Company Code: 688177
Company Abbreviation: Bio-Thera

Bio-Thera Solutions, Ltd

2024 Annual Report

Janssen Biotech, Inc.
Exhibit 2022
Accord v. Janssen
IPR2026-00256, -00257, -00258, -00259
Ex. 2022-001

Important Notice

1. The Company's Board of Directors, Supervisory Board, all directors, supervisors, and senior management guarantee the truthfulness, accuracy, and completeness of the content in this annual report. They confirm there is no false record, misleading statement, or material omission, and they bear individual and joint legal liabilities.

2. The Company was not profitable at the time of listing and has not yet achieved profitability

□ Yes √ No

3. Major Risk Notice

The Company has elaborated in detail on factors including risks related to the Company's core competitiveness, operational risks, industry risks, and macro-environmental risks in this report. Please refer to Section III, "Management's Discussion and Analysis," specifically subsection "IV. Risk Factors."

4. All directors of the Company attended the Board of Directors meeting.

5. The audit report issued by Lixin Certified Public Accountants (Special General Partnership) for our company is a standard unqualified audit report.

6. LI SHENGFENG (Li Shengfeng), the person in charge of the Company, Zhan Xianhong, the person in charge of accounting work, and Shi Lihua, the person in charge of the accounting establishment (chief accounting officer), declare: They guarantee the truthfulness, accuracy, and completeness of the financial report in this annual report.

7. Profit distribution plan or capital reserve conversion plan for the reporting period approved by the Board resolution

The Company’s 2024 annual profit distribution plan is as follows: No profit will be distributed, and no capital reserve will be converted into share capital. The above profit distribution plan has been reviewed and approved by the Company's Second Board of Directors at its Twenty-Fourth Meeting and is pending approval by the Company's General Shareholders Meeting.

8. Existence of important matters such as special arrangements for corporate governance

□ Applicable √ Not Applicable

9. Risk Statement Regarding Forward-Looking Statements

√ Applicable □ Not Applicable

The forward-looking statements concerning the Company's future plans, development strategies, etc., contained in this report do not constitute substantive commitments to investors by the Company. Investors are advised to pay attention to investment risks.

10. Existence of non-operating fund occupation by the controlling shareholder and other related parties

No

11. Existence of external guarantees provided in violation of prescribed decision-making procedures

No

12. Existence of more than half of the directors being unable to guarantee the truthfulness, accuracy, and completeness of the disclosed annual report

No

13. Other

□ Applicable √ Not Applicable

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List of Documents for Reference	Financial report bearing the signatures and seals of the legal representative of the Company, the person in charge of accounting work, and the person in charge of the accounting establishment.
	The original audit report bearing the accounting firm’s seal and the signatures and seals of the certified public accountants.
	Original copies of all publicly disclosed Company documents and announcement drafts during the reporting period.

Section III Management's Discussion and Analysis

I. Discussion and Analysis of Operations

The Company persists in innovation-driven development, focusing on the research and development of innovative drugs and biosimilars, committed to providing safe, effective, and affordable high-quality medicines for global patients, meeting the treatment needs of major diseases. In 2024, the Company's R&D projects progressed as planned, with multiple products achieving significant milestones. Overseas licensing collaborations proceeded smoothly, further strengthening the Company's core competitiveness.

（1） Products Approved for Marketing in Multiple Regions, R&D Innovation Steadily Advances

During the reporting period, the Company's first national Class 1 innovative drug BETAGRIN® (Bevifibatide Citrate Injection) received marketing approval from the NMPA, offering a new antiplatelet therapy option for acute coronary syndrome patients undergoing percutaneous coronary intervention (PCI). BAT1706 (bevacizumab) successfully received marketing approval from the EMA and ANVISA, achieving approvals in China, the U.S., Europe, and Brazil, becoming the first and currently only domestically produced bevacizumab biosimilar approved by the FDA, EMA, and ANVISA. BAT1806 (tocilizumab) successfully received marketing approval from the EMA, achieving approvals in China, the U.S., and Europe, becoming the first and currently only domestically produced tocilizumab biosimilar approved by the FDA and EMA.

