逐渐完整，公司产品在中国大陆地区全部省(自治区、直辖市)的全覆盖，成为国内胰岛素类似物的领跑者。报告期内，本公司正在积极推进北京总部制剂车间及山东临沂生产基地的建设工作，以保障胰岛素产品在全球范围内的高质量及稳定的供应。截至报告期末，北京总部的新建制剂车间已完成全部的施工及设备相关工作。山东临沂生产基地作为公司部署全球商业化网络的重要一步，将依照健全的产品标准、工艺标准、质量标准打造最值得信赖的产品。山东临沂生产基地一期项目包含研发中心、生物药、器械、化药药房以及相关配套设施建设，报告期内，装修工程施工正在按照计划顺利推进，生产设备采购、安装调试有序进行中。

4. Acceleration of projects under construction

Taking advantage of its own competitive advantages, Gan & Lee has been deeply engaged in the field of diabetes treatment and is actively committed to transforming innovative scientific discoveries into highly accessible healthcare solutions. With the gradual completion of the Company's insulin research and development pipeline, the Company's products are fully covered in all provinces (autonomous regions and municipalities) in mainland China, becoming the leader in domestic insulin analogs. During the reporting period, the Company is actively promoting the construction of the preparation workshop at the Beijing headquarters and the production base in Linyi, Shandong, to ensure the high quality and stable supply of insulin products worldwide. At the end of the reporting period, all construction and equipment-related work of the newly built preparation workshop at the Beijing headquarters has been completed. As an essential step in the Company's deployment of a global commercial network, the Shandong Linyi production base will create the most reliable products in accordance with sound, process, and quality standards. The first-phase project of the Shandong Linyi production base includes the construction of an R&D center, biological medicine, equipment, chemical medicine workshop, and related supporting facilities. During the reporting period, the construction of the decoration project is progressing smoothly according to the plan, and the procurement, installation, and commissioning of production equipment are proceeding in an orderly manner.



5. 强化生产质量管理

“质量第一 永远创新”是本公司的企业宗旨，公司视产品和服务质量为生命，始终致力于为人类持续提供更高品质的药品和服务。本报告期，公司质量部充分运用风险管理工具，整合了质量管理架构和职责，优化了关键质量管理流程，进一步提升了质量管理效能，在提升产品品质的道路上精益求精。

6. 开展精益生产活动，提升供应链韧性

本报告期，为积极应对带量采购中选结果执行后产品销量的安全供应，公司积极采取各项产能保障措施。一方面，公司通过对每一个员工进行精益生产管理培训，对每一个生产环节进行再梳理、再审视、再升级，缩短环节转换效率，不断挖掘生产潜力，推行以精益生产为核心的高效制造，进一步提高了生产效率和产能利用率。另一方面，对内公司通过提高生产计划准确性，制定合理的安全库存水位、最高最低库存水位及再订购点，持续优化研供产销计划一体化联动体系，提升供应链韧性，降本增效的同时保障高效安全生产；对外持续落实供应商管理及合作战略，以应对国际形势复杂多变及全球疫情的冲击。

7. 继续践行安全、环保、健康长效机制

2022年为全国安全生产专项整治三年行动的收官之年，为深入贯彻落实习近平总书记作出的“从根本消除事故隐患”的重要指示精神，公司深入开展安全标准化建设工作，持续完善环境、职业健康安全管理体系，为企业的安全运营保驾护航。

公司通过开展安全标准化评审等工作，不断完善安全生产责任制和各项安全管理规章制度，使安全生产的各项工作都趋于制度化、规范化，

5. Strengthen production quality management

“Quality First, Forever Innovation” is the Company’s corporate tenet. Quality is deemed to be the life of the enterprise, and it is always committed to continuously providing higher quality medicines and services for human beings. During the reporting period, the Company’s quality department made full use of risk management tools, integrated the quality management structure and responsibilities, optimized the critical quality management process, further improved the quality management efficiency, and kept improving on the road to enhancing product quality.

6. Carry out lean production activities Enhance supply chain resilience

During the reporting period, to actively respond to the safe supply of product sales after the implementation of the election results of the procurement with quantity, the Company actively took various production capacity guarantee measures. On the one hand, by implementing lean production management training for each employee, the Company reorganizes, re-examines and re-upgrades each production link, shortening the link conversion efficiency and continuously tapping the production potential. On the other hand, the Company also promotes efficient manufacturing with lean production as its core, which further improves production efficiency and capacity utilization. On the other hand, by improving the accuracy of production plans within the Company, The company formulates reasonable safety stock levels, maximum and minimum stock levels, and reorder points to continuously optimize the linkage system of research, supply, production, and sales planning, improve supply chain resilience, reduce costs and increase efficiency while ensuring efficient and safe production. Externally, the Company continues to implement supplier management and cooperation strategies to cope with the complex and ever-changing international situation and the impact of the global epidemic.

7. Continue to practice safety Long-term mechanism for environmental protection and health

The year 2022 is the final year of the three-year action of the “National Work Safety Special Rectification” To thoroughly implement the spirit of the necessary instructions given by General Secretary Xi Jinping to “eliminate the hidden dangers of accidents from the root” the Company has carried out in-depth safety standardization construction, continued to improve the environmental and occupational health, and safety management system, and escorted the Company’s safe operation.

By carrying out safety standardization reviews and other work, the Company continuously optimizes the safety production responsibility system and various safety management rules and regulations so that the safety production work tends to

并把制度落实到每个环节、每个岗位、每位员工，实现全员、全过程、全方位的安全管理。公司持续完善职业健康管理体系建设，全面推进员工健康保障工作，落实危害因素检测、配备劳动防护用品等保障措施，公司在新建、改建、扩建工程中安全设施严格坚持“三同时”的原则(建设项目职业病防护设施必须与主体工程同时设计、同时施工、同时投入生产和使用)，对员工进行职业健康教育等,为员工提供安全、健康的工作环境。

公司持续落实了风险辨识评估和隐患排查治理工作，于2022年上半年共进行日常巡查180余次，专项检查10次，并严格追踪整改各项隐患，为公司员工营造了一个安全稳定的工作环境。为切实有效地开展安全生产工作，增强员工的安全防范意识，提高员工的安全操作技能，公司于2022年上半年开展了十余次安全培训，包括线上培训、线下培训、应急演练以及线下安全活动等，保障了安全培训的深入性、广泛性与趣味性，使员工真正的参与到培训中。

此外，为扎实做好新冠疫情防控常态化工作，公司主动配合政府做好轨迹排查、核酸检测、人员隔离等防控工作，并建立相应的规范化制度与流程；持续宣传引导全体员工弘扬抗疫精神，严格配合扫码、测温、戴口罩、打疫苗等防疫措施，保障疫情防控工作顺利开展。

8. 打造精锐人才队伍

公司始终坚持人才高地战略，将培养人才、激励人才作为驱动公司发展的核心手段。本报告期，为加强人才梯队建设，公司积极完善人才培养机制，推进各项人才培养计划，例如通过“高潜人才”、“继任者”、“菁英人才”等项目，选拔出目标层级储备人才，并为其定制培养方案，为各业务领域储备了一支兼备专业技术与管理能力的综合性人才队伍，确管理层的连续性，缩短职位空缺

be institutionalized and standardized. At the same time, the Company implements the system to every link, every position, and every employee and realizes all-staff, whole-process, and all-around safety management. The Company continues to improve the construction of the occupational health management system, comprehensively promotes the health protection of employees, and implements safeguard measures such as detecting hazardous factors and providing labor protection equipment. In the new construction, reconstruction, and expansion projects, the Company strictly adheres to the principle of “three simultaneous” (the occupational disease protection facilities of the construction project must be designed, constructed, put into production, and used at the same time with the main project), and carry out career development and health education for employees, etc., to provide employees with a safe and healthy working environment.

The Company continued implementing risk identification, assessment, and investigation of hidden danger and governance. As a result, in the first half of 2022, the Company conducted more than 180 daily patrol and ten specific inspections. It strictly tracked and rectified various hidden dangers, creating a safe and stable working environment for the Company’s employees. To effectively carry out safety production work, enhance employees’ safety awareness, and improve employees’ safety operation skills, the Company has carried out more than ten safety training in the first half of 2022, including online training, offline training, emergency drills, and online training, safety activities, etc., while ensuring the depth, breadth, and interest of safety training, make employees genuinely participate in the movement.

In addition, to do a solid job of normalizing the prevention and control of the new crown epidemic, the Company actively cooperated with the government to do an excellent job of trajectory investigation, nucleic acid testing, personnel isolation, and other prevention and control work, and established corresponding standardized systems and procedures; continued to carry out publicity to guide all employees to promote the spirit of anti-epidemic, and strictly cooperate with anti-epidemic measures such as code scanning, temperature measurement, wearing masks, and vaccination to ensure the smooth development of epidemic prevention and control.

8. Build a team of elite talents

The Company always adheres to the “talent highland” strategy and takes training and motivating talents as the core means to drive the Company’s development. During the reporting period, to strengthen the construction of the talent echelon, the Company actively improved the talent training mechanism and promoted various talent training plans. Talents, and customized training programs for them, reserve a comprehensive talent team with both professional technology and management capabilities for various business fields, ensure the continuity of management, shorten the cycle of job vacancies, maintain the healthy development of the organization, and help the Company.

的周期，保持组织的健康发展，对公司战略实现和业务增长提供了重要保证。为最大程度激励人才以结果为导向，在实现自我目标的同时为公司创造价值，并充分培养人才的主人翁意识与凝聚力，公司持续优化绩效与薪酬管理体系，通过明确公司倡导的行为价值观并纳入考核，设置绩效考核、项目考核与项目激励制度，将高度匹配企业文化且高绩效员工进行识别，并予以激励。

本报告期内，公司正式成立企业科协，并邀请行业内相关领域的顶尖研究者举办学术论坛，为研发人才创造了浓厚的科研氛围与提升机会。

公司聚集着一群逐梦全球、有着伟大愿景的青年，将持续打造、壮大一支既有业务技术造诣，又有管理前瞻力的精锐人才队伍。公司倾力为他们提供更好的平台与条件，予以鼓励与尊重，最终实现为疾病解码，为健康加持，创造无限可能。

报告期内公司经营情况的重大变化，以及报告期内发生的对公司经营情况有重大影响和预计未来会有重大影响的事项

适用 不适用

Strategic realization and business growth provide important assurances. To motivate talents to be result-oriented to the greatest extent, create value for the Company while realizing their own goals, and fully cultivate the sense of ownership and cohesion of talents, the Company continues to optimize the performance and compensation management system. , Set up performance appraisal, project appraisal, and project incentive systems to identify and motivate high-performance employees that highly match the corporate culture.

During the reporting period, the Company formally established the Enterprise Science and Technology Association and invited top Key Opinion Leaders (KOLs) in the industry to hold academic forums, thus creating a robust scientific research atmosphere and opportunities for R&D talents.

The Company has gathered a group of young people who are dreaming around the world and have grand visions, and will continue to build and strengthen a team of elite talents with both business and technical attainments and management foresight. The Company strives to provide them with better platforms and conditions, encourage and respect them, and finally realize the decoding of diseases, the blessing of health, and the creation of infinite possibilities.

Significant changes in the Company's operating conditions during the reporting period, as well as events occurring during the reporting period that have a significant impact on the Company's operating conditions and items that are expected to have a significant impact in the future

Applicable Not Applicable



建立健全安全生产责任制和各项管理制度
Establish and improve production safety responsibility system and management system



开展线上及线下安全培训活动
Carried out online & offline safety training activities



组织开展各类安全检查
Carried out various safety inspections



组织开展应急救援演练
Organize emergency rescue drills

四、报告期内主要经营情况

IV Major operations during the reporting period

(一) 主营业务分析

(I) Analysis of principal business

1. 财务报表相关科目变动分析表

1. Table of movement analysis on the related items in financial statement

单位：元 币种：人民币
In RMB

科目	Item	本期数 Current period	上年同期数 Corresponding period of last year	变动比例 (%) Change (%)
营业收入	Operating income	834,799,215.95	1,475,429,759.92	-43.42
营业成本	Operating costs	152,985,808.84	171,918,319.11	-11.01
销售费用	Selling expenses	564,861,191.77	491,640,000.50	14.89
管理费用	General and administrative expenses	117,613,719.39	152,936,730.76	-23.10
财务费用	Financial expenses	-47,472,455.59	-10,375,959.96	不适用 Not applicable
研发费用	R&D expenses	244,429,009.16	223,236,010.38	9.49
经营活动产生的现金流量净额	Net cash flow from operating activities	281,247,985.16	445,995,750.73	-36.94
投资活动产生的现金流量净额	Net cash flow from investing activities	-422,475,293.43	-144,773,951.69	不适用 Not applicable
筹资活动产生的现金流量净额	Net cash flow from financing activities	-163,098,645.02	-154,258,102.28	不适用 Not applicable

营业收入变动原因说明：本报告期营业收入较上年同期减少6.41亿元，同比减少43.42%，变动原因详见“第二节 公司简介和主要财务指标/七、公司主要会计数据和财务指标/(二) 主要财务指标”

The reason for the change of operating income: The operating income for the reporting period decreased by RMB 641 million, 43.42% decreased year-on-year. For details of the reasons for the changes, please refer to “Section 2 Company Profile and Main Financial Indicators/VII. Main Accounting Data and Financial Indicators of the Company/(2) Main Financial Indicators” .

营业成本变动原因说明：本报告期营业成本较上年同期减少0.19亿元，同比减少11.01%，主要系毛利率相对较低的医疗器械及原料药产品本报告期销量下降所致；

The reason for the change of operating cost: the operating costs for the reporting period decreased by RMB 19 million, 11.01% decreased year-on-year, mainly due to the decrease in sales volume of medical devices and API products with relatively low gross margins for the reporting period.

销售费用变动原因说明：本报告期销售费用较上年同期增加0.73亿元，同比增长14.89%，主要系本报告期市场推广费增长所致；

The reason for the change of selling expenses: the selling expenses for the reporting period increased by RMB 73 million, 14.89% increased year-on-year, mainly due to the increase in marketing expenses for the reporting period.

管理费用变动原因说明：本报告期管理费用较上年同期减少0.35亿元，同比减少23.10%，主要系本报告期管理人员薪酬减少所致；

The reason for the change of management expenses: the management expenses for the reporting period decreased by RMB 35 million, 23.10% decreased year-on-year, mainly due to the decrease in compensation of management employees during the reporting period.

财务费用变动原因说明：本报告期财务费用较上年同期减少0.37亿元，主要系本报告期利息收入增加所致；

The reason for the change in financial expenses: financial expenses decreased by RMB 37 million in this reporting period compared with the same period of the previous year, mainly due to the increase in interest income in this reporting period.

研发费用变动原因说明：本报告期研发费用较上年同期增加0.21亿元，同比增长9.49%，主要系本报告期为满足持续增长的研发创新需求，加大研发人才的储备与培育力度、增加实验研究费所致；

The reason for the change of R&D expenditure: R&D expenses for the reporting period increased by RMB 21 million, 9.49% increased year-on-year, mainly due to the increase in the reserving and training of R&D talents and the increase in experimental research expenses to meet the continuously growing demand for R&D and innovation in the reporting period.

经营活动产生的现金流量净额变动原因说明：本报告期经营活动现金流量净额较上年同期减少1.65亿元，同比减少36.94%，主要系本报告期销售商品、提供劳务收到的现金减少所致；

The reason for the change of net cash flow from operating activities: the net cash flow of operating activities for the reporting period decreased by RMB 165 million, 36.94% decreased year-on-year, mainly due to the decrease in cash received from sales of goods and services in the reporting period.

投资活动产生的现金流量净额变动原因说明：本报告期投资活动现金流量净额较上年同期减少2.78亿元，主要系上年同期理财产品投资净流入较多且本报告期购建长期资产支付的现金流出增加所致；

The reason for the change in the net cash flow from investment activities: the net cash flow from investment activities decreased by RMB 278 million during this reporting period compared with the same period of the previous year, mainly due to the higher net inflow of investment in financial products in the same period of the previous year and the increase of cash outflow paid for the purchase and construction of long-term assets in this reporting period.

筹资活动产生的现金流量净额变动原因说明：本报告期和上年同期发生的筹资活动现金流量净额系实际已分派现金股利，较上年同期增加884.05万元。

The reason for the change in the net cash flow from fund-raising activities: the net cash flow from financing activities incurred during the reporting period and the same period of the previous year represents the actual cash dividends distributed, which increased by RMB 8.84 million compared with the same period of the previous year.

2. 本期公司业务类型、利润构成或利润来源发生重大变动的详细说明

适用 不适用

2. Detailed explanation on significant changes in the Company business types, components of profit or sources of profit of the Company

Applicable Not Applicable

(二) 非主营业务导致利润重大变化的说明

适用 不适用

(II) Explanations on the major changes in profits caused by non-principle businesses

Applicable Not Applicable

(三) 资产、负债情况分析

(III) Asset and liability analysis

√适用 □不适用

√ Applicable □ Not Applicable

1. 资产及负债状况

1. Assets and liabilities

单位：元 币种：人民币
In RMB

项目名称 Item	本期期末数 Amount as at the end of the period	本期期末数占 总资产的比例 (%) Percentage of amount at the end of the period over total assets (%)	上期期末数 Closing amount of last period	上期期末数占资 产的比例 (%) The ratio of the closing amount of the previous period to the total assets	本期期末金额较上 期期末变动比例 (%) Proportion of changes in the amount at the end of the current period compared with the end of the previous period (%)	情况说明 Condition instruction
应收账款 Net accounts receivable	272,619,257.86	2.62	933,817,309.12	8.60	-70.81	主要系报告期内应收账款期后回款良好和营业收入下降所致。 Mainly due to the good post-period recovery of accounts receivable and the decrease in operating income during the reporting period.
应收款项融 资 Net financing receivables	5,156,964.66	0.05	845,608.13	0.01	509.85	主要系报告期末未贴现或背书转让的银行承兑票据增加所致。 Mainly due to the increase in undiscounted or endorsed transfers of bank acceptance notes at the end of the reporting period.
其他应收款 Other accounts receivable	57,840,168.87	0.56	6,487,728.39	0.06	791.53	主要系报告期末已宣告发放未收到的现金股利增加所致。 Mainly due to the increase in cash dividends declared and not received at the end of the reporting period.
其他流动资 产 Other current assets	22,347,836.78	0.21	9,513,506.37	0.09	134.91	主要系报告期末预缴企业所得税增加所致。 Mainly due to the increase in prepayment of corporate income tax at the end of the reporting period.
债权投资 Debt investments			201,358,630.13	1.86	-100.00	主要系报告期末将一年内到期的大额存单重分类至一年内到期的非流动资产所致。 Mainly due to the reclassification of large certificates of deposit due within one year to non-current assets due within one year at the end of the reporting period.
在建工程 Construction in progress	1,155,974,589.96	11.10	874,912,702.42	8.06	32.12	主要系本报告期公司在建项目持续投入所致。 Mainly due to the continuous investment of the Company's projects under construction during the reporting period.

单位：元 币种：人民币
In RMB

项目名称	Item	本期末末数 Amount as at the end of the period	本期末末数 占总资产的 比例 (%) Percentage of amount at the end of the period over total assets (%)	上期期末数 Closing amount of last period	上期期末数 占总资产的 比例 (%) The ratio of the closing amount of the previous period to the total assets	本期末末金额较上期 末变动比例 (%) Proportion of changes in the amount at the end of the current period compared with the end of the previous period (%)	情况说明 Condition instruction
递延所得税 资产	Deferred tax assets	41,208,669.57	0.40	30,802,314.01	0.28	33.78	主要系对本报告期新发生的交易性金融资产公允价值变动、收到政府补助款确认了递延所得税资产所致。
其他非流动 资产	Other non- current assets	386,602,129.95	3.71	240,326,171.28	2.21	60.87	Mainly due to the confirmation of deferred tax assets for the new fair value changes of trading financial assets, deductible losses of subsidiaries, and government subsidies received during the reporting period.
应付账款	Accounts payable	50,291,610.77	0.48	37,740,865.36	0.35	33.26	主要系本报告期末预付设备款增加所致。 Mainly due to the increase in prepayments for equipment at the end of the reporting period.
应交税费	Taxes payable	17,834,233.19	0.17	129,688,497.93	1.19	-86.25	主要系本报告期末应付原辅料款增加所致。 Mainly due to the increase in the amount of raw materials payable at the end of the reporting period.
							主要系本报告期末应交企业所得税减少所致。 Mainly due to the reduction of income tax payable at the end of the reporting period.

其他说明	Other explanations
无	N/A
2. 境外资产情况	2. Foreign Assets
√适用 □不适用	√ Applicable □ Not Applicable
(1) 资产规模	(1) Asset size
其中：境外资产61,043,503.25(单位：元 币种：人民币)，占总资产的比例为0.59%。	Of which: Foreign assets 61,043,503.25 (Unit: Yuan Currency: RMB), accounting for 0.59% of the total assets.
(2) 境外资产占比较高的相关说明	(2) Relevant explanations for the relatively high proportion of overseas assets
□适用 √不适用	□ Applicable √ Not Applicable
3. 截至报告期末主要资产受限情况	3. Restrictions on major assets as of the end of reporting period
√适用 □不适用	√ Applicable □ Not Applicable
详见“第十节 财务报告/七、合并财务报表项目注释/81. 所有权或使用权受到限制的资产”。	For details, see “Section X Financial Reports/VII Item Notes to consolidated Financial Statements /81. Assets with limited ownership or use rights”.
4. 其他说明	4. Other explanations
□适用 √不适用	□ Applicable √ Not Applicable
(四) 投资状况分析	(IV) Analysis of investment
1. 对外股权投资总体分析	I. Overall analysis on external equity investment
□适用 √不适用	□ Applicable √ Not Applicable
(1) 重大的股权投资	(1) Significant equity investment
□适用 √不适用	□ Applicable √ Not Applicable
(2) 重大的非股权投资	(2) Significant non-equity investment
□适用 √不适用	□ Applicable √ Not Applicable
(3) 以公允价值计量的金融资产	(3) Financial assets measured at fair value
√适用 □不适用	√ Applicable □ Not Applicable

单位：元 币种：人民币
In RMB

项目	Project	期末余额 Closing balance	期初余额 Opening balance
交易性金融资产	Financial assets held for trading	1,466,002,832.74	1,624,183,495.26
应收款项融资	Financing receivables	5,156,964.66	845,608.13
其他非流动金融资产	Other non-current financial assets	30,000,000.00	30,000,000.00
合计	Total	1,501,159,797.40	1,655,029,103.39

(五) 重大资产和股权出售 适用 不适用**(六) 主要控股参股公司分析** 适用 不适用**(七) 公司控制的结构化主体情况** 适用 不适用**(V) Sale of major assets and equity** Applicable Not Applicable**(VI) Analysis of major holding companies** Applicable Not Applicable**(VII) Situation of structured entities controlled by the Company** Applicable Not Applicable**五、其他披露事项****(一) 可能面对的风险** 适用 不适用**1. 行业政策风险**

医药产业是我国重点发展的行业之一，医药产品是关系人民生命健康和安全的特殊消费品，同时医药产业又是一个受监管程度较高的行业。目前我国处于经济结构调整期，各项改革正在逐步深入。随着我国医疗卫生体制改革的不断深入和社会医疗保障体制的逐步完善，我国医疗卫生市场的政策环境可能面临重大变化，行业相关的监管政策仍在不断完善、调整。

V Other Disclosures**(I) Possible risks** Applicable Not Applicable**1. Industry policy risk**

The pharmaceutical industry is one of the key industries the government put great emphasis on in China. Pharmaceutical products are special consumer products related to people's health and safety, while the industry is under relatively stricter supervision than others. At present, China is in a period of economic restructuring, and reforms are gradually deepening. With the continuous reform of China's health care system and the gradual improvement of the social, medical security system, the policy environment of the healthcare market in China may face significant changes. The related regulatory policies are still being improved and adjusted.

截至目前，国家组织的胰岛素专项带量采购已在各省（自治区、直辖市）陆续落地执行。在此次胰岛素专项带量采购中，大幅降价使得生产企业的收入规模及盈利水平降低，同时国内胰岛素药物市场的格局也可能发生改变。

应对措施：公司将积极响应国家政策，及时调整自身的经营策略，适应因政策性风险带来的外部环境变化，例如：(1) 加大研发投入，丰富产品管线；(2) 加强成本和质量管控，降本增效，以应对2021年胰岛素专项集采结果实施后药品价格下行趋势；(3) 强化营销创新，利用集采政策红利，积极开拓国内市场，提高企业产品竞争力，提升市场份额；(4) 加快产品通过欧美国家认证，开拓公司新的利润增长点。

2. 收入结构单一风险

公司依靠自有核心技术和研发力量，专注于糖尿病治疗领域，公司营业收入主要来自胰岛素制剂及胰岛素干粉的销售收入。专注于糖尿病治疗领域使得公司具有显著的产品技术优势，但也使得公司面临收入结构单一的风险。一旦由于替代产品的出现导致市场对胰岛素制剂的需求大幅减少，或者由于竞争对手类似产品或新一代产品的推出导致公司现有主要产品竞争优势丧失，或者由于发生医疗责任事故，导致公司主要产品销售受限，都将对公司的经营业绩产生重大不利影响，可能导致公司业绩大幅波动。此外，糖尿病海外市场规模不容小觑，而公司营业收入主要来源国内销售收入，国际销售收入占营业收入比重较小，这不利于企业做大做强。

应对措施：在国内市场上，公司通过加强研发创新能力，在推动胰岛素类似物系列产品研发的同时，针对糖尿病的形成机理和药物作用机理

Up to now, the national volume-based procurement of insulin has been implemented in various provinces (autonomous regions and municipalities directly under the central government) one after another, during which the substantial price reduction reduces the profitability of the manufacturers and the scale of income, and the pattern of the domestic insulin market may also change.

Countermeasures: The Company is actively responding to the national policy and will timely adjust its business strategy to adapt to the changes in the external environment caused by the policy risk, such as (1) increase R&D investment and diversify product lines; (2) Strengthen cost and quality management, reduce costs and increase efficiency, in order to cope with the downward trend of drug prices after the implementation of the centralized procurement of insulin in 2021; (3) strengthen marketing innovation, make use of the advantages of the centralized procurement policy, further expand the domestic market, and increase the market share; (4) Speed up the certification of products in Europe and the United States and create new growth areas for profits.

2. Risk of single leading product structure

The Company relies on its core technology and R&D strength to focus on the diabetes treatment field. The Company's operating income mainly comes from the sales of insulin injections and insulin API. Concentrate on the diabetes treatment field gives the Company a significant product technology advantage and exposes the Company to the risk of a single leading product structure. If the market demand for insulin injections decrease significantly due to the emergence of substitute products, or if the Company loses the competitive advantage of its existing main products due to the launch of similar products or new generation products by competitors, or if the sales of its main products are restricted due to medical accidents, it will have a significant adverse impact on the Company's operating results. It may lead to substantial fluctuations in the Company's performance. Moreover, the scale of the overseas market for diabetes is not to be underestimated, while the Company's operating income mainly comes from domestic sales revenue, and the proportion of international sales revenue to operating income is small, which is not conducive to the enterprise's expansion and strengthening.

Countermeasures: By strengthening the R&D and innovation capabilities, the Company conducts research on the formation mechanism of diabetes and the mechanism of drug action while promoting the research and development of insulin

进行研究。因此，公司不仅在餐时、基础、预混胰岛素类似物三大赛道形成了产品全覆盖，更有新型降糖生物药及超长效胰岛素等进展迅速的在研产品，此外公司首个自主研发的口服降糖药磷酸西格列汀片产品已于近期获批上市。在国外市场上，公司积极推进公司产品在海外市场的临床试验进程和注册批件的取得，同时持续拓展海外市场，加强与海外客户的交流与合作，为国际业务拓展积累资源，借助海外市场打造新的利润增长点。

与此同时，公司提升了研发平台和产学研一体化的建设水平，布局了肿瘤、自身免疫疾病等多个领域的治疗药物，从而丰富了公司的产品结构，进而优化公司的收入构成，以确保公司未来盈利能力的持续性和稳定性。

3. 新品研发风险

由于医药产品具有高科技、高风险、高附加值的特点，新药开发的前期研发以及产品从研制、临床试验报批到投产的周期长、环节多，容易受到一些不可预测因素的影响，存在新产品开发和审批风险。根据《药品注册管理办法》等法规的相关规定，新药注册一般需经过临床前基础工作、新药临床研究审批、新药生产审批等阶段，如果最终未能通过新药注册审批，则可能导致新药研发失败，进而影响到本公司效益的实现。此外，如果公司开发的新药不能适应不断变化的市场需求，将对公司的盈利水平和未来发展产生不利影响。

应对措施：(1) 公司一方面结合当前的国内临床需求，在国际新药产品的基础上，开发药效和安全性相似的Me Too新药或更好的Me Better新药；一方面利用公司的研发平台优势，逐步尝试一类新药的研发。(2) 对研发项目前期(例如赛道选择、研发周期、

analog series products. Therefore, our company has not only formed a full coverage of products in the three major tracks of mealtime, basal, and premixed insulin analogs, but also has rapidly developed products under development such as new hypoglycemic biological drugs and ultra-long-acting insulin. In addition, the Company's first independently developed oral hypoglycemic drug sitagliptin phosphate tablets has been approved to market recently. In the foreign market, the Company actively promotes the clinical trial process and registration approval of the Company's products in overseas markets, and at the same time continues to expand overseas markets, strengthen exchanges and cooperation with overseas customers, accumulate resources for international business development, and create new profit growth points with the help of overseas markets.

At the same time, the Company has improved the construction level of the R&D platform and the integration of production, education and research, and has deployed therapeutic drugs in various fields such as tumors, autoimmune diseases, and blood diseases, thus enriching the Company's product structure and optimize the Company's revenue composition to ensure the sustainability and stability of the Company's future profitability.

3. New product R&D risks

Due to the high-tech, high-risk, and high value-added characteristics of pharmaceutical products, the pre-development of new drug development, as well as the long cycle and many links from development, clinical trial submission, and production approval, are susceptible to the impact of some unpredictable factors, and there are new product development and approval risks. According to the relevant provisions of the "Drug Registration Administration" and other regulations, the registration of new drugs generally requires pre-clinical basic work, approval of new drug clinical studies, approval of new drug manufacturing, etc. If the new drug registration is ultimately not approved, it may lead to the failure of new drug development, which may affect the realization of the Company's benefits. In addition, if the new drugs developed by the Company cannot adapt to the changing market demand, it will harm the Company's profit level and future development.

Countermeasures : (1) On the one hand, based on the current domestic clinical demand and international new drug products, the Company will develop Me Too or Me Better drugs with similar efficacy and safety; On the other hand, the Company takes advantage of the existing R&D platform to gradually try to develop a class of new drugs. (2) The Company conducts technology assessment and risk control at the early stage of

费用等投入和经济效益产出评估、行业政策趋势对新药收益的影响、新药使用技术的迭代情况等)和关键节点进行技术评估和风险管控,降低研发风险。(3)公司积极寻找契合未来发展战略的优质资源,与具有互补性的、具有一定盈利能力的、具有前沿技术优势的生物药研发创新企业进行合作,进而增强企业研发能力,扩充产品管线,持续提高企业核心竞争力。(4)评估研发各环节的投入产出比,将低附加值的研发环节进行外包,并做相应的组织架构调整,以加快新药上市进程。

4. 新品替代风险

经济发展的过程,既是一个产业结构不断转换的过程,也是新产品不断取代老产品,新服务不断取代旧服务的过程。随着全球科技发展的不断加快,各国药品研发能力的不断上涨,各企业对新品研发的重视程度的不断提高,可能存在新品替代的风险。

应对措施:公司一直关注糖尿病以及相关领域的先进研发项目进展,积极跻身于高精尖研发产品的研发项目中,开拓与国内知名高校的产学研合作,积极拓展与全球跨国知名企业的合作模式和范围,丰富研发产品管线,保持并提高公司研发能力,为成为国际一流医药企业而砥砺前行。

(二) 其他披露事项

适用 不适用

R&D projects (such as track selection, R&D cycle, cost and other inputs and economic benefit output evaluation, the impact of industry policy trends on the revenue of new drugs, the iteration of new drug application technology, etc.) and key nodes to reduce R&D risks. (3) The Company actively seeks for high-quality resources that fit its future development strategy, and cooperations with complementary, profitable and cutting-edge pharmaceutical enterprises, so as to enhance its research and development capabilities, expand product pipelines and continuously improve its core competitiveness. (4) The Company evaluates the input-output ratio of all R&D links, outsources the R&D links with low added value, and adjusts the corresponding organizational structure to speed up the listing process of new drugs.

4. New product substitution risks

The process of economic development is not only a process of continuous transformation of industrial structure, but also the process of new products constantly replacing old products and new services constantly replacing old services. With the accelerating development of global science and technology, there may be a risk of new product substitution by the rising capacity of pharmaceutical research and development in various countries and the constant attention to new product development of various enterprises.

Countermeasures: The Company has been paying attention to the progress of advanced R&D projects in diabetes and related fields, actively participating in the R&D projects of high precision R&D products, exploring the cooperation with famous domestic universities, actively expanding the cooperation mode and scope with famous global multinational enterprises, enriching the R&D product pipeline, maintaining and improving the Company's R&D capability, and forging ahead to become an international first-class pharmaceutical enterprise.

(II) Other disclosures

Applicable Not Applicable

公司治理

CORPORATE GOVERNANCE



第四节 公司治理

SECTION IV CORPORATE GOVERNANCE

一、股东大会情况简介

I Briefing on the shareholders' meeting

会议届次	Meeting	2021年年度股东大会 2021 Annual General Meeting
召开日期	Date	2022年5月19日 May 19, 2022
决议刊登的指定网站的查询索引	Index for details of websites designated for publishing	www.sse.com.cn
决议刊登的披露日期	Date of disclosure	2022年5月20日 May 20, 2022
会议决议	Conference Resolutions	《关于<公司董事会2021年度工作报告>的议案》《关于<公司监事会2021年度工作报告>的议案》《关于公司<2021年年度报告>及摘要的议案》《关于<公司2021年度决算方案>的议案》《关于公司2021年度利润分配方案的议案》《关于公司2022年度董事薪酬方案的议案》《关于公司2022年度监事薪酬方案的议案》《关于续聘公司2022年度会计师事务所及决定其报酬的议案》《关于修订<公司章程>的议案》《关于选举公司第四届董事会非独立董事的议案》《关于选举公司第四届董事会独立董事的议案》《关于选举公司第四届监事会股东代表监事的议案》 “Proposal on the 2021 annual work report of the board of directors of the Company”, “Proposal on the 2021 annual work report of the board of supervisors of the Company”, “Proposal on the 2021 annual report and summary of the Company”, “Proposal on the 2021 annual final account plan of the Company”, “Proposal on the 2021 annual profit distribution plan of the Company”, “Proposal on the 2022 annual director's compensation plan of the Company”, “Proposal on the 2022 annual supervisor's compensation plan of the Company”, “Proposal on renewing the employment of the Company's accounting firm in 2022 and determining its remuneration”, “Proposal on Amending the articles of association”, “Proposal on electing non independent directors of the Fourth Board of directors of the Company”, “Proposal on electing independent directors of the Fourth Board of directors of the Company”, “Proposal on electing shareholder representative supervisors of the Fourth Board of supervisors of the Company”

表决权恢复的优先股股东请求召开临时股东大会

适用 不适用

股东大会情况说明

适用 不适用

Preferred stockholders whose voting rights have been restored request an extraordinary general meeting

Applicable Not Applicable

Explanation of Shareholders' general meeting

Applicable Not Applicable

二、公司董事、监事、高级管理人员变动情况 II Changes in directors, supervisors and senior management of the Company