Company R&D projects progressed steadily. During the reporting period, marketing applications for BAT2206 (ustekinumab) submitted to the NMPA, FDA, and EMA were all accepted. The marketing authorization application for BAT2306 (secukinumab) was accepted by the NMPA in January 2025. Marketing applications for BAT2506 (golimumab) were accepted by the EMA and NMPA in January and March 2025, respectively. BAT5906 completed enrollment for its wet age-related macular degeneration (wAMD) clinical Phase III study. The I/III phase clinical study for BAT3306 (pembrolizumab) in patients with advanced non-squamous non-small cell lung cancer progressed smoothly. The clinical trial application for BAT2406 (dupilumab) was approved by the NMPA in August, marking China's first approved clinical trial for a dupilumab biosimilar.

（2） Global market coverage continues to expand, driving steady revenue growth.

The Company has a global presence and actively seeks collaborations to explore overseas markets. During the reporting period, the Company engaged in global collaborations for multiple products across various regions: The Company granted Macter International Limited exclusive distribution and sales rights for BAT1706 (bevacizumab) in Pakistan and Afghanistan markets. The Company granted SteinCares exclusive distribution and sales rights for BAT2506 (golimumab), BAT2606 (mepolizumab), and BAT2306 (secukinumab) in Brazil and other Latin American markets. The Company granted STADA Arzneimittel AG exclusive product commercialization rights for BAT2506 (golimumab) in the EU, UK, Switzerland, and other European markets. The Company granted Gedeon Richter Plc. exclusive product commercialization rights for BAT2206 (ustekinumab)in the EU, UK, Switzerland, Australia, and other European markets, and granted TABUK exclusive product commercialization rights for BAT2206 (ustekinumab) in Saudi Arabia markets. The Company granted Pharmapark LLC exclusive product commercialization rights for BAT2306 (secukinumab) in Russia and other CIS countries.

During the reporting period, the Company successfully passed re-certification as a High-Tech Enterprise, was awarded the title of Guangdong Provincial Manufacturing Champion Enterprise, and QLETLI® was awarded the 2024 Guangdong Provincial Manufacturing Single-Item Champion Product. All 4 of the Company's marketed products have been included in the “Guangzhou Innovative Drug and Medical Device

Product Directory" product list. In the future, the Company will continue its efforts, hoping to provide safe, effective, and affordable biologics to global patients in need.

（3） Production Line Upgrades Continue to Advance, Supporting Product Development

The Company has achieved commercial production of QLETLI®, POBEVCY®, TOFIDENCE®, and BETAGRIN®, and possesses the experience and capability for organizing commercial production. At the same time, the Company has established a comprehensive GMP management system. The requirements for production quality management standards are benchmarked against international advanced levels. The Company has passed GMP certifications and routine inspections by global core regulators, including the NMPA, FDA, EMA, and ANVISA, achieving full coverage of market access qualifications for major pharmaceutical markets such as China, the United States, the European Union, and Latin America.

During the reporting period, the Company continued to advance the Yonghe Phase 2 expansion project. The total capacity of the drug substance production lines has reached 66,500L, including: 6 units of 6,000L stainless steel bioreactors with their supporting 2 downstream purification production lines; 4 units of 4,000L stainless steel bioreactors with their supporting downstream purification production lines; 2 units of 3,500L stainless steel bioreactors with their supporting downstream purification production lines; 3 units of 2,000L single-use bioreactors with their supporting downstream purification lines; and 3 units of 500L single-use bioreactors with their supporting downstream purification production lines. Additionally, the facility includes: 1 unit of a 200L antibody-drug conjugate (ADC) reaction vessel with its supporting isolator system and purification production line; 1 vial sterile injection solution washing-drying-filling-sealing integrated production line; 1 pre-filled syringe filling production line; 1 lyophilized formulation production line; 1 intelligent isolator-based high-speed integrated line for pre-filled injections; and 1 high-speed integrated vial line. Moreover, the R&D center located on Bio-Island is expected to be fully operational in 2025, further accelerating the Company's drug discovery and development processes.

（4） Building a Lean Management Model and Continuously Strengthening the Talent Pipeline

The Company consistently places enterprise management at the core of its strategy, continuously optimizing management systems covering key areas such as R&D management and quality management. This comprehensive effort enhances the Company's scientific management level and risk prevention and control capabilities, laying a solid foundation for the Company's sustained and healthy development. During the reporting period, the Company successfully obtained ISO 22301 Business Continuity Management System certification. This is not only a key indicator of the improvement in the Company's governance level but also an important guarantee for business stability. The Company will continue to uphold a rigorous approach to ensure the robust operation of business processes, creating long-term value for all stakeholders.
The Company continuously optimized its talent cultivation and recruitment system, steadily improving talent quality and expanding the team size. The Company has gathered several experts with overseas research and industry backgrounds. The core team possesses extensive experience across the entire drug development lifecycle (from early discovery to commercial production) and in biopharmaceutical strategic management, covering key areas such as target screening, clinical development, registrational submission, GMP production, quality management, and intellectual property, with both an international perspective and local implementation capabilities. As of December 31, 2024, the Company had a total of 399 R&D personnel, accounting for 31.89% of total staff. Among R&D personnel, 21 hold doctoral degrees and 147 hold master's degrees. The Company will continue to deepen team building, providing comprehensive support for the Company's sustained growth and expansion.

Analysis and Outlook on Non-IFRS Performance Changes

□ Applicable √ Not Applicable

(II) Main Business Model

The Company is an innovative biopharmaceutical enterprise focused on the research and development of innovative drugs and biosimilars. Its main business encompasses drug research and development, production, and sales, possessing an independent and complete R&D, procurement, production, and commercialization system.

1. R&D Model

Drug development is characterized by long cycles and high risks. The Company's R&D is primarily conducted through in-house team-led independent research. Drug development generally involves stages such as antibody discovery, screening, preclinical testing, IND application, clinical research, marketing application, approval for marketing, and post-marketing studies.

The Company's R&D team is dedicated to drug discovery, formulation and media development, process development, preclinical research, and clinical trial research, while also participating in drug registration and intellectual property management. Over the years, the Company has established a comprehensive preclinical R&D platform and accumulated extensive clinical trial experience. The Company's R&D team plays a leading role in designing and executing research projects and actively participates in the preclinical research, drug clinical application, clinical trial, and regulatory approval processes. Concurrently, departments such as Intellectual Property, Clinical, and Production also participate in the Company's early-stage R&D processes, assisting the Company in selecting products with market potential and mitigating technical risks that may be encountered during the manufacturing stage.

2. Procurement Model

The Company's main raw materials include clinical trial comparator drugs, cell culture media raw materials, chromatography resins, pharmaceutical excipients, and other R&D reagents and consumables. During the R&D phase, the Company procures clinical trial comparator drugs as needed based on clinical trial research plans. Production plans for trial drugs are formulated according to the clinical trial research plans, and procurement plans for raw material types, specifications, and quantities are then made based on production plans and actual inventory levels. When selecting suppliers for key raw materials and packaging materials, the Company investigates market supply conditions, market prices, and other information, and selects the optimal supplier based on commercial negotiations. The Company typically enters into procurement contracts or purchase orders with suppliers to establish the buyer-seller relationship. Procured services primarily include clinical trial services and technical services. The Company selects the optimal providers from its pool of long-term cooperative suppliers. Clinical trial services mainly involve the Company directly commissioning hospitals to conduct clinical trial services. Technical services mainly refer to the Company commissioning third-party CROs (non-hospital) to assist in conducting preclinical trial services and clinical trial services.

3. Production Model

The Company strictly adheres to laws, regulations related to drug production, and relevant provisions from regulators during the production process. The Company has established a rigorous quality management system, building an integrated CMC R&D-to-commercialization quality management system that complies with European, American, and Chinese regulatory requirements. The platform's quality, technology, and capabilities are aligned with international standards, incorporating the entire lifecycle from project R&D to material management, product production, quality control, product release, product supply chain, and post-marketing product tracking. This lays a solid foundation for the commercialization of the Company's products in China and other overseas regions. Upholding the philosophy of "Quality First, Advancing with the Times", the Company implements data integrity, traceability, and quality risk management within the quality system, continuously researching, developing, and producing high-quality pharmaceuticals.