√适用 □不适用

√ Applicable □ Not Applicable

姓名 Name	担任的职务 Position held	变动情形 Changes
孙彦 Sun Yan	独立董事 Independent Director	离任 Resign
昌增益 Chang ZengYi	独立董事 Independent Director	选举 Election
何艳青 He Yanqing	独立董事 Independent Director	选举 Election
郑国钧 Zheng Guojun	独立董事 Independent Director	选举 Election
陈伟 Chen Wei	董事 Director	选举 Election
尹磊 Yin Lei	董事 Director	选举 Election
焦娇 Jiao Jiao	董事 Director	选举 Election
宋维强 Song Weiqiang	董事 Director	选举 Election
甘忠如 Gan Zhongru	董事长 Chairman of the Board	选举 Election
张涛 Zhang Tao	监事会主席 Chairman of the Supervisory Board	选举 Election
王毅 Wang Yi	监事 Supervisors	选举 Election
王嘉鑫 Jiixin Wang	职工代表监事 Employee Representative Supervisor	选举 Election
都凯 Du Kai	总经理 General Manager	聘任 Hiring
都凯 Du Kai	董事 Director	选举 Election
宋维强 Song Weiqiang	副总经理 Vice President	聘任 Hiring
邢程 Xing Cheng	副总经理 Vice President	聘任 Hiring
苑宇飞 Yuan Zifei	副总经理 Vice President	聘任 Hiring
孙程 Sun Cheng	副总经理、财务负责人 Vice President Finance Director	聘任 Hiring
邹蓉 Zou Rong	董事会秘书 Board Secretary	聘任 Hiring
王斌 Wang Bin	副总经理 Vice President	离任 Resign

公司董事、监事、高级管理人员变动的情况说明

Description of changes in directors, supervisors and senior management of the Company

√适用 □不适用

√ Applicable □ Not Applicable

2022年5月19日，2021年年度股东大会审议通过《关于选举公司第四届董事会非独立董事的议案》《关于选举公司第四届董事会独立董事的议案》《关于选举公司第四届监事会股东代表监事的议案》，同意选举甘忠如先生、都凯先生、宋维强先生、焦娇女士、尹磊先生、陈伟先生担任公司非独立董事；同意选举昌增益先生、郑国钧先生、何艳青女士担任公司独立董事；同意选举张涛先生、王毅先生担任公司监事，与职工代表监事王嘉鑫女士一起组成公司新一届监事会。任期自股东大会选举通过之日起至本届董事会任期届满。详见公告：2022-021。

On May 19, 2022, the 2021 Annual General Meeting of Shareholders deliberated and passed the "Proposal on the Election of Non-independent Directors of the Fourth Meeting of the Board of Directors of the Company", "the Proposal on the Election of Independent Directors of the Fourth Meeting of the Board of Directors of the Company", and "the Proposal on the Election of Shareholder Representative Supervisors of the Fourth Meeting of the Supervisory Committee of the Company", agreeing to elect Mr. Gan Zhongru, Mr. Du Kai, Mr. Song Weiqiang, Ms. Jiao Jiao, Mr. Yin Lei and Mr. Chen Wei as non-independent directors of the Company; agreed to elect Mr. Chang Zengyi, Mr. Zheng Guojun and Ms. He Yanqing as independent directors of the Company; agreed to elect Mr. Zhang Tao and Mr. Wang Yi as supervisors of the Company. The new board of supervisors of the company was formed together with Ms. Wang Jiabin, the employee representative supervisor. The term of office is from the date of election by the general meeting of shareholders to the expiration of the term of office of the current board of directors. For details, please refer to the announcement: 2022-021.

2022年5月22日，甘李药业股份有限公司第四届董事会第一次会议审议通过了《关于公司选举董事长的议案》《关于聘任总经理的议案》《关于聘任除总经理外其他高级管理人员的议案》，同意选举甘忠如先生为公司董事长；同意聘任都凯先生担任公司总经理；同意聘任宋维强先生、邢程女士、苑宇飞女士担任公司副总经理，孙程先生担任公司副总经理兼财务负责人，邹蓉女士担任公司董事会秘书。任期与公司第四届董事会一致。详见公告：2022-023。

On May 22, 2022, the First Meeting of the Fourth Session of the Board of Directors of Gan & Lee Pharmaceuticals. considered and passed "The Proposal on the Election of the Chairman of the Company", "The Proposal on the Appointment of the General Manager", and "The Proposal on the Appointment of Senior Management Other than the General Manager", agreeing to elect Mr. Gan Zhongru as the Chairman of the Company; agreed to appoint Mr. Du Kai as the General Manager of the Company; agreed to appoint Mr. Song Weiqiang, Ms. Xing Cheng and Ms. Yuan Zifei as the vice managers of the Company, Mr. Sun Cheng as the vice manager and financial director of the Company, and Ms. Zou Rong as the secretary of the Board of Directors of the Company. The term of office is consistent with the fourth meeting of the Board of Directors of the Company. For details, please refer to the announcement: 2022-023.

2022年5月22日，甘李药业股份有限公司第四届监事会第一次会议审议通过了《关于选举监事会主席的议案》，同意选举张涛先生为公司第四届监事会主席，任期与公司第四届监事会一致。详见公告：2022-024。

On May 22, 2022, the First Meeting of the Fourth Meeting of the Supervisory Committee of Gan & Lee Pharmaceuticals. deliberated and passed "The Proposal on the Election of the Chairman of the Supervisory Committee" and agreed to elect Mr. Zhang Tao as the Chairman of the Fourth Supervisory Committee of the Company for the same term as the Fourth Supervisory Committee of the Company. For details, please refer to the announcement: 2022-024.

三、利润分配或资本公积金转增预案

III Profit distribution or capital reserve conversion plan

半年度拟定的利润分配预案、公积金转增股本预案

Semi-annual profit distribution plan and plan for converting accumulation fund into share capital

是否分配或转增

Whether to allocate or increase

否
No

四、公司股权激励计划、员工持股计划或其他员工激励措施的情况及其影响	IV The Company's share option incentive plan employee shareholding scheme or other employee incentive measures and its influence
(一) 相关股权激励事项已在临时公告披露且后续实施无进展或变化的	(I) Relevant incentive matters have been disclosed in the temporary announcement and subsequent progress or change
<input type="checkbox"/> 适用 <input checked="" type="checkbox"/> 不适用	<input type="checkbox"/> Applicable <input checked="" type="checkbox"/> Not Applicable
(二) 临时公告未披露或有后续进展的激励情况	(II) Share incentives not disclosed in temporary announcements or with subsequent progress
股权激励情况	Equity incentives
<input type="checkbox"/> 适用 <input checked="" type="checkbox"/> 不适用	<input type="checkbox"/> Applicable <input checked="" type="checkbox"/> Not Applicable
其他说明	Other Notes
<input type="checkbox"/> 适用 <input checked="" type="checkbox"/> 不适用	<input type="checkbox"/> Applicable <input checked="" type="checkbox"/> Not Applicable
员工持股计划情况	Employee stock ownership plan
<input type="checkbox"/> 适用 <input checked="" type="checkbox"/> 不适用	<input type="checkbox"/> Applicable <input checked="" type="checkbox"/> Not Applicable
其他激励措施	Other Incentives
<input type="checkbox"/> 适用 <input checked="" type="checkbox"/> 不适用	<input type="checkbox"/> Applicable <input checked="" type="checkbox"/> Not Applicable

环境与社会责任

ENVIRONMENTAL AND SOCIAL RESPONSIBILITY



第五节 环境与社会责任

SECTION V ENVIRONMENTAL AND SOCIAL RESPONSIBILITY

一、环境信息情况

(一) 属于环境保护部门公布的重点排污单位的公司及其主要子公司的环保情况说明

适用 不适用

报告期内，公司持续贯彻落实绿色发展理念，大力推进生态文明建设，强化综合治理措施，落实目标责任，推进清洁生产，扩大绿色植被，努力打造绿色药企，提升企业可持续发展竞争力。报告期内，甘李药业股份有限公司属于环境保护部门公布的重点排污单位。

1. 排污信息

适用 不适用

- a 主要污染物及特征污染物：化学需氧量、氨氮、总磷、氮氧化物。
- b 排放方式：废水经北京总部厂区污水处理站处理至接管标准后，进入潮县镇污水处理厂集中处理。
废气经废气污染防治设施处理后，经15米及以上高度排气筒排放。
- c 排放口数量和分布情况：全厂设污水排放口1个，位于北京总部厂区西厂界。
全厂设废气排放口11个，位于北京总部厂内。
- d 主要污染物及特征污染物排放浓度和总量：
化学需氧量排放平均浓度28.2mg/L，2022年上半年排

I Environmental Information

(I) Explanation of the environmental protection status of companies and their important subsidiaries that are key emission units announced by the environmental protection department

Applicable Not Applicable

During the reporting period, the Company continued to implement the concept of green development, vigorously promote the construction of ecological civilization, strengthen comprehensive treatment measures, implement target responsibilities, promote cleaner production, expand green vegetation, strive to build a green pharmaceutical enterprise, and improve the competitiveness of sustainable development of enterprises. Gan & Lee Pharmaceuticals. is a critical pollutant discharge entity announced by the environmental protection department during the reporting period.

1. Information on pollutant discharge

Applicable Not Applicable

- a Major and characteristic pollutants: Chemical oxygen demand, ammonia nitrogen, total phosphorus; nitrogen oxide.
- b Discharge methods: After the wastewater is treated by the sewage treatment station in the Beijing HQ plant area to the takeover standard, it enters the sewage treatment plant in Huoxian town for centralized treatment.
After the exhaust gas is treated by the exhaust gas pollution prevention and control facilities, it is discharged through an exhaust cylinder with a height of 15 meters and above.
- c Number and distribution of discharge ports: The whole plant set up one sewage discharge port, which is located in the west of the Beijing HQ factory area.
The whole plant set up 11 exhaust gas pipes, which are located inside the Beijing HQ factory.
- d Concentration and the total amount of main pollutants and characteristic pollutants:
The average concentration of COD emission is 28.2 mg/L, and the total emission in the first half of 2022 is 10.14

放总量10.14吨；氨氮排放平均浓度3.8mg/L，2022年上半年排放总量1.35吨；氮氧化物平均浓度26.0mg/m³，2022年上半年排放总量1.66吨。

tonnes; the average concentration of ammonia nitrogen emission is 3.8 mg/L, and the total emission is 1.35 tonnes in the first half of 2022; the average concentration of nitrogen oxides is 26.0 mg/m³, and the total emission is 1.66 tonnes in the first half of 2022.

e 执行的污染物排放标准：
废水污染物排放标准主要执行《水污染物综合排放标准》(DB11/307-2013) 排污公共污水处理系统的水污染物排放限值，化学需氧量≤500mg/L、氨氮≤45mg/L、总磷≤8mg/L。

e Implementation of pollutant emission standards:
The discharge standard of wastewater pollutants mainly complies with the water pollutant discharge limit of sewage public sewage treatment system in the "Integrated Discharge Standard of Water Pollutants"(DB11-307-2013), with chemical oxygen demand ≤ 500mg/L, ammonia nitrogen ≤ 45mg/L, and total phosphorus ≤ 8mg/L.

废气污染物排放标准主要执行《锅炉大气污染物排放标准》(DB11/139-2015)，氮氧化物 ≤80mg/m³ (2017年3月31日前的新建锅炉)，氮氧化物 ≤30mg/m³ (2017年4月1日起的新建锅炉)。

The emission standards for exhaust gases are mainly following the "Emission Standard of Air Pollutants for Boilers"(DB11-139-2015), with nitrogen oxides ≤ 80mg/m³ (new boilers until March 31, 2017), and nitrogen oxides ≤ 30mg/m³ (new boilers as of April 1, 2017).

f 核定的排放总量：
化学需氧量5,940吨/年、氨氮534.6吨/年、总磷暂0吨/年。氮氧化物4.941505吨/年。

f Total approved emissions:
Chemical oxygen demand 5,940 tons/year, ammonia nitrogen 534.6 tons/year, total phosphorus temporarily 0 tons/year. Nitrogen oxides 4.941505 tons/year.

2. 防治污染设施的建设和运行情况

2. Construction and operation of pollution control and prevention facility

适用 不适用

Applicable Not Applicable

本公司污水处理站位于北京总部厂区西侧分为清/重污处理系统，①设备冷却水、水机浓水等清污单独收集调节pH检测合格后进行排放，设计处理能力1,800m³/d，处理工艺为：收集系统-pH调节-终端排放；②发酵废水、溶剂废水等各类重污单独收集先经过不同的预处理工序，再调节水质进入生化系统处理，处理完毕检测合格后进行排放，设计处理能力800m³/d，处理工艺为：收集系统-预处理-两级AO生化处理-终端排放。

Gan & Lee Pharmaceuticals. sewage treatment station is located on the west side of the Beijing HQ plant and is divided into a clear/heavy pollution treatment system. ① component cooling water, concentrated water from the machine, and other pollutants are collected and adjusted separately and discharged after qualifying pH testing. The designed treatment capacity is 1,800m³/d. The treatment process is as follows: collection system -pH adjustment - terminal discharge. ② Fermentation wastewater, solvent wastewater, and other types of heavy pollution collection are collected separately, first through different pretreatment processes, and then adjust the water quality to enter the biochemical system for treatment. After the treatment, they are qualified to discharge. The design processing capacity is 800 m³/d, and the treatment process is as follows: collection system - pretreatment - two-stage AO biochemical treatment - terminal discharge.

甘李药业股份有限公司发酵废气采用除菌过滤-碱液吸收装置，对发酵生产尾气进行处理；QC实验室与灭菌废气采用活性炭吸附进行处理；食堂废气采用油烟净化器和活性炭吸附进行收集处理；盐酸配置废气采用碱液吸收进行处理；尿素打包车间废气采用水吸收进行处理。

The fermentation waste gas of Gan & Lee Pharmaceuticals is treated by sterilization filtration-alkali absorption device; the QC laboratory and sterilization waste gas are treated by activated carbon adsorption; the canteen waste gas is collected and treated by oil fume purifier and activated carbon adsorption; the waste gas of hydrochloric acid configuration is treated by alkali absorption; the waste gas of urea packing plant is treated by water absorption.

2017年对企业老锅炉进行低氮改造，2017年4月份之后新建锅炉，采用低氮燃烧器，保障氮氧化物合格达标。

In 2017, the Company carried out low-nitrogen transformation of old boilers, and built new boilers after April 2017, using low-nitrogen burners to ensure that nitrogen oxides qualified and reached the standard.

3. 建设项目环境影响评价及其他环境保护行政许可情况

适用 不适用

本公司之子公司甘李药业山东有限公司2022年4月2日临沂生产基地一期项目获得环评批复，批复文号：临经开行审环字[2022]19号。

3. Environmental impact assessment of construction projects and other environmental administration license

Applicable Not Applicable

On April 2, 2022, Gan & Lee Pharmaceutical Shandong Co., Ltd., a subsidiary of the Company, obtained the EIA approval for the first-phase project of the Linyi production base Approval No.[2022]19.

甘李药业股份有限公司2021年9月6日公司三期新建生产车间项目(危险品库)获得环评批复，批复文号：通环审[2021]0027号。

On September 6, 2021, Gan & Lee Pharmaceuticals. obtained the EIA approval for the third-phase new production workshop project (dangerous goods warehouse), with the approval document number: Tonghuan Shen [2021] No. 0027.

甘李药业股份有限公司污水处理站改造项目环境影响登记表于2021年8月23日完成备案，备案号：20211101120000317。

The registration form of environmental impact of the sewage treatment station renovation project of Gan & Lee Pharmaceuticals. was put on record on August 23, 2021. The registration number is 20211101120000317.

甘李药业股份有限公司2020年12月29日更新排污许可证，排污许可证主码：91110000102382249M001U。

Gan & Lee Pharmaceuticals. updated the pollutant discharge permit on December 29, 2020. The main code of the pollutant discharge permit is 91110000102382249M001U.

甘李药业股份有限公司胰岛素产业化项目于2017年7月3日通过竣工环境保护验收，验收文号：通环保验字[2017]0030号。

The insulin industrialization project of Gan & Lee Pharmaceuticals. passed the acceptance by the Environmental Protection Bureau of Tongzhou District, [2017] No. 0030.

4. 突发环境事件应急预案

适用 不适用

甘李药业股份有限公司于2021年3月30日签署发布了突发环境事件综合应急预案，已报北京市通州区生态环境局备案，备案编号：110112-2021-008-L。

4. Emergency plan for environmental emergencies

Applicable Not Applicable

Gan & Lee Pharmaceuticals. signed and issued the comprehensive emergency plan for environmental emergencies on March 30, 2021, which has been reported to Tongzhou District Ecological Environment Bureau for the record, with the record number of 110112-2021-008-L.

5. 环境自行监测方案

适用 不适用

2022年上半年，甘李药业股份有限公司编制环境自行监测方案，按照自行监测要求，委托第三方检测机构对废水、废气和厂界噪声进行了监测，监测结果显示各项污染物指标均达标排放。

5. Environmental self-monitoring plan

Applicable Not Applicable

In the first half of 2022, Gan & Lee Pharmaceuticals. prepared the environmental self-monitoring plan and entrusted a third-party testing organization with monitoring the wastewater, waste gas, and plant boundary noise according to the self-monitoring requirements. The monitoring results showed that all pollutant indicators were discharged up to the standard.