4. Commercialization Model

As of the end of the reporting period, the Company has four drugs approved for marketing in the Chinese market:

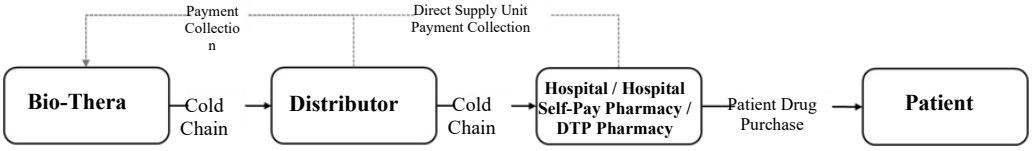
QLETLI®, POBEVCY®, TOFIDENCE®, and BETAGRIN®. Among these, tocilizumab (TOFIDENCE®) and bevacizumab (Avzivi®) have both received marketing approval from the FDA and EMA.

Tocilizumab (TOFIDENCE®) is already being marketed and sold in the United States. The Company has formulated targeted commercialization strategies for different products and markets.

The Company's commercialization department consists of 4 teams: Marketing Promotion, Domestic Sales, Commercial Affairs, and Medical Projects. Among them, the Marketing Promotion team is primarily responsible for product positioning and promotion, market strategy analysis, and planning and execution of marketing activities. The Domestic Sales team is primarily responsible for formulating and executing market sales strategies, promoting academic activities, customer management and expansion, etc., working within their respective regions to ensure adequate market coverage and improve market penetration. The Commercial Affairs team is primarily responsible for sales channels, distribution and logistics, market access, and government affairs. The Medical Projects team is primarily responsible for post-marketing clinical research and medical support, product introduction, training, and expert Q&A. The various functional teams under the commercialization department possess extensive experience in promoting, commercializing, and managing commercial, medical, and business affairs for innovative drugs and drugs in the autoimmune disease field. The Company emphasizes the management and training of the overall commercialization team. Through scientific internal organizational structure design, the Company effectively enhances the operational efficiency of the sales team. The Company's sales are conducted through a combination of three models: direct distribution, agency sales, and revenue-sharing from licensing agreements for specific products. When selecting market promotion partners, the Company implements a strict screening and review mechanism. This includes online searches to investigate their operational status, management models, and compliance to ensure they meet the Company's basic requirements. On-site inspections are arranged when necessary. The Company also conducts annual evaluations and ad-hoc on-site assessments, establishing an “elimination mechanism”. The Company has established strict internal controls for sales promotion. Relying on internal control systems, such as the "Financial Management System," "Supplier Management System," "Marketing Department Management Charter," and "Marketing Department Personnel Code of Conduct," the Company regulates and constrains sales personnel and suppliers involved in sales promotion activities. This includes: Requiring sales personnel to execute an “Anti-Bribery Commitment Letter“ upon employment; and providing vocational education and training for sales personnel on preventing commercial bribery and unfair competition.

The Company has entered into “Product Distribution Agreements” with multiple distributors possessing GSP qualifications. The Company sells products to these distributors, who then distribute the drugs to hospitals or retail pharmacies within authorized regions. The drugs are ultimately prescribed by clinicians to suitable patients. The Company's products primarily reach hospitals or retail pharmacies through distributor sales, with distributors executing contracts directly with hospitals or pharmacies.

The Company's sales process flow is as follows:



In major global markets, the Company adopts a commercialization strategy primarily based on global partners. In international emerging markets, the strategy combines global partners with regional strategic collaborations.

Through overseas collaborations, the Company not only demonstrates Bio-Thera's international capabilities in R&D and production, bringing its products to more patients in need globally, but also, more importantly, expands into broader markets via overseas commercial strategic partnerships, especially within the highly competitive domestic market for biosimilars. Based on the Company's development strategy, commercial collaborations can optimize the Company's product portfolio, strengthen its strategic focus, and achieve complementary advantages and mutual benefits between enterprises. Moving forward, Bio-Thera will persist in independent R&D while actively seeking external collaboration opportunities

worldwide.

(III) Industry Overview

1. Industry Development Stage, Basic Characteristics, and Main Technical Barriers

The Company is an innovative biopharmaceutical enterprise focused on the research and development of innovative drugs and biosimilars. According to the China Securities Regulatory Commission's "Guidelines for the Industry Classification of Listed Companies (2012 Revision)", the Company's industry classification falls under "Pharmaceutical Manufacturing (Industry Code: C27)". Based on the "National Economic Industry Classification Code (GB/T 4754-2017)", the Company's industry is the sub-category "Pharmaceutical Manufacturing (C27)" under the major category "C Manufacturing".

（1） Industry Development Stage

① Overview of Pharmaceutical Industry Development

The pharmaceutical manufacturing industry is not only a foundational sector for safeguarding national health but also a crucial strategic field for driving technological innovation, enhancing national competitiveness, and promoting high-quality economic development. "Made in China 2025" identifies the development of pharmaceutical manufacturing as one of the ten key areas for building a strong manufacturing nation. The "14th Five-Year Plan for the Pharmaceutical Industry" places the health and pharmaceutical sector at a strategic height. The "2024 Government Work Report" included accelerating the development of the innovative drug industry, actively fostering new growth engines such as biomanufacturing, and opening up new tracks like life sciences as part of the government's tasks for 2024. This signifies that China will prioritize the strategic development of the biopharmaceutical, biomanufacturing, and life sciences industries.
In recent years, the global elderly population has been increasing annually, and China's aging trend continues to deepen. According to the United Nations' "World Population Prospects 2024", the global population aged 65 or over is projected to reach 2.2 billion by the late 2070s, surpassing the population under 18. Data from the National Bureau of Statistics shows that as of 2024, China's population aged 65 and above reached 220.23 million, accounting for 15.4% of the national population. According to the United Nations' classification standards for aging, China has fully entered a stage of moderate aging. Simultaneously, according to National Bureau of Statistics data, the national per capita disposable income in 2024 was 41,314 RMB, a nominal increase of 5.3% year-on-year, and a real increase of 5.1% after adjusting for price factors. Looking at data from the past decade, national per capita consumption expenditure grew by 79.65%, with healthcare expenditure showing the largest increase, growing by 118.63% over the ten years. Thus, the intensification of population aging promotes the continuous growth of pharmaceutical market demand, the increase in per capita disposable income enhances medical payment capacity, and the growing public awareness of healthcare collectively drives the development of China's pharmaceutical industry.

② Pharmaceutical Market Overview

According to Frost & Sullivan data, the global pharmaceutical market has maintained steady growth in the past. From 2019 to 2023, the global pharmaceutical market size increased from US$1,324.5 billion to US$1,472.3 billion, and is expected to reach US$1,766.7 billion and US$2,069.4 billion by 2026 and 2030, respectively. Within this, the Chinese pharmaceutical market ranks second globally, following the U.S. market, reaching US$231.5 billion in 2023. It is projected to grow to US$291.1 billion and US$373.2 billion by 2026 and 2030, respectively.

③ Market Overview of the Company's Main Product Areas

i. Overview of the Oncology Treatment Area

According to data from the International Agency for Research on Cancer (IARC), a part of the World Health Organization (WHO), the number of new cancer cases

globally continues to rise, increasing from 18.529 million cases in 2019 to 20.781 million cases in 2023. It is projected that there will be over 35 million new cancer cases globally by 2050. The incidence of malignant tumors increases with age. However, recent data indicate that while cancer incidence is rising, there is an overall trend of an increasing proportion of cases occurring in younger age groups, meaning the age of cancer onset in the population is shifting earlier.

Influenced by the rising cancer incidence, the earlier age of onset, and advancements in medical technology, the global anti-tumor drug market continues to grow. According to Frost & Sullivan analysis, the global anti-tumor drug market size has grown from US$143.5 billion in 2019 to US$228.9 billion in 2023, with a compound annual growth rate (CAGR) of 12.4%. It is projected that by 2030, the global anti-tumor drug market size will reach US$419.8 billion, with a CAGR of 9.1% The Chinese anti-tumor drug market size grew from 182.7 billion RMB in 2019 to 241.6 billion RMB in 2023, with a CAGR of 7.2% during this period. It is projected that the Chinese anti-tumor drug market will reach 548.4 billion RMB by 2030, with a CAGR of 12.4% from 2023 to 2030.