6. 报告期内因环境问题受到行政处罚的情况

适用 不适用

6. Administrative penalties imposed for environmental issues during the reporting period

Applicable Not Applicable

7. 其他应当公开的环境信息

适用 不适用

7. Other environmental information to be disclosed

Applicable Not Applicable

(二) 重点排污单位之外的公司环保情况说明

适用 不适用

(II) Statement on environmental protection of companies other than key pollutant discharge units

Applicable Not Applicable

(三) 报告期内披露环境信息内容的后续进展或变化情况的说明

适用 不适用

(III) Statement of subsequent progress or changes in the environmental information disclosed during the reporting period

Applicable Not Applicable

(四) 有利于保护生态、防治污染、履行环境责任的相关信息

适用 不适用

(IV) Relevant information conducive to protecting the ecology, preventing and controlling pollution, and fulfilling environmental responsibilities

Applicable Not Applicable

(五) 在报告期内为减少其碳排放所采取的措施及效果

适用 不适用

(v) Measures taken to reduce carbon emissions during the reporting period and their effects

Applicable Not Applicable

二、巩固拓展脱贫攻坚成果、乡村振兴等工作具体情况

适用 不适用

II Consolidate and expand the results of poverty eradication, rural revitalization and other specific work

Applicable Not Applicable

重要事项

SIGNIFICANT EVENTS



第六节 重要事项

SECTION VI SIGNIFICANT EVENTS

一、承诺事项履行情况

(一) 公司实际控制人、股东、关联方、收购人以及公司等承诺相关方在报告期内或持续到报告期内的承诺事项

适用 不适用

I Implementation of Commitments

(I) The commitments made by the ultimate controllers, shareholders, related parties, acquirer as well as the Company and other relevant parties during or up to the reporting period

Applicable Not Applicable

承诺背景 Background of commitments	承诺类型 Type of commitments	承诺方 Covenanter	承诺内容 Contents of commitments	承诺时间及期限 Date and term of commitments	是否 有履行期限 Any deadline for performance	是否及时严格履行 Whether performed in a timely and strict way	如未能及时履行应说明未 完成履行的具体原因 In case of failure to perform in time, the specific reasons for the failure to perform	如未能及时履行应说 明下一步计划 If it is not fulfilled in time, the next step should be explained
		控股股东、实际控制人甘忠如及其亲属甘喜茹、周立华、周国安、甘建军、甘建民 Controlling shareholder and actual controller Gan Zhongru and his relatives Gan Xiru, Zhou Lihua, Zhou Guoan, Gan Jianjun, Gan Jianmin	详见注1 Note 1	自公司股票上市之日起36个月，特定条件下自动延长6个月 36 months from the date of listing of the Company's stock, and automatically extended for 6 months under certain conditions	是 Yes	是 Yes	不适用 Not applicable	不适用 Not applicable
与首次公开发行相关的承诺 Commitments Related to IPO	股份限售 Share restriction	股东旭特宏达 Shareholder Xute Hongda	详见注2 Note 2	自公司股票上市之日起36个月，特定条件下自动延长6个月 36 months from the date of listing of the Company's stock, and automatically extended for 6 months under certain conditions	是 Yes	是 Yes	不适用 Not applicable	不适用 Not applicable
	股份限售 Share restriction	股东明华创新、Wintersweet、Hillhouse、STRONG LINK、GS Direct、宽街博华、景林投资、铸成顺康 Shareholders Ming Hua Technology Investment, Wintersweet, Hillhouse, STRONG LINK, GS Direct, Kuanjie Bohua, Jinglin Investment, Zhucheng Shunkang	详见注3 Note 3	自公司股票上市之日起12个月，特定条件下延长股份锁定 12 months from the date of listing of the Company's shares, with extension of share lock-up under certain conditions	是 Yes	是 Yes	不适用 Not applicable	不适用 Not applicable

承诺背景 Background of commitments	承诺类型 Type of commitments	承诺方 Covenanter	承诺内容 Contents of commitments	承诺时间及期限 Date and term of commitments	是否有履行期限 Any deadline for performance	是否及时严格履行 Whether performed in a timely and strict way	如未能及时履行应说明完成履行的具体原因 In case of failure to perform in time, the specific reasons for the failure to perform	如未能及时履行应说明下一步计划 If it is not fulfilled in time, the next step should be explained
与首次公开发行相关的承诺 Commitments Related to IPO	其他 Others	间接持有公司股份的董事王大梅、宋维强、都凯，高级管理人员邹蓉、宁军军 Directors Wang Damei, Song Weiqiang, and Du Kai, who indirectly hold the Company's shares, and senior executives Zou Rong and Ning Junjun	详见注4 Note 4	承诺股份锁定期满2年内，特定条件下自动延长6个月 Within 2 years after the promised share lock-up period expires, it will be automatically extended for 6 months under certain conditions	是 Yes	是 Yes	不适用 Not applicable	不适用 Not applicable
	其他 Others	公司全体董事、监事、高级管理人员 All directors, supervisors and senior managers of the Company	详见注5 Note 5	长期有效 Permanent	否 No	是 Yes	不适用 Not applicable	不适用 Not applicable

承诺背景 Background of commitments	承诺类型 Type of commitments	承诺方 Covenanter	承诺内容 Contents of commitments	承诺时间及期限 Date and term of commitments	是否有履行期限 Any deadline for performance	是否及时严格履行 Whether performed in a timely and strict way	如未能及时履行应说明完成履行的具体原因 In case of failure to perform in time, the specific reasons for the failure to perform	如未能及时履行应说明下一步计划 If it is not fulfilled in time, the next step should be explained
	其他 Others	实际控制人及控股股东甘忠如 Gan Zhongru, the de facto controller and controlling shareholder	详见注6 Note 6	长期有效 Permanent	否 No	是 Yes	不适用 Not applicable	不适用 Not applicable
与首次公开发行相关的承诺 Commitments Related to IPO	其他 Others	控股股东及实际控制人甘忠如、持股5%以上股东明华创新、旭特宏达、Wintersweet、Hillhouse	详见注7 Note 7	承诺的股份锁定期满后2年内 Within 2 years after the promised share lock-up period expires	是 Yes	是 Yes	不适用 Not applicable	不适用 Not applicable

承诺背景 Background of commitments	承诺类型 Type of commitments	承诺方 Covenanter	承诺内容 Contents of commitments	承诺时间及期限 Date and term of commitments	是否 有履行期限 Any deadline for performance	是否及时严格履行 Whether performed in a timely and strict way	如未能及时履行应说明未 完成履行的具体原因 In case of failure to perform in time, the specific reasons for the failure to perform	如未能及时履行应说明 下一步计划 If it is not fulfilled in time, the next step should be explained
	解决土地等 权瑕疵 Resolving property de fects and controlling such as land	实际控制人及控股 股东甘忠如 Gan Zhongru, the de facto controller	详见注8 Note 8	长期有效 Permanent	否 No	是 Yes	不适用 Not applicable	不适用 Not applicable
与首次公开发 行相关的承诺 Commitments Related to IPO	解决同业竞争 Resolving horizontal de facto controller competition and controlling shareholder	实际控制人及控股 股东甘忠如 Gan Zhongru, the de facto controller and controlling shareholder	详见注9 Note 9	长期有效 Permanent	否 No	是 Yes	不适用 Not applicable	不适用 Not applicable
	解决关联交易 Resolve affiliate Transactions	控股股东及实际控 制人甘忠如、持有 5%以上股份的其他 主要股东 Gan Zhongru, the controlling shareholder and de facto controller, and other major shareholders holding more than 5% of the shares	详见注10 Note 10	长期有效 Permanent	否 No	是 Yes	不适用 Not applicable	不适用 Not applicable

承诺背景 Background of commitments	承诺类型 Type of commitments	承诺方 Covenanter	承诺内容 Contents of commitments	承诺时间及期限 Date and term of commitments	是否 有履行期限 Any deadline for performance	是否及时严格 履行 Whether performed in a timely and strict way	如未能及时履行应说明未 完成履行的具体原因 In case of failure to perform in time, the specific reasons for the failure to perform	如未能及时履行应说明 下一步计划 If it is not fulfilled in time, the next step should be explained
	其他 Others	本公司、控股股东、公司董事 (不含独立董事)、高级管理人员等 The Company, controlling shareholders, company directors (excluding independent directors), senior management personnel, etc.	详见注11 Note 11	自公司股票上市 之日起三年内有效 Valid for three years from the date of listing of the Company's shares	是 Yes	是 Yes	不适用 Not applicable	不适用 Not applicable
与首次公开发 行相关的承诺 Related to IPO	其他 Others	控股股东、实际控制人、董 事、高级管理人员 Controlling shareholders, de facto controller, directors, senior managers	详见注12 Note 12	长期有效 Permanent	否 No	是 Yes	不适用 Not applicable	不适用 Not applicable
	其他 Others	实际控制人及控股股东甘忠如 Gan Zhongru, the de facto controller and controlling shareholder	详见注13 Note 13	长期有效 Permanent	否 No	是 Yes	不适用 Not applicable	不适用 Not applicable

承诺背景 Background of commitments	承诺类型 Type of commitments	承诺方 Covenanter	承诺内容 Contents of commitments	承诺时间及期限 Date and term of commitments	是否有履行期限 Any deadline for performance	是否及时严格履行 Whether performed in a timely and strict way	如未能及时履行应说明完成履行的具体原因 In case of failure to perform in time, the specific reasons for the failure to perform	如未能及时履行应说明未如未能及时履行应说明下一步计划 If it is not fulfilled in time, the next step should be explained
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自首次股票期权授予之日起至激励对象获授的股票期权全部行权或注销之日止
From the date of the first stock option grant to the day when all the stock options granted to the incentive object are exercised or cancelled

详见注14
Note 14

本公司
The Company

其他
Others

是
Yes

不适用
Not applicable

不适用
Not applicable

与股权激励相关的承诺
Equity incentive related commitments

自首次股票期权授予之日起至激励对象获授的股票期权全部行权或注销之日止
From the date of the first stock option grant to the day when all the stock options granted to the incentive object are exercised or cancelled

详见注15
Note 15

激励对象
Incentive object

其他
Others

是
Yes

不适用
Not applicable

不适用
Not applicable

注1: 本公司控股股东、实际控制人甘忠如及其亲属甘喜茹、周立华、周国安、甘建军、甘建民承诺: 自公司股票上市之日起三十六个月内, 不转让或者委托他人管理在本次发行前直接或间接所持有的公司的股份, 也不由公司回购该部分股份。本人在锁定期届满后两年内减持公司股票, 股票减持的价格不低于公司首次公开发行股票的发价(如公司发生分红、派息、送股、资本公积金转增股本等除权除息事项, 则为按照相应比例进行除权除息调整后用于比较的发价, 以下统称发价); 若公司上市后6个月内公司股票连续20个交易日的收盘价均低于发价, 或者公司上市后6个月期末股票收盘价低于发价, 本人持有公司股票的锁定期将自动延长6个月; 本人不因甘忠如职务变更、离职等原因而放弃履行上述延长锁定期限的承诺。

注2: 本公司股东旭特宏达承诺: 自公司股票上市之日起三十六个月内, 不转让或者委托他人管理在本次发行前所持公司股份, 也不由公司回购该部分股份。在锁定期届满后两年内减持公司股票的, 股票减持的价格不低于公司首次公开发行股票的发价(如公司发生分红、派息、送股、资本公积金转增股本等除权除息事项, 则为按照相应比例进行除权除息调整后用于比较的发价, 以下统称发价); 若公司上市后6个月内公司股票连续20个交易日的收盘价均低于发价, 或者公司上市后6个月期末股票收盘价低于发价, 本机构持有公司股票的锁定期将自动延长6个月。

注3: 本公司股东明华创新、Wintersweet、Hillhouse、STRONG LINK、GS Direct、宽街博华、景林投资、铸成顺康承诺: 自公司股票上市之日起十二个月内, 不转让或者委托他人管理在本次发行前所持公司股份, 也不由公司回购该部分股份。同时与公司控股股东、实际控制人

Note 1: The Company's controlling shareholder and actual controller Gan Zhongru and his relatives Gan Xiru, Zhou Lihua, Zhou Guoan, Gan Jianjun, and Gan Jianmin promised that within 36 months from the date of listing of the Company's shares, they would not transfer or entrust others to manage the Company's shares at this time. The Company shall not repurchase the shares of the Company held directly or indirectly before the issuance. If I reduce my shareholding of the Company within two years after the expiration of the lock-up period, the price of the share reduction shall not be lower than the issue price of the Company's initial public offering. (For example, the Company has dividends, bonus shares, capital reserve transfers to increase capital stock and other ex-dividend matters; it is in accordance with the corresponding proportion of ex-dividend adjustment for the issuance price for comparison, hereinafter referred to as the issue price.) If the closing price of the Company's shares is lower than the issue price for 20 consecutive trading days within 6 months after the Company's listing, or the closing price of the Company's shares is lower than the issue price at the end of 6 months after the Company's listing, the lock-up period of the Company's shares held by me will be automatically extended for 6 months. I will not give up the above commitment to extend the lock-up period due to Gan Zhongru's job change, resignation, and other reasons.

Note 2: The Company's shareholder Xute Hongda promised that within 36 months from the date of listing the Company's shares, they would not transfer or entrust others to manage the Company's shares. The Company's shares held directly or indirectly before the issuance shall not be repurchased by the Company. If I reduce my shareholding of the Company within two years after the expiration of the lock-up period, the price of the share reduction shall not be lower than the issue price of the Company's initial public offering. (For example, the Company has dividends, bonus shares, capital reserves transfers to increase capital stock and other ex-dividend matters; it follows the corresponding proportion of ex-dividend adjustment for the issuance price for comparison, hereinafter referred to as the issue price.) If the closing price of the Company's shares is lower than the issue price for 20 consecutive trading days within 6 months after the Company's listing, or the closing price of the Company's shares is lower than the issue price at the end of 6 months after the Company's listing, the lock-up period of the Company's shares held by me will be automatically extended for 6 months.

Note 3: The shareholders of the Company, namely, Minghua Technology Investment, Wintersweet, Hillhouse, STRONG LINK, GS Direct, Kuanjie Bohua, Jinglin Investment and Zhucheng Shunkang, committed not to transfer or entrust others to manage the shares of the Company held prior to the issuance, nor to have the Company repurchase such shares within twelve months from the date of listing of the shares of the Company. At the same time, the agreement on "The Extension Of Share Lock-

甘忠如分别签署的《关于延长股份锁定期的协议》(以下简称“锁定协议”)的约定: (1) 在甘忠如直接及间接持有发行人股份不低于其当前持股总额的55%的前提下, 各延长锁定股东愿意分别将其各自当前所持发行人股份的16.91% (以下简称“标的股份”) 在法定锁定期届满后继续延长锁定, 直至甘忠如书面通知解除延长锁定或出现锁定协议约定的其他终止锁定的情形。延长锁定解除后, 上述股东减持公司股份仍需遵守法律、法规、规范性文件及证券交易所业务规则的要求。(2) 作为延长锁定的执行保证, 如延长锁定股东在法定锁定期届满后选择减持届时仍受限于延长锁定的标的股份, 则减持股东将其每一笔减持届时仍受限于延长锁定的标的股份所得收益的50%支付予甘忠如(其中, STRONGLINK的该等减持收益由明华创新向甘忠如支付), 在这种情况下的减持不应构成对锁定协议的违反。(3) 延长锁定股东就标的股份所享有的股东权利不受影响, 标的股份所对应的知情权、表决权、分红权等股东权利, 由各延长锁定股东独立拥有并自行行使。

注4: 间接持有公司股份的董事王大梅、宋维强、都凯, 高级管理人员邹蓉、宁军军承诺: 本人在锁定期届满后两年内减持公司股票, 股票减持的价格不低于公司首次公开发行股票的发价(如公司发生分红、派息、送股、资本公积金转增股本等除权除息事项, 则为按照相应比例进行除权除息调整后用于比较的发价, 以下统称发价); 若公司上市后6个月内公司股票连续20个交易日的收盘价均低于发价, 或者公司上市后6个月期末股票收盘价低于发价, 本人持有公司股票的锁定期限将自动延长6个月; 本人不因职务变更、离职等原因而放弃履行上述延长锁定期限的承诺。

注5: 公司全体董事、监事、高级管理人员承诺: 在担任公司董事、监事、高级管理人员期间, 每年转让

up Period) (hereinafter referred to as *“Lock-up Agreement”*) signed with Gan Zhongru, the controlling shareholder and de facto controller of the Company, respectively: (1) On the premise that Gan Zhongru’s direct and indirect shareholding in the Issuer is not less than 55% of his total current shareholding, each shareholder who extends the lock-up is willing to transfer 16.91% of their respective shareholding in the Issuer. After the lifting of the extended lock-up, the above shareholders’ reduction of the Company’s shares shall still be subject to the requirements of laws, regulations, regulatory documents and business rules of the Stock Exchange. (2) As a guarantee for the implementation of the extended lock-up, if the shareholders with extended lock-up period choose to reduce their holdings of the Subject Shares that are still subject to the extended lock-up at that time after the expiration of the statutory lock-up period, the reducing shareholders shall pay 50% of the proceeds from each reduction of their holdings of the Subject Shares that are still subject to the extended lock-up at that time to Gan Zhongyu (Among them, the proceeds of such reduction of STRONGLINK shall be paid by Minhua Innovation to Gan Zhongru), and the reduction in such circumstances shall not constitute a breach of the Lock-up Agreement. (3) The shareholders’ rights entitled to the Subject Shares by the Extended Lock-up Shareholders shall not be affected, and the shareholders’ rights such as the right to information, voting rights and dividend rights corresponding to the Subject Shares shall be independently owned and exercised by each Extended Lock-up Shareholder on its own.

Note 4: Directors Wang Damei, Song Weiqiang, and Du Kai, who indirectly hold the Company’s shares, and senior executives Zou Rong and Ning Junjun promised that if they reduce their shareholding of the Company within two years after the expiration of the lock-up period, the price of the share reduction shall not be lower than the issue price of the Company’s initial public offering (For example, the Company has dividends, bonus shares, capital reserve transfers to increase capital stock and other ex-dividend matters; it follows the corresponding proportion of ex-dividend adjustment for the issuance price for comparison, hereinafter referred to as the issue price.). If the closing price of the Company’s shares is lower than the issue price for 20 consecutive trading days within 6 months after the Company’s listing, or the closing price of the Company’s shares is lower than the issue price at the end of 6 months after the Company’s listing, the lock-up period of the Company shares held by me will be automatically extended for 6 months. I will not give up fulfilling the commitment to extend the lock-up time due to changes in position, resignation, etc. I will not give up the above commitment to extend the lock-up period due to job change, resignation or other reasons.

Note 5: All directors, supervisors, and senior management personnel of the Company promised that during their tenure as directors, supervisors, and senior management personnel of the

的股份不超过其直接或间接持有的公司股份总数的百分之二十五，自离职后半年内，不转让或委托他人管理直接或间接持有的公司股份，也不由公司回购该部分股份。

注6: 关于社保及住房公积金的影响，公司实际控制人甘忠如出具承诺：如公司及其控股子公司被要求为员工补缴或追偿社会保险金或住房公积金，本人将对此承担责任，无条件连带地全额承担应补缴或被追偿的金额、承担罚款等相关经济责任及因此所产生的相关费用，保证公司不会因此遭受任何损失。

注7: 公司控股股东、实际控制人甘忠如承诺：在本人承诺的股份锁定期满后两年内，本人每年减持公司股份的数量不超过上一年度末本人直接及/或间接持有的公司股份总数的10%，且减持价格不低于公司首发上市的发行价。

公司持股5%以上股东明华创新、旭特宏达、Wintersweet、Hillhouse承诺：在符合相关法律法规以及不违反其关于股份锁定承诺的前提下，本企业将根据自身经济的实际状况和二级市场的交易表现，有计划地就所持股份进行减持，意向在所持公司股份锁定期满后两年内减持完毕，但不排除根据其自身资金需求、实现投资收益、公司股票价格波动等情况调整减持时间的可能性。如本人/企业未履行上述承诺，本人/企业自愿将违反承诺减持获得的收益上交公司，如未将违规减持所得上交公司，则公司有权扣留应付现金分红中与应上交公司的违规减持所得金额相等的现金分红。本人/企业将在公司的股东大会及中国证监会指定报刊上公开说明未履行承诺的具体原因，并向公司其他股东和社会公众投资者道歉。同时本人/企业持有的公司股票的锁定期限自动延长6个月。如因未履行上述承诺事项致使投资者在证券交易中遭受损失的，本人/企业将依法赔偿投资者损失，并承担相应的法律责任。

company, the number of shares transferred each year will not exceed 25% of the total number of company shares held directly or indirectly by them. Furthermore, within half a year after resignation, they shall not transfer or entrust others to manage the Company's shares directly or indirectly held, nor shall the Company repurchase such shares.