In recent years, significant breakthroughs have been made in both the number of anti-tumor drugs approved and the range of diseases they treat. Between 2000 and 2004, the FDA approved an average of 7.4 new drugs per year. In 2023, the FDA's Center for Drug Evaluation and Research approved 55 new drugs. This change is primarily driven by the increase in approvals for targeted drugs and biologics. According to Frost & Sullivan analysis, the global anti-tumor drug market in 2023 was dominated by targeted drugs (including antibody and small molecule targeted drugs, etc.), accounting for 60.7% of the total market. However, with the development and adoption of immunotherapy, it is projected that by 2030, immunotherapy will account for 47.9% of the global anti-tumor drug market, becoming a major driver of growth in the anti-tumor drug market. In 2023, the Chinese anti-tumor drug market was dominated by chemotherapy drugs, accounting for 47.5% of the total anti-tumor drug market. There remains a gap compared to some developed countries and regions in terms of the introduction, independent R&D, and clinical adoption of targeted drugs domestically.

With the launch and adoption of targeted drugs and immunotherapies, the market share of these related drugs in China is expected to further increase in the future. According to Frost & Sullivan analysis, it is projected that by 2030, in the Chinese anti-tumor drug market, the market share of targeted drugs will rise, and the market share of immunotherapies will increase substantially, reaching 43.9% by 2030, becoming the mainstay of the Chinese anti-tumor drug market and supporting the further expansion of its market size.

ii. Overview of the Autoimmune Disease Treatment Area

Autoimmune diseases (AID) refer to conditions where the body's immune system breaks tolerance to its own components, attacking its own organs, tissues, or cells, leading to damage. Currently, global autoimmune diseases can be broadly categorized into three major groups: rheumatological, dermatological, and gastrointestinal. Common autoimmune diseases include rheumatoid arthritis, systemic lupus erythematosus, multiple sclerosis, etc. In recent years, the overall market in the autoimmune disease treatment segment has maintained rapid growth. According to statistics from the American Autoimmune Related Diseases Association (AARDA), the patient population for various autoimmune diseases in recent years accounts for approximately 7.6%-9.4% of the global total population. Frost & Sullivan statistics show that the global patient population for various autoimmune diseases is nearly 500 million. In 2022, the global autoimmune drug market size reached approximately US$132.3 billion, making it the second-largest disease market after oncology. By 2030, the global autoimmune disease treatment market is projected to

grow to US$176.7 billion. The Chinese autoimmune drug market started late but is developing rapidly. By 2030, its market size is expected to

reach US$24.7 billion by 2030, achieving a tenfold increase compared to 2020.

The Chinese autoimmune market is primarily driven by psoriasis and ankylosing spondylitis. Among these, psoriasis has the highest prevalence rate, reaching 2.7%.

The prevalence rates of ankylosing spondylitis and rheumatoid arthritis are similar, while the prevalence rates of ulcerative colitis and Crohn's disease are lower. In the past, autoimmune diseases were mainly treated with traditional anti-inflammatory drugs such as non-steroidal anti-inflammatory drugs (NSAIDs). With the continuous development of medical

technology, the commonly used innovative drugs in the autoimmune disease field have now shifted to innovative targeted agents, including biologics and small-molecule targeted drugs, such as anti-TNF (tumor necrosis factor) agents, anti-IL (interleukin) agents, and JAK1 inhibitors, etc.

iii. Overview of the Cardiovascular Treatment Area

Currently, unhealthy lifestyles are prevalent among Chinese residents, and the population with cardiovascular disease risk factors is enormous. Coupled with the accelerating aging of the population, cardiovascular disease remains one of the greatest threats to the health of Chinese residents. The "Report on Cardiovascular Health and Diseases in China 2023" indicates that the prevalence of cardiovascular diseases in China is in a stage of continuous increase, with an estimated 330 million people currently living with cardiovascular diseases. The “China Health Statistics Yearbook 2022” shows that cardiovascular disease ranks first in the composition of causes of death among urban and rural residents in China. In October 2023, the National Health Commission, in conjunction with multiple departments, formulated the "Healthy China Action—Implementation Plan for Cardiovascular and Cerebrovascular Disease Prevention and Control (2023–2030)", proposing to reduce the mortality rate of cardiovascular and cerebrovascular diseases to below 190.7 per 100,000 by 2030. Acute coronary syndrome (ACS) is one of the most severe clinical syndromes among cardiovascular diseases, and its incidence in China is increasing year by year. Globally, over 7 million people are diagnosed with acute coronary syndrome (ACS) each year. Although acute coronary syndrome (ACS) is common in the elderly population, its incidence in younger populations is gradually increasing. Percutaneous coronary intervention (PCI) is currently one of the primary methods for treating acute coronary syndrome. With the enhancement of national medical payment capacity and willingness, along with policy support and improved accessibility to interventional cardiovascular procedures, the volume of PCI procedures in China is expected to maintain rapid growth. According to data from the National Health Commission's Coronary Heart Disease Interventional Technology Quality Control Center, the total number of registered coronary heart disease interventional treatment cases in mainland China in 2023 was 1.6361 million, with a growth rate of 26.44% in PCI case numbers.