Note 6: Regarding the impact of social security and housing provident fund, the Company's actual controller, Gan Zhongru, issued a promise: If the Company and its holding subsidiaries are required to pay or recover social insurance funds or housing provident funds for employees, I will bear the responsibility. Furthermore, I will unconditionally and jointly bear the amount that should be paid or recovered and the relevant economic responsibilities such as fines and related expenses and guarantee that the Company will not suffer any loss.

Note 7: The Company's controlling shareholder and actual controller Gan Zhongru promised that within two years after the expiration of the share lock-up period that I promised, the number of my company's shares shall not be reduced by more than 10% of the Company's shares held directly and/or indirectly at the end of the previous year. Furthermore, the reduction price shall not be lower than the issue price of the initial listing.

The Company's shareholders Minghua Innovation, Xute Hongda, Wintersweet, and Hillhouse, holding more than 5% of the Company's shares, promised that on the premise of complying with relevant laws and regulations and not violating its commitment to lock-in shares, the Company will plan to reduce its holdings following the actual economic conditions and the trading performance of the secondary market, and intends to lock-in the shares of the Company it holds. The reduction of holdings will be completed within two years after the expiration, but the possibility of adjusting the time of holdings reduction based on its own capital needs, realized investment income, fluctuations in the Company's stock prices, etc., is not ruled out. If the person/the Company fails to fulfill the above commitments, the person/ the Company voluntarily submits the proceeds obtained from the reduction of holdings in violation of the promise to the Company. If the proceeds from the illegal reduction of holdings are not submitted to the Company, the Company has the right to withhold the cash dividends payable, and the Company shall have a cash dividend equal to the amount obtained from the illegal reduction of holdings. The person/ the Company will publicly explain the specific reasons for not fulfilling the promise in the Company's general meeting of shareholders and the newspapers designated by the China Securities Regulatory Commission and apologize to other shareholders of the Company and public investors. At the same time, the lock-up period of the Company's stock held by the person/the Company will automatically extend for 6 months. If investors suffer losses in securities trading due to failure to fulfill the above commitments, the person/company will compensate the investors for losses following the law and bear corresponding legal liabilities.

注8：作为公司合规经营的总负责人，实际控制人甘忠如承诺：甘李药业及其各分子公司所用物业，如因占用土地、无房产证或其他不合规情形而遭遇拆迁、强制搬迁或其他导致甘李药业或其分子公司无法继续使用该物业的情况或遭受处罚的，甘李药业控股股东及实际控制人均承诺将提前为其寻找其他适用场所，并愿意对甘李药业及其分子公司因此所遭受的实际经济损失予以补偿。

注9：为避免将来可能与本公司发生的同业竞争，本公司实际控制人及控股股东甘忠如先生，已经向本公司出具了有法律约束力的《关于避免同业竞争的承诺函》，并作出如下承诺：

(1) 本人将尽职、勤勉地履行《公司法》《公司章程》所规定的股东职责，不利用股份公司的股东地位损害股份公司及股份公司其他股东、债权人的合法权益。

(2) 在本承诺书签署之日，本人或本人控制的其他企业均未生产、开发任何与股份公司生产、开发的产品构成竞争或可能构成竞争的产品，未直接或间接经营任何与股份公司经营的业务构成竞争或可能构成竞争的业务，也未参与投资任何与股份公司生产、开发的产品或经营的业务构成竞争或可能构成竞争的其他公司、企业或其他组织、机构。

(3) 自本承诺书签署之日起，本人或本人控制的其他企业将不生产、开发任何与股份公司生产、开发的产品构成竞争或可能构成竞争的产品，不直接或间接经营任何与股份公司经营的业务构成竞争或可能构成竞争的业务，也不参与投资任何与股份公司生产的产品或经营的业务构成竞争或可能构成竞争的其他企业。

(4) 自本承诺书签署之日起，如本人或本人控制的其他企业进一步拓展产品和业务范围，或股份公司进一步拓展产品和业务范围，本人或本人控制的其他企业将不与股份公司现有或拓展后的产品或业务相竞争；若与股份公司及其下属子公司拓展后的产品或业务产生竞争，则本人

Note 8: As the person in charge of the Company's total compliance management, the actual controller Gan Zhongru promised: if the property used by Gan & Lee Pharmaceuticals. and its subsidiaries is subject to demolition, forced relocation, or other circumstances that make Gan & Lee Pharmaceuticals. or its subsidiary companies unable to continue to use the property or be punished due to the occupation of land, lack of property ownership certificate or other non-compliance. Furthermore, the controlling shareholders and actual controllers of Gan & Lee Pharmaceuticals. have promised to find other suitable places for them in advance and are willing to compensate Gan & Lee Pharmaceuticals. and its subsidiaries for the actual economic losses suffered as a result.

Note 9: To avoid the Company from the possible horizontal competition in the future, the actual controller and controlling shareholder of the Company, Mr. Gan Zhongru, has issued a legally binding "Letter of Commitment on Avoiding Horizontal Competition" to the Company and made the following commitments:

(1) I will perform my duties as a shareholder under "The Company Law" and "The Articles of Association with diligence", and will not impair the lawful rights and interests of the joint-stock company and other shareholders and creditors of the joint-stock company by taking advantage of the shareholder status.

(2) On the date of signing this undertaking, neither I nor any other enterprise under my control has produced or developed any products that compete with or may compete with the joint-stock company, nor does I directly or indirectly operate any business that competes or may compete with the business conducted by the Joint-stock Company. Nor is it involved in investing in any other company, enterprise, or organization, or institution that may compete with the products or businesses produced or developed by the joint-stock company.

(3) As of the date of signing of this undertaking, I or any other enterprise controlled by me will not produce or develop any product that is or may be in competition with the products produced or developed by me, nor will I directly or indirectly engage in any business that is or may be in competition with the business carried on by me, nor will I participate in any investment in any other enterprise that is or may be in competition with the products produced or carried on by me.

(4) As of the date of signing of this undertaking, if I or any other enterprise controlled by me further expand its products and business scope, or the joint-stock company further expands its products and business scope, I or any other enterprise controlled by me will not compete with the existing or expanded products or business of the joint-stock company; If there is competition with the expanded products or businesses of the joint-stock company and its subsidiaries, then I or other

或本人控制的其他企业将以停止生产或经营相竞争的业务或产品，或者将相竞争的业务或产品纳入到股份公司经营，或者将相竞争的业务或产品转让给无关联关系的第三方的方式避免同业竞争。

(5) 如以上承诺事项被证明不真实或未被遵守，本人将向股份公司赔偿一切直接和间接损失，并承担相应的法律责任。

注10：公司控股股东、实际控制人、持有5%以上股份的其他主要股东出具了《关于避免和减少关联交易的承诺函》，承诺方承诺：(1) 确保公司的业务独立、资产完整，具有独立、完整的产、供、销以及其他辅助配套的系统，以尽可能避免和减少关联交易；(2) 承诺方及承诺方控制的其他企业将尽可能避免和减少与公司之间的关联交易，并不与公司发生任何资金拆借行为（正常经营活动中预支的备用金除外）；(3) 若有关的关联交易为公司日常经营所必需或者无法避免，则将本着诚实信用、公平公正、尽职尽责、公开披露的原则，处理关联交易的有关事项，并按照市场公平原则确定交易价格，严格履行有关关联股东及关联董事回避表决程序及独立董事独立发表意见的程序，确保关联交易程序的合法公正、关联交易结果的公平合理，且不损害公司及公司股东利益。

注11：公司首发上市后三年内，公司股票收盘价连续20个交易日的收盘价低于上一个会计年度末经审计的每股净资产（若公司股票在此期间发生派息、送股、资本公积转增股本等除权除息事项的，应按照上海证券交易所的有关规定做相应调整，下同）。如出现上述情形，应采取如下措施稳定公司股价：(1) 发行人回购股票。采取该等措施的，发行人需按照《公司法》《证券法》《上市公司回购社会公众股份管理办法（试行）》（证监发[2005]51号）、《关于上市公司以集中竞价交易方式回购股份的补充规定》（中国证监会公告[2008]39号）、《上海证券交易所股票上市规则》等法律法规及业务规则规定的条件及程序办理。(2) 控股股东、公司董事（不

enterprises controlled by me will stop producing or operating the competing businesses or products, or bring the competing businesses or products into the operation of the joint-stock company, or transfer the competing businesses or products to an unrelated third party to avoid competition in the same industry.

(5) If the above undertakings are proved to be untrue or not complied with, I shall indemnify the joint-stock company against all direct and consequential losses and bear corresponding legal liabilities.

Note 10: The Company's controlling shareholders, actual controllers, and other major shareholders holding more than 5% of the shares issued the "Letter of Commitment on Avoiding and Reducing Related Party Transactions", and the promiser promised to: (1) ensure the Company's business independence, asset integrity, independent and complete production, supply, sales and other supporting systems to avoid and reduce related party transactions as much as possible; (2) The Commitment Party and other enterprises controlled by the Commitment Party will try their best to avoid and reduce the affiliated transactions with the Company, and will not have any fund borrowing activities with the Company (except for the advance fund in normal business activities); (3) If the related party transactions are necessary or unavoidable for the Company's daily operations, it will handle the related matters of related party transactions based on the principles of good faith, fairness and justice, due diligence and public disclosure, and determine the transaction price in accordance with the principle of market fairness, strictly implement the procedures for related party shareholders and related party directors to avoid voting and the procedures for independent directors to express their opinions, and ensure the legality and fairness of the related party transaction procedures and the fairness and reasonableness of the related party transaction results without harming the interests of the Company and its shareholders.

Note 11: Within three years after the IPO, the closing price of the Company's shares for 20 consecutive trading days is lower than the audited net assets per share at the end of the previous fiscal year (in case of any ex-rights and ex-dividends of the Company's shares such as dividends, bonus shares, capitalization of capital reserve during this period, the corresponding adjustments shall be made in accordance with the relevant regulations of the Shanghai Stock Exchange, the same below). In the above situation, the following measures shall be taken to stabilize the Company's stock price: (1) the issuer repurchases shares. If such measures are taken, the issuer shall comply with the conditions and procedures prescribed by "The Company Law", "The Securities Law", "The Administrative Measures for the Repurchase of Public Shares by Listed Companies (for Trial Implementation)" (Zheng Jian Fa[2005]No. 51), "The Supplementary Provisions on Share Repurchase by Listed Companies through Centralized Auction Trading (China Securities Regulatory Commission Announcement[2008]No. 39)", "The Stock Listing Rules of the Shanghai Stock Exchange and other laws, regulations and business rules". (2) If the controlling shareholders,

含独立董事)、高级管理人员增持公司股票采取该等措施的,相关增持主体需按照《上市公司收购管理办法》(中国证监会令第77号)、《上海证券交易所股票上市规则》等法律法规及业务规则规定的条件及程序办理。本公司或控股股东、公司董事(不含独立董事)、高级管理人员在启动上述股价稳定措施时应提前公告具体实施方案。

注12:公司的控股股东、实际控制人承诺:不得越权干预公司经营管理活动,不得侵占公司利益。公司的董事、高级管理人员将忠实、勤勉地履行职责,维护公司和全体股东的合法权益,尽最大努力确保公司签署填补回报措施能够得到切实履行,并就此作出承诺:(1)本人承诺不得无偿或以不公平条件向其他单位或者个人输送利益,也不得采用其他方式损害公司利益。(2)本人承诺对本人的职务消费行为进行约束。(3)本人承诺不得动用公司资产从事与本人履行职责无关的投资、消费活动。(4)本人承诺全力支持董事会或薪酬与考核委员会制订薪酬制度时,应与公司填补回报措施的执行情况相挂钩的董事会和股东大会会议案,并愿意投票赞成(若有投票权)该等议案。(5)本人承诺全力支持拟公布的公司股权激励行权条件与公司填补回报措施的执行情况相挂钩的董事会和股东大会会议案,并愿意投票赞成(若有投票权)该等议案。(6)本人承诺切实履行公司制定的有关填补回报措施以及本人对此作出的任何有关填补回报措施的承诺,若本人违反该等承诺并给公司或者投资者造成损失的,本人愿意依法承担对公司或者投资者的补偿责任。作为填补回报措施相关责任主体之一,若本人若违反上述承诺或拒不履行上述承诺,本人同意按照中国证监会和上海证券交易所等证券监管机构按照其制定或发布的有关规定、规则,对本人作出处罚或采取相关管理措施。

注13:实际控制人甘忠如承诺:如因公司销售人员违反合规制度等不当行为,导致公司违反相关法律并实

the Company's directors (excluding independent directors) and senior managers increase their shares of the Company by taking such measures, the relevant entities that increase their shares shall follow the conditions and procedures prescribed by the "Measures for the Administration of Acquisitions of Listed Companies" (Order No. 77 of the China Securities Regulatory Commission), the "Stock Listing Rules of the Shanghai Stock Exchange" and other laws, regulations and business rules. The Company, its controlling shareholders, its directors (excluding independent directors) and senior managers shall announce the specific implementation plan in advance when launching the above-mentioned stock price stabilization measures.

Note 12: The controlling shareholder and actual controller of the Company promise that they shall not ultra vires interfere with the Company's operation and management activities, and shall not encroach on the Company's interests. The Company's directors and senior managers will perform their duties faithfully and diligently, safeguard the lawful rights and interests of the Company and all shareholders, use their best efforts to ensure that the Company's signing of compensation measures can be effectively performed, and make promises in this regard: (1) I promise not to convey benefits to other units or individuals for free or on unfair terms, and shall not harm the interests of the Company in any other way. (2) I promise to restrain my professional consumption. (3) I promise not to use the Company's assets to engage in investment and consumption activities unrelated to the performance of my duties. (4) I undertake to fully support the proposals of the board of directors and general meeting of shareholders which shall be linked to the implementation of compensation measures when the remuneration system is formulated by the board of directors or the Remuneration and Appraisal Committee, and I am willing to vote for (if voting) such proposals. (5) I promise to fully support the proposals of the board of directors and the general meeting of shareholders that the Company's equity incentive exercise conditions to be announced are linked to the implementation of the Company's compensation measures, and I am willing to vote for (if voting) such proposals. (6) I undertake to faithfully implement the compensation measures formulated by the Company and any promises made by me in respect of such compensation measures. If I breach such promises and cause losses to the Company or the investors, I am willing to be liable for compensation to the Company or the investors in accordance with the law. As one of the subjects responsible for compensatory measures, if I violate or refuse to perform the above commitments, I agree to impose penalties on myself or take relevant management measures in accordance with the relevant rules and regulations formulated or promulgated by the securities regulatory authorities such as the China Securities Regulatory Commission and the Shanghai Stock Exchange.

Note 13: Gan Zhongru, the actual controller, promised that if the Company violates relevant laws and actually suffers economic losses due to improper actions such as violations of

际遭受经济损失的，实际控制人将预先补偿公司，并将敦促并协助公司依法主张求偿权利。

注14：公司承诺：不为激励对象依本计划获取有关股票期权提供贷款以及其他任何形式的财务资助，包括为其贷款提供担保。

注15：激励对象承诺：若在《激励计划》实施过程中，出现《激励计划》所规定的不能成为激励对象情形的，自不能成为激励对象年度起将放弃参与本计划的权利，并不向公司主张任何补偿；但激励对象可申请行权的股票期权继续有效，尚未确认为可申请行权的股票期权由公司注销。若公司因信息披露文件中有虚假记载、误导性陈述或者重大遗漏，导致不符合授予权益或行使权益安排的，激励对象自相关信息披露文件被确认存在虚假记载、误导性陈述或者重大遗漏后，将由股权激励计划所获得的全部利益返还公司。

the compliance system by the Company's sales staff, the actual controller will compensate the Company in advance, and will urge and assist the Company to claim compensation rights according to law.

Note 14: The Company promises that it will not provide loans and other financial assistance in any form for the incentive objects to obtain relevant stock options according to the plan, including providing guarantees for their loans.

Note 15: Incentive object commitment: in case of failure to become an incentive object as specified in the "Incentive Plan" during the implementation of the "Incentive Plan", the incentive object will give up the right to participate in the plan and will not claim any compensation from the Company from the year when it cannot become an incentive object; However, the stock options that can be applied for exercise by the incentive objects shall continue to be valid, and the stock options that have not been confirmed as exercisable shall be cancelled by the Company. If the Company fails to comply with the arrangement for granting rights and interests or exercising rights and interests due to false records, misleading statements or major omissions in the information disclosure documents, the incentive objects will return all the benefits obtained from the equity incentive plan to the Company after the relevant information disclosure documents are confirmed to have false records, misleading statements or major omissions.

二、报告期内控股股东及其他关联方非经营性占用资金情况

适用 不适用

三、违规担保情况

适用 不适用

四、半年报审计情况

适用 不适用

五、上年年度报告非标准审计意见涉及事项的变化及处理情况

适用 不适用

六、破产重整相关事项

适用 不适用

七、重大诉讼、仲裁事项

本报告期公司有重大诉讼、仲裁事项

本报告期公司无重大诉讼、仲裁事项

八、上市公司及其董事、监事、高级管理人员、控股股东、实际控制人涉嫌违法违规、受到处罚及整改情况

适用 不适用

II Non-operating capital occupation by controlling shareholders and other related parties during the reporting period

Applicable Not Applicable

III Violation of guarantees

Applicable Not Applicable

IV Audit of the semi-annual report

Applicable Not Applicable

V Changes and handling of matters related to non-standard audit opinions in the previous year's annual report

Applicable Not Applicable

VI Matters relating to bankruptcy and reorganization

Applicable Not Applicable

VII Major litigation and arbitration matters

The Company had significant litigation and arbitration matters during the reporting period

The Company had no significant litigation and arbitration matters during the reporting period

VIII Listed company and its directors, supervisors, senior managers, controlling shareholders, and actual controllers suspected of violations of laws and regulations, punishment and rectification

Applicable Not Applicable

九、报告期内公司及其控股股东、实际控制人诚信状况的说明

适用 不适用

IX Description of the integrity of the Company, its controlling shareholders and actual controllers during the reporting period

Applicable Not Applicable

十、重大关联交易

X Significant related-party transactions

(一) 与日常经营相关的关联交易

(I) Related-party transactions related to daily operations

1. 已在临时公告披露且后续实施无进展或变化的事项

1. Matters that have been disclosed in temporary announcements and with no subsequent progress or change

适用 不适用

Applicable Not Applicable

2. 已在临时公告披露，但有后续实施的进展或变化的事项

2. Matters that have been disclosed in temporary announcements and with subsequent progress or change

适用 不适用

Applicable Not Applicable

3. 临时公告未披露的事项

3. Matters have not been disclosed in temporary announcements

适用 不适用

Applicable Not Applicable

(二) 资产收购或股权收购、出售发生的关联交易

(II) Related party transactions arising from asset acquisition or equity acquisition or sale

1. 已在临时公告披露且后续实施无进展或变化的事项

1. Matters that have been disclosed in temporary announcements and with no subsequent progress or change

适用 不适用

Applicable Not Applicable

2. 已在临时公告披露，但有后续实施的进展或变化的事项

2. Matters that have been disclosed in temporary announcements and with subsequent progress or change

适用 不适用

Applicable Not Applicable

3. 临时公告未披露的事项

3. Matters have not been disclosed in temporary announcements

适用 不适用

Applicable Not Applicable

4. 涉及业绩约定的，应当披露报告期内的业绩实现情况

4. In case of performance agreement, the achievement of performance during the reporting period shall be disclosed

适用 不适用

Applicable Not Applicable

(三) 共同对外投资的重大关联交易

1. 已在临时公告披露且后续实施无进展或变化的事项

适用 不适用

2. 已在临时公告披露，但有后续实施的进展或变化的事项

适用 不适用

3. 临时公告未披露的事项

适用 不适用

(四) 关联债权债务往来

1. 已在临时公告披露且后续实施无进展或变化的事项

适用 不适用

2. 已在临时公告披露，但有后续实施的进展或变化的事项

适用 不适用

3. 临时公告未披露的事项

适用 不适用

(五) 公司与存在关联关系的财务公司、公司控股财务公司与关联方之间的金融业务

适用 不适用

(六) 其他重大关联交易

适用 不适用

(III) Significant related transactions of joint external investments

1. Matters that have been disclosed in temporary announcements and with no subsequent progress or change

Applicable Not Applicable

2. Matters that have been disclosed in temporary announcements and with subsequent progress or change

Applicable Not Applicable

3. Matters have not been disclosed in temporary announcements

Applicable Not Applicable

(IV) Related party debts and liabilities

1. Matters that have been disclosed in temporary announcements and with no subsequent progress or change

Applicable Not Applicable

2. Matters that have been disclosed in temporary announcements and with subsequent progress or change

Applicable Not Applicable

3. Matters have not been disclosed in temporary announcements

Applicable Not Applicable

(V) Financial business between the Company and the finance company with which it has an affiliated relationship, the Company's controlling finance company and related parties

Applicable Not Applicable

(VI) Other significant related-party transactions

Applicable Not Applicable

(七) 其他 适用 不适用**(VII) Others** Applicable Not Applicable**十一、重大合同及其履行情况****1. 托管、承包、租赁事项** 适用 不适用**2. 报告期内履行的及尚未履行完毕的重大担保情况** 适用 不适用**3. 其他重大合同** 适用 不适用**XI Significant contracts and their fulfillment****1. Trusteeship, contracting and leasing** Applicable Not Applicable**2. Significant guarantees performed and not yet completed during the reporting period** Applicable Not Applicable**3. Other major contracts** Applicable Not Applicable**十二、其他重大事项的说明** 适用 不适用**XII Description of other significant matters** Applicable Not Applicable

股份变动及股东情况

CHANGES IN SHARES AND SHAREHOLDERS



第七节 股份变动及股东情况

SECTION VII CHANGES IN SHARES AND SHAREHOLDERS

一、股本变动情况

I Changes in share capital

(一) 股份变动情况表

(I) Statement of changes in shares

1. 股份变动情况表

1. Statement of changes in shares

单位：股
Unit: Share

		本次变动前		本次变动增减(+,-)		本次变动后	
		数量	比例(%)	其他	小计	数量	比例(%)
		Quantity	Proportion	Other	Subtotal	Quantity	Proportion
一、有限售条件股份	I. Shares with Trading Limited Conditions	272,994,596	48.62	-3,867,656	-3,867,656	269,126,940	47.93
1. 国家持股	1. Shares Held By State						
2. 国有法人持股	2. Shares Held By Domestic Legal Entity	4,256,033	0.76			4,256,033	0.76
3. 其他内资持股	3. Shares Held by Domestic Capital	238,851,174	42.54	-3,867,656	-3,867,656	234,983,518	41.85
其中：境内非国有法人持股	Of which: Shares Held By Domestic non-state legal entity	55,492,691	9.88	-3,867,656	-3,867,656	51,625,035	9.19
境内自然人持股	Shares Held by Domestic Natutal Person	183,358,483	32.66			183,358,483	32.66
4. 外资持股	4. Shares Held by Foreign Capital	29,887,389	5.32			29,887,389	5.32
其中：境外法人持股	Of which: Shares held by foreign legal entity	29,887,389	5.32			29,887,389	5.32
境外自然人持股	Shares Held by Foreign Natural Person						
二、无限售条件流通股	II. Floating Shares	288,545,404	51.38	3,867,656	3,867,656	292,413,060	52.07
1. 人民币普通股	1. RMB ordinary shares	288,545,404	51.38	3,867,656	3,867,656	292,413,060	52.07
2. 境内上市的外资股	2. Domestically listed foreign shares						
3. 境外上市的外资股	3. Foreign shares listed overseas						
4. 其他	4. Other						
三、股份总数	III. Total number of shares	561,540,000	100.00			561,540,000	100.00

2. 股份变动情况说明

√适用 □不适用

2022年01月21日，公司首次公开发行前限售股259,358股上市流通，详情请查阅公司于2022年01月18日刊登在上海证券交易所网站(www.sse.com.cn)的《甘李药业股份有限公司首次公开发行部分限售股上市流通公告》(公告编号：2022-002)。

2022年03月04日，公司首次公开发行前限售股3,608,298股上市流通，详情请查阅公司于2022年03月01日刊登在上海证券交易所网站(www.sse.com.cn)的《甘李药业股份有限公司首次公开发行部分限售股上市流通公告》(公告编号：2022-008)。

3. 报告期后到半年报披露日期间发生股份变动对每股收益、每股净资产等财务指标的影响（如有）

□适用 √不适用

4. 公司认为必要或证券监管机构要求披露的其他内容

□适用 √不适用

2. Statement on the changes in shares

√Applicable □ Not Applicable

On January 21, 2022, 259,358 shares of the Company's pre-IPO restricted shares were listed for circulation. For details, please refer to the "Announcement on the Listing and Circulation of Some trading limited Shares in the IPO of Gan & Lee Pharmaceutical". (Announcement No. 2022-002) published on the website of the Shanghai Stock Exchange (www.sse.com.cn) on January 18, 2022.

On March 04, 2022, 3,608,298 shares of the Company's pre-IPO restricted shares were listed for circulation, please refer to the "Announcement on the Listing and Circulation of Some trading limited Shares in the IPO of Gan & Lee Pharmaceutical". (Announcement No. 2022-008) published on the website of the Shanghai Stock Exchange (www.sse.com.cn) on March 01, 2022.

3. The impact of share changes on financial indicators such as earnings per share and net assets per share from the reporting period to the disclosure date of the semi-annual report (if any)

□ Applicable √ Not Applicable

4. Other information the Company deems necessary or required by securities regulators to disclose

□ Applicable √ Not Applicable

(二) 限售股份变动情况

√适用 □不适用

(II) Changes in shares with trading limited conditions

√Applicable □ Not Applicable

股东名称	Shareholder Name	期初限售股数 Number of shares with trading limited condition at the beginning of the period	报告期解除限售股数 Number of shares lifted of the period	报告期末限售股数 Number of restricted shares at the end of the period	限售原因 Reasons for restricted sales	解除限售日期 Release date
高林投资	Gaolin Investment	259,358	259,358		首发上市 Initial public offering	2022/01/21
天津启明	Tianjin Qiming	1,661,487	1,661,487		首发上市 Initial public offering	2022/03/04
北京启明	Beijing Qiming	853,186	853,186		首发上市 Initial public offering	2022/03/04
苏州启明	Suzhou Qiming	1,093,625	1,093,625		首发上市 Initial public offering	2022/03/04
合计	Total	3,867,656	3,867,656		/	/

二、股东情况

II Shareholders

(一) 股东总数:

(I) Total number of shareholders:

截止报告期末普通股股东总数(户)	Total number of ordinary shareholders by the end of the reporting period	84,453
截至报告期末表决权恢复的优先股股东总数(户)	The total number of preferred shareholders whose voting rights have been restored by the end of the reporting period	0

(二) 截至报告期末前十名股东、前十名流通股东(或无限售条件股东)持股情况表

(II) Table of shareholdings of top ten shareholders, top ten shareholders of floating shares (or shares without trading limited conditions) by the end of the reporting period

单位：股
Unit: Share

前十名股东持股情况									
Shareholdings of the top ten shareholders									
股东名称(全称)	Shareholder name (full name)	报告期内增减 Increase/Decrease during the reporting period	期末 持股数量 Number of shares held at the end of the period	比例(%) Percentage(%)	持有有限售条件股 份数量 Number of shares held with selling restrictions	质押、标记或冻结情况 Status of shares pledged, tagged or frozen	股份状态 Share status	数量 Number	股东性质 Nature of shareholders
甘忠如	Gan Zhongru		177,135,207	31.54	177,135,207	无 N/A	无 N/A		境内自然人 Domestic Natural Persons
明华创新技术投资(香港)有限公司	MING HUA TECHNOLOGY INVESTMENT (HK) LIMITED	-11,830,120	72,162,693	12.85	15,875,800	无 N/A	无 N/A		境外法人 Overseas Legal Person
北京旭特宏达科技有限公司	Beijing Xute Hongda Technology Co., Ltd.		47,494,437	8.46	47,494,437	无 N/A	无 N/A		境内非国有法人 Domestic Non-state- owned Legal Person
Vast Wintersweet Limited	Vast Wintersweet Limited		34,056,996	6.06	5,777,913	无 N/A	无 N/A		境外法人 Overseas Legal Person
STRONG LINK INTERNATIONAL LIMITED	STRONG LINK INTERNATIONAL LIMITED	-5,591,464	19,577,273	3.49	4,256,033	无 N/A	无 N/A		国有法人 State-owned Legal Person
GS Direct,L.L.C.	GS Direct,L.L.C.	-11,230,745	12,055,144	2.15	3,937,644	无 N/A	无 N/A		境外法人 Overseas Legal Person
北京宽街博华投资中心(有限合伙)	Beijing Kuanjie Bohua Investment Center (L. P)		8,397,341	1.50	2,781,922	无 N/A	无 N/A		其他 Other
香港中央结算公司	Hong Kong Securities Clearing Company Limited	4,283,287	6,388,813	1.14		无 N/A	无 N/A		其他 Other
甘喜茹	Gan Xiru		6,223,276	1.11	6,223,276	无 N/A	无 N/A		境内自然人 Domestic Natural Person
Hillhouse G&L Holdings (HK) Limited	Hillhouse G&L Holdings (HK) Limited	-5,615,001	4,357,832	0.78	4,296,032	无 N/A	无 N/A		境外法人 Overseas Legal Person

单位：股
In Share

前十名无限售条件股东持股情况 Shareholding status of the top ten unlimited conditions shareholders				股份种类及数量 Category and number of shares
股东名称 Shareholder name	持有无限售条件流通股的数量 Numbers of shares held without trading limited conditions	种类 Category	数量 Number	
明华创新技术投资(香港)有限公司 MING HUA TECHNOLOGY INVESTMENT (HK) LIMITED	56,286,893	人民币普通股 RMB ordinary shares	56,286,893	
Vast Wintersweet Limited	28,279,083	人民币普通股 RMB ordinary shares	28,279,083	
STRONG LINK INTERNATIONAL LIMITED	15,321,240	人民币普通股 RMB ordinary shares	15,321,240	
GS Direct,L.L.C.	8,117,500	人民币普通股 RMB ordinary shares	8,117,500	
香港中央结算有限公司	6,388,813	人民币普通股 RMB ordinary shares	6,388,813	
北京宽街博华投资中心(有限合伙)	5,615,419	人民币普通股 RMB ordinary shares	5,615,419	
中国银行股份有限公司一招商国证生物医药指数分级证券投资基金	3,360,321	人民币普通股 RMB ordinary shares	3,360,321	
甘一如	2,215,637	人民币普通股 RMB ordinary shares	2,215,637	
中信里昂资产管理有限公司一睿户资金	1,415,501	人民币普通股 RMB ordinary shares	1,415,501	
中国建设银行股份有限公司一易方达沪深300医药卫生交易型开放式指数证券投资基金	1,201,600	人民币普通股 RMB ordinary shares	1,201,600	

单位：股
In Share

前十名无限售条件股东持股情况			
Shareholder name	Shareholding status of the top ten unlimited conditions shareholders	持有无限售条件流通股的数量 Numbers of shares held without trading limited conditions	股份种类及数量 Category and number of shares 种类 Category 数量 Number
前十大股东中回购专户情况说明	Description of the special account for repurchase among the top ten shareholders	不适用	不适用
上述股东委托表决权、受托表决权、放弃表决权的说明	Explanation on the above-mentioned shareholders' entrusted voting rights, entrusted voting rights and abstention from voting rights	不适用	不适用
上述股东关联关系或一致行动的说	Explanation of the related relationship or concerted action of the above shareholders	公司控股股东、实际控制人甘忠如持有旭特宏达65.02%的股权；甘喜茹为甘忠如胞妹；GS Direct与宽街博华的实际控制人均均为The Goldman Sachs Group, Inc (高盛集团)。除以上情况外，其他股东之间不存在关联关系或一致行动。Gan Zhongru, the controlling shareholder and actual controller of the Company, holds 65.02% of the shares of Xutehonda; Gan Xiru is Gan Zhongru's sister; the actual controllers of GS Direct and Kuanjie Bohua are The Goldman Sachs Group, Inc (Goldman Sachs Group); there is no associated relationship or concerted action among other shareholders.	
表决权恢复的优先股股东及持股数量的说明	Description of preferred shareholders with restored voting rights and the number of shares they hold	无	N/A

前十名有限售条件股东持股数量及限售条件

The number of shares held by the top ten shareholders with trading limited conditions and trading limited conditions

√适用 □不适用

√ Applicable □ Not Applicable

单位：股
Unit: Share

有限售条件股东名称	Name of shareholders with trading limited conditions	持有的有限售条件股份数量	Number of shares with trading limited conditions	有限售条件股份可上市交易情况	Conditions of listing and trading of shares with trading limited conditions	限售条件	Trading limited conditions
可上市交易时间	Available trading hours	新增可上市交易股份数量	The number of newly listed shares				
甘忠如	Gan Zhongru	177,135,207		2023/6/29		自公司股票上市之日起36个月，特定条件下自动延长6个月	36 months from the date of listing of the Company's stock, automatically extended by 6 months under certain conditions
北京旭特宏达科技有限公司	Beijing Xute Hongda Technology Co., Ltd.	47,494,437		2023/6/29		自公司股票上市之日起36个月，特定条件下自动延长6个月	36 months from the date of listing of the Company's stock, automatically extended by 6 months under certain conditions
明华创新技术投资(香港)有限公司	MING HUA TECHNOLOGY INVESTMENT (HK) LIMITED	15,875,800		2021/6/29		目前持有的有限售条件股份属于特定条件下延长股份锁定的情况	The shares with limited sale conditions currently held belong to the situation of extended share locking under specific conditions
甘喜茹	Gan Xiru	6,223,276		2023/6/29		自公司股票上市之日起36个月，特定条件下自动延长6个月	36 months from the date of listing of the Company's stock, automatically extended by 6 months under certain conditions
Vast Wintersweet Limited	Vast Wintersweet Limited	5,777,913		2021/6/29		目前持有的有限售条件股份属于特定条件下延长股份锁定的情况	The shares with limited sale conditions currently held belong to the situation of extended share locking under specific conditions
Hillhouse G&L Holdings(HK) Limited	Hillhouse G&L Holdings(HK)Limited	4,296,032		2021/6/29		目前持有的有限售条件股份属于特定条件下延长股份锁定的情况	The shares with limited sale conditions currently held belong to the situation of extended share locking under specific conditions
S T R O N G L I N K INTERNATIONAL LIMITED	STRONG LINK INTERNATIONAL LIMITED	4,256,033		2021/6/29		目前持有的有限售条件股份属于特定条件下延长股份锁定的情况	The shares with limited sale conditions currently held belong to the situation of extended share locking under specific conditions
GS DIRECT,L.L.C.	GS DIRECT,L.L.C.	3,937,644		2021/6/29		目前持有的有限售条件股份属于特定条件下延长股份锁定的情况	The shares with limited sale conditions currently held belong to the situation of extended share locking under specific conditions

单位：股
Unit: Share

有限售条件股东名称	名称 of shareholders with trading limited conditions	持有的有限售条件股份数量 Number of shares with trading limited conditions	有限售条件股份可上市交易情况 Conditions of listing and trading of shares with trading limited conditions	可上市交易时间 Available trading hours	新增可上市交易股份数量 The number of newly listed shares	限售条件 Trading limited conditions
北京宽街博华投资中心(有限合伙)	Beijing Kuanjie Bohua Investment Center(L.P.)	2,781,922	目前持有的有限售条件股份属于特定条件下延长股份锁定的情况 The shares with limited sale conditions currently held belong to the situation of extended share locking under specific conditions	2021/6/29		
上海景林景麒投资中心(有限合伙)	Shanghai Jinglin Jingqi Investment Center (Limited Partnership)	1,089,349	目前持有的有限售条件股份属于特定条件下延长股份锁定的情况 The shares with limited sale conditions currently held belong to the situation of extended share locking under specific conditions	2021/6/29		
上述股东关联关系或一致行动的说明 Explanation of the related relationship or concerted action of the above shareholders	公司控股股东、实际控制人甘忠如持有旭特宏达65.02%的股权；甘喜茹为甘忠如胞妹；GS Direct与宽街博华的实际控制人均均为The Goldman Sachs Group, Inc (高盛集团)。除以上情况外，其他股东之间不存在关联关系或一致行动。 Gan Zhongru, the Company's controlling shareholder and actual controller, holds 65.02% of Xutehongda's shares; Gan Xiru is Gan Zhongru's sister; The actual controllers of GS Direct and Broad Street Bohua are The Goldman Sachs Group, Inc (Goldman Sachs Group); there is no associated relationship or concerted action among other shareholders.					

- | | |
|--|---|
| <p>(三) 战略投资者或一般法人因配售新股成为前十名股东</p> <p><input type="checkbox"/> 适用 <input checked="" type="checkbox"/> 不适用</p> | <p>(III) Strategic investors or general legal persons who became the top ten shareholders due to placing of new shares</p> <p><input type="checkbox"/> Applicable <input checked="" type="checkbox"/> Not Applicable</p> |
| <p>三、董事、监事和高级管理人员情况</p> | |
| <p>(一) 现任及报告期内离任董事、监事和高级管理人员持股变动情况</p> <p><input type="checkbox"/> 适用 <input checked="" type="checkbox"/> 不适用</p> <p>其它情况说明</p> <p><input type="checkbox"/> 适用 <input checked="" type="checkbox"/> 不适用</p> | <p>(I) Shareholding changes of current and outgoing directors, supervisors and senior managers during the reporting period</p> <p><input type="checkbox"/> Applicable <input checked="" type="checkbox"/> Not Applicable</p> <p>Other</p> <p><input type="checkbox"/> Applicable <input checked="" type="checkbox"/> Not Applicable</p> |
| <p>(二) 董事、监事、高级管理人员报告期内被授予的股权激励情况</p> <p><input type="checkbox"/> 适用 <input checked="" type="checkbox"/> 不适用</p> | <p>(II) Equity incentives granted to directors, supervisors and senior managers during the reporting period</p> <p><input type="checkbox"/> Applicable <input checked="" type="checkbox"/> Not Applicable</p> |
| <p>(三) 其他说明</p> <p><input type="checkbox"/> 适用 <input checked="" type="checkbox"/> 不适用</p> | <p>(III) Other</p> <p><input type="checkbox"/> Applicable <input checked="" type="checkbox"/> Not Applicable</p> |
| <p>四、控股股东或实际控制人变更情况</p> | |
| <p><input type="checkbox"/> 适用 <input checked="" type="checkbox"/> 不适用</p> | <p>(IV) Change of controlling shareholder or actual controller</p> <p><input type="checkbox"/> Applicable <input checked="" type="checkbox"/> Not Applicable</p> |

优先股相关情况

RELEVANT INFORMATION OF PREFERRED SHARES



第八节 优先股相关情况

SECTION VIII RELEVANT INFORMATION OF PREFERRED SHARES

适用 不适用

Applicable Not Applicable

债券相关情况

BOND-RELATED INFORMATION



第九节 债券相关情况

SECTION IX BOND-RELATED INFORMATION

- | | |
|---|--|
| 一、企业债券、公司债券和非金融企业债务融资工具 | I Corporate bonds, corporate bonds and non-financial corporate debt financing instruments |
| <input type="checkbox"/> 适用 <input checked="" type="checkbox"/> 不适用 | <input type="checkbox"/> Applicable <input checked="" type="checkbox"/> Not Applicable |
| 二、可转换公司债券情况 | II Status of convertible bonds |
| <input type="checkbox"/> 适用 <input checked="" type="checkbox"/> 不适用 | <input type="checkbox"/> Applicable <input checked="" type="checkbox"/> Not Applicable |

财务报告

FINANCIAL REPORT



十、财务报表

X Financial statements

合并资产负债表

Consolidated Statement of Financial Position

2022年6月30日
30 June 2022编制单位:甘李药业股份有限公司
Prepared by: Gan & Lee Pharmaceuticals.单位:元 币种:人民币 审计类型:未经审计
Unit: RMB, Unaudited

项目	Item	2022年6月30日 30 June 2022	2021年12月31日 31 December 2021
流动资产:	Current Assets:		
货币资金	Cash and Cash equivalents	3,272,324,325.91	3,305,707,725.80
交易性金融资产	Financial assets held for trading	1,466,002,832.74	1,624,183,495.26
应收账款	Accounts receivable	272,619,257.86	933,817,309.12
应收款项融资	Financing receivables	5,156,964.66	845,608.13
预付款项	Prepayments	49,163,833.67	62,115,672.31
其他应收款	Other receivables	57,840,168.87	6,487,728.39
其中: 应收股利	Including: Dividend receivable	53,078,000.00	
存货	Inventories	732,717,849.16	651,329,199.56
一年内到期的非流动资产	Current portion of non-current assets	312,798,287.67	276,442,945.21
其他流动资产	Other current assets	22,347,836.78	9,513,506.37
流动资产合计	Total current assets	6,190,971,357.32	6,870,443,190.15
非流动资产:	Non-current Assets:		
债权投资	Debt investment		201,358,630.13
其他非流动金融资产	Other non-current financial assets	30,000,000.00	30,000,000.00
固定资产	Fixed assets	1,647,965,906.74	1,704,289,335.05
在建工程	Construction in progress	1,155,974,589.96	874,912,702.42
使用权资产	Right-of-use assets	14,171,223.42	16,168,455.72
无形资产	Intangible assets	287,989,661.23	295,989,757.60
开发支出	Development expenditures	651,577,136.87	576,495,277.97
长期待摊费用	Long-term prepaid expenses	11,507,848.90	12,377,643.77
递延所得税资产	Deferred tax assets	41,208,669.57	30,802,314.01
其他非流动资产	Other non-current assets	386,602,129.95	240,326,171.28
非流动资产合计	Total non-current assets	4,226,997,166.64	3,982,720,287.95
资产总计	Total assets	10,417,968,523.96	10,853,163,478.10

合并资产负债表 (续)

Consolidated Statement of Financial Position(Continued)

项目	Item	2022年6月30日 30 June 2022	2021年12月31日 31 December 2021
流动负债：	Current Liabilities		
应付账款	Accounts payable	50,291,610.77	37,740,865.36
合同负债	Contract liabilities	44,761,549.00	36,563,187.93
应付职工薪酬	Payroll and employee benefits payable	112,874,659.17	135,888,765.67
应交税费	Taxes payable	17,834,233.19	129,688,497.93
其他应付款	Other payables	148,743,063.97	137,580,423.10
其中：应付股利	Including: Dividend payable		
一年内到期的非流动负债	Current portion of non-current liabilities	7,296,649.38	7,954,225.55
其他流动负债	Other current liabilities	167,814.03	115,137.93
流动负债合计	Total current liabilities	381,969,579.51	485,531,103.47
非流动负债：	Non-current Liabilities:		
租赁负债	Lease liabilities	13,246,601.62	12,166,086.58
长期应付款	Long-term payable	10,738,792.95	10,199,292.94
递延收益	Deferred income	165,253,235.68	141,977,135.69
递延所得税负债	Deferred tax liabilities	31,110,712.35	36,147,457.18
非流动负债合计	Total non-current liabilities	220,349,342.60	200,489,972.39
负债合计	Total liabilities	602,318,922.11	686,021,075.86
所有者权益(或股东权益)：	Owners (or Shareholders') Equity:		
实收资本(或股本)	Paid-in capital (or share capital)	561,540,000.00	561,540,000.00
资本公积	Capital reserve	2,486,727,676.15	2,476,158,119.34
其他综合收益	Other comprehensive income	566,776.94	-3,440,036.19
盈余公积	Surplus reserve	291,531,843.96	291,531,843.96
未分配利润	Retained earnings	6,475,445,832.92	6,841,514,967.88
归属于母公司所有者权益(或股东权益)合计	Equity attributable to owners of the parent	9,815,812,129.97	10,167,304,894.99
少数股东权益	Non-controlling interests	-162,528.12	-162,492.75
所有者权益(或股东权益)合计	Total owners' (or shareholders') equity	9,815,649,601.85	10,167,142,402.24
负债和所有者权益(或股东权益)总计	Total Liabilities and Shareholders' Equity	10,417,968,523.96	10,853,163,478.10

公司负责人：
Person in charge of the
Company:

甘忠如
Gan Zhongru

主管会计工作负责人：
Chief accountant:

孙程
Sun Cheng

会计机构负责人：
Head of accounting
department:

周丽
Zhou Li

母公司资产负债表

Parent Company Statement of Financial Position

2022年6月30日
30 June 2022编制单位:甘李药业股份有限公司
Prepared by: Gan & Lee Pharmaceuticals.单位:元 币种:人民币 审计类型:未经审计
Unit: RMB, Unaudited

项目	Item	2022年6月30日 30 June 2022	2021年12月31日 31 December 2021
流动资产:	Current Assets:		
货币资金	Cash and Cash equivalents	3,173,853,968.88	3,211,731,031.65
交易性金融资产	Financial assets held for trading	1,466,002,832.74	1,624,183,495.26
应收账款	Accounts receivable	242,522,377.25	905,398,808.68
应收款项融资	Financing receivables	5,156,964.66	845,608.13
预付款项	Prepayments	42,521,248.02	60,637,904.27
其他应收款	Other receivables	1,549,375,749.40	1,076,315,016.13
其中: 应收股利	Including: Dividend receivable	53,078,000.00	
存货	Inventories	681,213,477.52	610,373,454.49
一年内到期的非流动资产	Current portion of non-current assets	312,798,287.67	276,442,945.21
其他流动资产	Other current assets	14,737,471.32	
流动资产合计	Total current assets	7,488,182,377.46	7,765,928,263.82
非流动资产:	Non-current Assets:		
债权投资	Debt investment		201,358,630.13
长期股权投资	Long-term equity investment	601,532,431.91	547,874,695.53
其他非流动金融资产	Other non-current financial assets	30,000,000.00	30,000,000.00
固定资产	Fixed assets	1,497,249,088.24	1,564,458,317.92
在建工程	Construction in progress	371,547,821.54	333,483,822.21
使用权资产	Right-of-use assets	275,264.15	396,407.28
无形资产	Intangible assets	158,005,003.89	163,997,895.92
开发支出	Development expenditures	648,698,091.52	576,495,277.97
其他非流动资产	Other non-current assets	37,260,132.69	26,024,483.49
非流动资产合计	Total non-current assets	3,344,567,833.94	3,444,089,530.45
资产总计	Total assets	10,832,750,211.40	11,210,017,794.27

母公司资产负债表 (续)

Parent Company Statement of Financial Position (Continued)

项目	Item	2022年6月30日 30 June 2022	2021年12月31日 31 December 2021
流动负债：	Current Liabilities		
应付账款	Accounts payable	38,616,175.60	30,463,683.52
合同负债	Contract liabilities	44,138,500.73	35,759,431.75
应付职工薪酬	Payroll and employee benefits payable	103,130,168.23	124,798,359.49
应交税费	Taxes payable	15,688,678.38	127,306,763.06
其他应付款	Other payables	192,960,627.63	184,945,228.34
其中：应付股利	Including: Dividend payable		
一年内到期的非流动负债	Current portion of non-current liabilities	2,462,606.26	2,906,400.35
其他流动负债	Other current liabilities	86,820.77	57,064.72
流动负债合计	Total current liabilities	397,083,577.60	506,236,931.23
非流动负债：	Non-current Liabilities:		
租赁负债	Lease liabilities	184,039.22	129,514.88
长期应付款	Long-term payable	10,608,792.95	10,199,292.94
递延收益	Deferred income	56,801,824.03	60,040,735.39
递延所得税负债	Deferred tax liabilities	31,110,712.35	36,147,457.18
非流动负债合计	Total non-current liabilities	98,705,368.55	106,517,000.39
负债合计	Total liabilities	495,788,946.15	612,753,931.62
所有者权益(或股东权益)：	Owners (or Shareholders') Equity:		
实收资本(或股本)	Paid-in capital (or share capital)	561,540,000.00	561,540,000.00
资本公积	Capital reserve	2,486,726,915.98	2,476,157,359.17
盈余公积	Surplus reserve	291,531,843.96	291,531,843.96
未分配利润	Retained earnings	6,997,162,505.31	7,268,034,659.52
所有者权益(或股东权益)合计	Total owners' (or shareholders') equity	10,336,961,265.25	10,597,263,862.65
负债和所有者权益(或股东权益)总计	Total Liabilities and Shareholders' Equity	10,832,750,211.40	11,210,017,794.27

公司负责人：甘忠如
Person in charge of the Company: Gan Zhongru

主管会计工作负责人：孙程
Chief accountant: Sun Cheng

会计机构负责人：周丽
Head of accounting department: Zhou Li

合并利润表

Consolidated Income Statement

2022年1—6月
January-June 2022编制单位:甘李药业股份有限公司
Prepared by: Gan & Lee Pharmaceuticals.单位:元 币种:人民币 审计类型:未经审计
Unit: RMB, Unaudited

项目	Item	2022年半年度 2022H1	2021年半年度 2021H1
一、营业总收入	I. Total Revenue	834,799,215.95	1,475,429,759.92
其中:营业收入	Including: Operating income	834,799,215.95	1,475,429,759.92
二、营业总成本	II. Total Operating Costs	1,043,926,486.79	1,041,120,728.39
其中:营业成本	Including: Operating costs	152,985,808.84	171,918,319.11
税金及附加	Taxes and surcharges	11,509,213.22	11,765,627.60
销售费用	Selling expenses	564,861,191.77	491,640,000.50
管理费用	General and administrative expenses	117,613,719.39	152,936,730.76
研发费用	R&D expenses	244,429,009.16	223,236,010.38
财务费用	Financial expenses	-47,472,455.59	-10,375,959.96
加:其他收益	Add: Other income	11,146,654.64	37,595,449.37
投资收益(损失以“-”号填列)	Investment income/(loss) (loss is indicated with "-")	71,679,397.70	26,150,980.22
公允价值变动收益(损失以“-”号填列)	Gain/(loss) on the changes in fair value (loss is indicated with "-")	-67,177,603.73	-22,507,175.56
信用减值损失(损失以“-”号填列)	Credit impairment losses (loss is indicated with "-")	-8,117,245.74	-3,036,935.65
资产减值损失(损失以“-”号填列)	Assets impairment losses (loss is indicated with "-")		
资产处置收益(损失以“-”号填列)	Gain/(loss) from disposal of assets (loss is indicated with "-")	-1,521.66	504,576.83
三、营业利润(亏损以“-”号填列)	III. Operating Profit (loss is indicated with "-")	-201,597,589.63	473,015,926.74
加:营业外收入	Add: Non-operating income	906,498.09	63,506.52
减:营业外支出	Less: Non-operating expenses	3,174,373.31	3,197,102.01
四、利润总额(亏损总额以“-”号填列)	IV. Profit Before Tax (loss is indicated with "-")	-203,865,464.85	469,882,331.25
减:所得税费用	Less: Income tax expense	-6,258,294.52	97,112,931.67
五、净利润(净亏损以“-”号填列)	V. Net Profit (loss is indicated with "-")	-197,607,170.33	372,769,399.58
(一)按经营持续性分类	(I) Categorized by operation continuity		
1.持续经营净利润(净亏损以“-”号填列)	1. Net profit from continuing operations (loss is indicated with "-")	-197,607,170.33	372,769,399.58

合并利润表 (续)

Consolidated Income Statement (Continued)

项目	Item	2022年半年度 2022H1	2021年半年度 2021H1
(二) 按所有权归属分类	(II) Categorized by ownership		
1. 归属于母公司股东的净利润 (净亏损以“-”号填列)	1. Net profit attributable to owners of the parent (loss is indicated with "-")	-197,607,134.96	372,769,630.83
2. 少数股东损益(净亏损以“-”号填列)	2. Net profit attributable to non- controlling interests (loss is indicated with "-")	-35.37	-231.25
六、其他综合收益的税后净额	VI. Other Comprehensive Income, Net of Tax	4,006,813.13	-2,199,935.15
(一) 归属母公司所有者的其他综合收益的税后净额	(I) Other comprehensive income, net of tax, attributable to owners of the parent	4,006,813.13	-2,199,935.15
1. 不能重分类进损益的其他综合收益	1. Other comprehensive income will not be reclassified to profit or loss		
2. 将重分类进损益的其他综合收益	2. Other comprehensive income to be reclassified to profit or loss	4,006,813.13	-2,199,935.15
(1) 外币财务报表折算差额	(1) Exchange differences on translation of foreign currency financial statements	4,006,813.13	-2,199,935.15
(二) 归属于少数股东的其他综合收益的税后净额	(II) Other comprehensive income, net of tax, attributable to non-controlling interests		
七、综合收益总额	VII. Total Comprehensive Income	-193,600,357.20	370,569,464.43
(一) 归属于母公司所有者的综合收益总额	(I) Total comprehensive income attributable to owners of the parent	-193,600,321.83	370,569,695.68
(二) 归属于少数股东的综合收益总额	(II) Total comprehensive income attributable to non-controlling interests	-35.37	-231.25
八、每股收益：	VIII. Earnings Per Share:		
(一) 基本每股收益(元/股)	(I) Basic earnings per share (RMB/share)	-0.35	0.66
(二) 稀释每股收益(元/股)	(2) Diluted earnings per share (RMB/share)	-0.35	0.66

本期发生同一控制下企业合并的，被合并方在合并前实现的净利润为：0元，上期被合并方实现的净利润为：0元。

Amongst business combination under common control in the current period, the net profit realized by the mergee prior to the combination is [0] RMB (previous year: [0] RMB).

公司负责人：	甘忠如	主管会计工作负责人：	孙程	会计机构负责人：	周丽
Person in charge of the Company:	Gan Zhongru	Chief accountant:	Sun Cheng	Head of accounting department:	Zhou Li

母公司利润表

Income Statement of the Parent Company

2022年1-6月
January - June 2022

编制单位:甘李药业股份有限公司
Prepared by: Gan & Lee Pharmaceuticals.

单位:元 币种:人民币 审计类型:未经审计
Unit: RMB, Unaudited

项目	Item	2022半年度 2022H1	2021半年度 2021H1
一、营业收入	I. Operating Revenue	786,339,301.13	1,421,130,567.84
减:营业成本	Less: Operating costs	127,774,425.01	134,351,776.04
税金及附加	Taxes and surcharges	9,491,785.85	9,979,638.24
销售费用	Selling expenses	559,069,913.76	462,448,347.51
管理费用	General and administrative expenses	69,223,577.64	113,199,192.19
研发费用	R&D expenses	196,935,328.97	184,262,007.05
财务费用	Financial expenses	-66,521,168.48	-18,823,149.74
加:其他收益	Add: Other income	8,681,763.48	35,378,888.19
投资收益(损失以“-”号填列)	Investment income/(loss) (loss is indicated with "-")	71,679,397.70	26,150,980.22
公允价值变动收益(损失以“-”号填列)	Gain/(loss) on the changes in fair value (loss is indicated with "-")	-67,177,603.73	-22,507,175.56
信用减值损失(损失以“-”号填列)	Credit impairment losses (loss is indicated with "-")	640,756.48	-2,690,026.25
资产减值损失(损失以“-”号填列)	Assets impairment losses (loss is indicated with "-")		
资产处置收益(损失以“-”号填列)	Gain/(loss) from disposal of assets (loss is indicated with "-")		620,762.83
二、营业利润(亏损以“-”号填列)	II. Operating Profit (loss is indicated with "-")	-95,810,247.69	572,666,185.98
加:营业外收入	Add: Non-operating income	645,034.62	24,652.59
减:营业外支出	Less: Non-operating expenses	3,134,371.15	569,783.66
三、利润总额(亏损总额以“-”号填列)	III. Profit Before Tax (loss is indicated with "-")	-98,299,584.22	572,121,054.91
减:所得税费用	Less: Income tax expense	4,110,569.99	105,765,481.30
四、净利润(净亏损以“-”号填列)	IV. Net Profit (loss is indicated with "-")	-102,410,154.21	466,355,573.61
(一)持续经营净利润(净亏损以“-”号填列)	(I) Net profit from continuing operations (loss is indicated with "-")	-102,410,154.21	466,355,573.61
五、其他综合收益的税后净额	V. Other Comprehensive Income, Net of Tax		
六、综合收益总额	VI. Total Comprehensive Income	-102,410,154.21	466,355,573.61

合并现金流量表

Consolidated Statement of Cash Flows

2022年1—6月
January-June 2022编制单位:甘李药业股份有限公司
Prepared by: Gan & Lee Pharmaceuticals.单位:元 币种:人民币 审计类型:未经审计
Unit: RMB, Unaudited

项目	Item	2022年半年度 2022H1	2021年半年度 2021H1
一、经营活动产生的现金流量:	I. Cash Flows from Operating Activities:		
销售商品、提供劳务收到的现金	Cash receipts from the sale of goods and the rendering of services	1,497,577,712.07	1,597,487,651.08
收到的税费返还	Tax refunds received	58,309,647.06	2,997,504.89
收到其他与经营活动有关的现金	Cash received relating to other operating activities	39,499,830.12	59,976,053.98
经营活动现金流入小计	Subtotal of cash inflows from operating activities	1,595,387,189.25	1,660,461,209.95
购买商品、接受劳务支付的现金	Cash paid for purchase of goods and services	269,892,716.67	243,505,297.20
支付给职工及为职工支付的现金	Cash paid to and on behalf of employee	329,947,728.83	299,396,736.11
支付的各项税费	Cash paid for taxes	189,590,640.43	192,511,650.15
支付其他与经营活动有关的现金	Cash paid relating to other operating activities	524,708,118.16	479,051,775.76
经营活动现金流出小计	Sub-total of cash outflows from operating activities	1,314,139,204.09	1,214,465,459.22
经营活动产生的现金流量净额	Net cash flow from operating activities	281,247,985.16	445,995,750.73
二、投资活动产生的现金流量:	II. Cash Flows from Investing Activities:		
收回投资收到的现金	Cash received from disposal of investments	2,283,000,000.00	1,390,000,000.00
取得投资收益收到的现金	Cash receipts from investment income	56,261,936.30	46,989,068.04
处置固定资产、无形资产和其他长期资产收回的现金净额	Net proceeds from disposal of fixed assets intangible assets and other long-term assets		690,389.38
收到其他与投资活动有关的现金	Cash received relating to other investing activities		
投资活动现金流入小计	Subtotal of cash inflows from investing activities	2,339,261,936.30	1,437,679,457.42
购建固定资产、无形资产和其他长期资产支付的现金	Purchase of fixed assets, intangible assets and other non-current assets	447,541,478.08	382,408,209.11
投资支付的现金	Cash paid for investments	2,286,000,000.00	830,000,200.00
支付其他与投资活动有关的现金	Cash paid relating to other investing activities	28,195,751.65	370,045,000.00
投资活动现金流出小计	Sub-total of cash outflows from investing activities	2,761,737,229.73	1,582,453,409.11
投资活动产生的现金流量净额	Net cash flow from investing activities	-422,475,293.43	-144,773,951.69

合并现金流量表 (续)

Consolidated Statement of Cash Flows (Continued)

项目	Item	2022年半年度 2022H1	2021年半年度 2021H1
三、筹资活动产生的现金流量：	III. Cash Flows from Financing Activities:		
吸收投资收到的现金	Cash received from investments		
筹资活动现金流入小计	Subtotal of cash inflows from financing activities		
分配股利、利润或偿付利息支付的现金	Cash payments for distribution of dividends or profit and interest expenses	162,599,206.44	151,927,461.12
支付其他与筹资活动有关的现金	Cash payments relating to other financing activities	499,438.58	2,330,641.16
筹资活动现金流出小计	Sub-total of cash outflows from financing activities	163,098,645.02	154,258,102.28
筹资活动产生的现金流量净额	Net cash flow from financing activities	-163,098,645.02	-154,258,102.28
四、汇率变动对现金及现金等价物的影响	IV. Effect of Exchange Rate Changes on Cash and Cash Equivalents	3,776,092.87	13,823,274.86
五、现金及现金等价物净增加额	V. Net Increase in Cash and Cash Equivalents	-300,549,860.42	160,786,971.62
加：期初现金及现金等价物余额	Add: Cash and cash equivalents at beginning of year	639,768,344.07	291,335,227.78
六、期末现金及现金等价物余额	VI. Cash and Cash Equivalents at End of Year	339,218,483.65	452,122,199.40

公司负责人：甘忠如

Gan Zhongru

主管会计工作负责人：孙程

Chief accountant: Sun Cheng

会计机构负责人：周丽

Head of accounting department: Zhou Li

Person in charge of the Company:

母公司现金流量表

Parent Company Statement of Cash Flows

2022年1—6月
January-June 2022编制单位:甘李药业股份有限公司
Prepared by: Gan & Lee Pharmaceuticals.单位:元 币种:人民币 审计类型:未经审计
Unit: RMB, Unaudited

项目	Item	2022年半年度 2022H1	2021年半年度 2021H1
一、经营活动产生的现金流量:	I. Cash Flows from Operating Activities:		
销售商品、提供劳务收到的现金	Cash receipts from the sale of goods and the rendering of services	1,454,128,828.26	1,564,816,838.85
收到其他与经营活动有关的现金	Cash received relating to other operating activities	556,323,958.05	181,810,643.55
经营活动现金流入小计	Subtotal of cash inflows from operating activities	2,010,452,786.31	1,746,627,482.40
购买商品、接受劳务支付的现金	Cash paid for purchase of goods and services	231,533,937.29	204,248,710.55
支付给职工及为职工支付的现金	Cash paid to and on behalf of employee	281,665,383.51	248,388,985.18
支付的各项税费	Cash paid for taxes	187,324,242.17	173,908,425.75
支付其他与经营活动有关的现金	Cash paid relating to other operating activities	1,037,311,219.10	728,989,556.46
经营活动现金流出小计	Subtotal of cash outflows from operating activities	1,737,834,782.07	1,355,535,677.94
经营活动产生的现金流量净额	Net cash flow from operating activities	272,618,004.24	391,091,804.46
二、投资活动产生的现金流量:	II. Cash Flows from Investing Activities:		
收回投资收到的现金	Cash received from disposal of investments	2,283,000,000.00	1,390,000,000.00
取得投资收益收到的现金	Cash receipts from investment income	56,261,936.30	46,989,068.04
处置固定资产、无形资产和其他长期资产收回的现金净额	Net proceeds from disposal of fixed assets intangible assets and other long-term assets		678,000.00
收到其他与投资活动有关的现金	Cash received relating to other investing activities	71,376,733.82	23,160,000.00
投资活动现金流入小计	Subtotal of cash inflows from investing activities	2,410,638,670.12	1,460,827,068.04
购建固定资产、无形资产和其他长期资产支付的现金	Purchase of fixed assets, intangible assets and other non-current assets	65,224,924.66	197,852,615.20
投资支付的现金	Cash paid for investments	2,339,301,127.56	917,965,075.90
支付其他与投资活动有关的现金	Cash paid relating to other investing activities	422,635,575.47	579,536,669.06
投资活动现金流出小计	Sub-total of cash outflows from investing activities	2,827,161,627.69	1,695,354,360.16
投资活动产生的现金流量净额	Net cash flow from investing activities	-416,522,957.57	-234,527,292.12

母公司现金流量表(续)

Parent Company Statement of Cash Flows (Continued)

项目	Item	2022年半年度 2022H1	2021年半年度 2021H1
三、筹资活动产生的现金流量：	III. Cash Flows from Financing Activities:		
吸收投资收到的现金	Cash received from investments		
筹资活动现金流入小计	Subtotal of cash inflows from financing activities		
分配股利、利润或偿付利息支付的现金	Cash payments for distribution of dividends or profit and interest expenses	162,599,206.44	151,927,461.12
支付其他与筹资活动有关的现金	Cash payments relating to other financing activities	61,669.49	
筹资活动现金流出小计	Sub-total of cash outflows from financing activities	162,660,875.93	151,927,461.12
筹资活动产生的现金流量净额	Net cash flow from financing activities	-162,660,875.93	-151,927,461.12
四、汇率变动对现金及现金等价物的影响	IV. Effect of Exchange Rate Changes on Cash and Cash Equivalents	-112,844.33	-504,849.61
五、现金及现金等价物净增加额	V. Net Increase in Cash and Cash Equivalents	-306,678,673.59	4,132,201.61
加：期初现金及现金等价物余额	Add: Cash and cash equivalents at beginning of year	587,007,535.57	266,657,782.88
六、期末现金及现金等价物余额	VI. Cash and Cash Equivalents at End of Year	280,328,861.98	270,789,984.49

公司负责人：	甘忠如	主管会计工作负责人：	孙程	会计机构负责人：	周丽
Person in charge of the Company:	Gan Zhongru	Chief accountant:	Sun Cheng	Head of accounting department:	Zhou Li

Consolidated Statement of Changes in Equity

合并所有者权益变动表

2022年1 - 6月
January - June 2022编制单位：甘李药业股份有限公司
Prepared by: Gan & Lee Pharmaceuticals.单位：元 币种：人民币 审计类型：未经审计
Unit: RMB, Unaudited

项目	Item	2022半年度 2022H1					少数股东权益 Non-controlling interests	所有者权益合计 Total shareholders' equity	
		实收资本(或股本) Paid-in capital (or share)	资本公积 Capital reserve	其他综合收益 Other comprehensive income	盈余公积 Surplus reserve	未分配利润 Retained earnings			小计 Sub-total
一、上年年末余额	I Closing balance of last year	561,540,000.00	2,476,158,119.34	-3,440,036.19	291,531,843.96	6,841,514,967.88	10,167,304,894.99	-162,492.75	10,167,142,402.24
二、本年期初余额	II Opening balance of current year	561,540,000.00	2,476,158,119.34	-3,440,036.19	291,531,843.96	6,841,514,967.88	10,167,304,894.99	-162,492.75	10,167,142,402.24
三、本期增减变动金额(减少以“-”号填列)	III Increase/decrease for current year		10,569,556.81	4,006,813.13		-366,069,134.96	-351,492,765.02	-35.37	-351,492,800.39
(一) 综合收益总额	(I) Total comprehensive income			4,006,813.13		-197,607,134.96	-193,600,321.83	-35.37	-193,600,357.20
(二) 所有者投入和减少资本	(II) Owner's contributions to and withdrawals of capital		10,569,556.81				10,569,556.81		10,569,556.81
1. 股份支付计入所有者权益的金额	1. Amount of share-based payment included in owner's equity		10,569,556.81				10,569,556.81		10,569,556.81
(三) 利润分配	(III) Profits distribution					-168,462,000.00	-168,462,000.00		-168,462,000.00
1. 对所有者(或股东)的分配	1. Others Distribution to owners (or shareholders)					-168,462,000.00	-168,462,000.00		-168,462,000.00
四、本期末余额	IV Closing balance of current year	561,540,000.00	2,486,727,676.15	566,776.94	291,531,843.96	6,475,445,832.92	9,815,812,129.97	-162,528.12	9,815,649,601.85

项目	2021半年度 2021H1					少数股东权益 Non-controlling interests	所有者权益合计 Total shareholders' equity	
	归属于母公司所有者权益 Equity attributable to parent company							
Item	实收资本(或股本) Paid-in capital (or share capital)	资本公积 Capital reserve	其他综合收益 Other comprehensive income	盈余公积 Surplus reserve	未分配利润 Retained earnings	小计 Sub-total		
一、上年年末余额	561,540,000.00	2,473,623,419.43	-1,550,987.58	291,531,843.96	5,613,376,105.59	8,938,520,381.40	-162,275.22	8,938,358,106.18
二、本年期初余额	561,540,000.00	2,473,623,419.43	-1,550,987.58	291,531,843.96	5,613,376,105.59	8,938,520,381.40	-162,275.22	8,938,358,106.18
三、本期增减变动金额 (减少以“-”号填列)			-2,199,935.15	148,153,630.83		145,953,695.68	-231.25	145,953,464.43
(一) 综合收益总额			-2,199,935.15	372,769,630.83		370,569,695.68	-231.25	370,569,464.43
(二) 所有者投入和减少资本								
(三) 利润分配								
1. 对所有者(或股东)的分配								
四、本期末余额	561,540,000.00	2,473,623,419.43	-3,750,922.73	291,531,843.96	5,761,529,736.42	9,084,474,077.08	-162,506.47	9,084,311,570.61

公司负责人：
Person in charge of the Company:

甘忠如
Gan Zhongru

主管会计工作负责人：
Chief accountant:

孙程
Sun Cheng

会计机构负责人：
Head of accounting department:

周丽
Zhou Li

母公司所有者权益变动表

Parent Company Statement of Changes in Equity

2022年1 - 6月
January - June 2022编制单位：甘李药业股份有限公司
Prepared by: Gan & Lee Pharmaceuticals.单位：元 币种：人民币 审计类型：未经审计
Unit: RMB; Unaudited

项目	Item	2022半年度 2022H1				
		实收资本(或股本) Paid-in capital (or share capital)	资本公积 Capital reserve	盈余公积 Surplus reserve	未分配利润 Retained earnings	所有者权益合计 Total shareholders' equity
一、上年年末余额	I Closing balance of last year	561,540,000.00	2,476,157,359.17	291,531,843.96	7,268,034,659.52	10,597,263,862.65
二、本年期初余额	II Opening balance of current year	561,540,000.00	2,476,157,359.17	291,531,843.96	7,268,034,659.52	10,597,263,862.65
三、本期增减变动金额(减少 以“一”号填列)	III Increase/decrease for current year		10,569,556.81		-270,872,154.21	-260,302,597.40
(一) 综合收益总额	(I) Total comprehensive income				-102,410,154.21	-102,410,154.21
(二) 所有者投入和减少资本	(II) Owner's contributions to and withdrawals of capital		10,569,556.81			10,569,556.81
1. 股份支付计入所有者权益 的金额	1. Amount of share-based payment included in owner's equity		10,569,556.81			10,569,556.81
(三) 利润分配	(III) Profits distribution				-168,462,000.00	-168,462,000.00
1. 对所有者(或股东)的分配	1. Others Distribution to owners(or shareholders)				-168,462,000.00	-168,462,000.00
四、本期期末余额	IV Closing balance of current year	561,540,000.00	2,486,726,915.98	291,531,843.96	6,997,162,505.31	10,336,961,265.25

项目	Item	2021半年度 2021H1				所有者权益合计 Total shareholders' equity
		实收资本(或股本) Paid-in capital (or share capital)	资本公积 Capital reserve	盈余公积 Surplus reserve	未分配利润 Retained earnings	
一、上年年末余额	I Closing balance of last year	561,540,000.00	2,473,622,659.26	291,531,843.96	5,863,070,160.01	9,189,764,663.23
二、本年期初余额	II Opening balance of current year	561,540,000.00	2,473,622,659.26	291,531,843.96	5,863,070,160.01	9,189,764,663.23
三、本期增减变动金额(减少以“一”号填列)	III Increase/decrease for current year				241,739,573.61	241,739,573.61
(一) 综合收益总额	(I) Total comprehensive income				466,355,573.61	466,355,573.61
(二) 所有者投入和减少资本	(II) Owner's contributions to and withdrawals of capital					
(三) 利润分配	(III) Profits distribution				-224,616,000.00	-224,616,000.00
1. 对所有者(或股东)的分配	1. Others Distribution to owners(or shareholders)				-224,616,000.00	-224,616,000.00
四、本期期末余额	IV Closing balance of current year	561,540,000.00	2,473,622,659.26	291,531,843.96	6,104,809,733.62	9,431,504,236.84

公司负责人：
Person in charge of the Company:

甘忠如
Gan Zhongru

主管会计工作负责人：
Chief accountant:

孙程
Sun Cheng

会计机构负责人：
Head of accounting department:

周丽
Zhou Li



SCIENCE & EXCELLENCE

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