iv. Overview of the Ophthalmology Treatment Area

Accompanied by population growth and the acceleration of the aging process, the burden of eye diseases, especially age-related eye diseases such as cataracts and age-related macular degeneration, is showing an increasing trend in the number of affected individuals. According to data released in the "Current Status and Thirty-Year Changing Trends of the Burden of Eye Diseases in China 2021", the total number of people with eye diseases in China in 2019 was 210 million. Excluding near vision loss and refractive errors, eye diseases with significant harm mainly include cataracts, glaucoma, age-related macular degeneration, etc. The disability-adjusted life years (DALY) caused by eye diseases in 2019 increased by 113.0% compared to 1990. Among these, the DALY caused by cataracts and age-related macular degeneration showed significant increases of 158.8% and 142.1%, respectively.

The "Chinese Guidelines for Clinical Diagnosis and Treatment of Age-Related Macular Degeneration (2023)" indicate that age-related macular degeneration (AMD) is the main cause of low vision and even blindness in the elderly population. With the intensification of population aging in China, the number of AMD patients is also continuously rising. The number of AMD patients in China increased from 12.01 million in 1990 to 26.65 million in 2015, and is projected to increase to 55.19 million by 2050. The prevalence of AMD in the population aged 70 and above is 20.2%.

（2） Industry Basic Characteristics and Main Technical Barriers

The biomanufacturing industry is a highly technology-intensive and capital-intensive sector. Drug research and development, as well as production, rely on advanced R&D technologies

and production processes, requiring substantial investment and long cycles. The main barriers lie in technology and capital. Regarding technology, the competitive advantage of biomanufacturing enterprises is reflected in their core technologies and production process technologies. As market competition intensifies further, technology is increasingly concentrated in the hands of a few new biopharmaceutical companies and international pharmaceutical giants. New entrants find it difficult to overcome patent barriers and gain a competitive advantage in the biopharmaceutical field. Regarding capital, to construct production facilities that meet GMP requirements and maintain advantages in R&D technology and production process technology, the development of biomanufacturing enterprises is highly dependent on financial support. The enormous capital requirement also significantly raises the industry's entry barrier.

2. Analysis of the Company's Industry Position and Its Changes

Bio-Thera is an innovation-driven new drug R&D company. Since its establishment, it has built R&D platforms with leading technological levels and production technology platforms with cost advantages. Through continuous optimization and upgrades, it has overcome technological gaps and bottlenecks in new drug R&D and production, consistently developing and commercializing innovative drugs with independent intellectual property rights that are safe, effective, and affordable for patients. The goal is to enable China's independently developed and produced biological drugs to enter domestic and overseas markets, benefit global patients, and establish a leading international biopharmaceutical brand.

In the first "Guangzhou Innovative Drug and Medical Device Product Directory" product list released by the Guangzhou Municipal Industry and Information Technology Bureau in 2024, a total of 7 items were drugs. All 4 of the Company's marketed products were included in the list:

The Company's independently developed adalimumab (QLETLI®) received marketing approval from the National Medical Products Administration (NMPA) in November 2019. It is the first adalimumab biosimilar approved for marketing in China, the only domestic adalimumab biosimilar approved with 2 specifications and 8 indications. Before the launch of QLETLI®, the cost of the original adalimumab drug was high. After the launch of QLETLI®, the price of the original drug significantly decreased. All eight indications of QLETLI® have been included in the National Reimbursement Drug List (NRDL), allowing patients access to high-quality biological drugs. During the reporting period, QLETLI® was awarded the 2024 Guangdong Provincial Manufacturing Single-Item Champion Product, and the Company was awarded the title of Guangdong Provincial Manufacturing Single-Item Champion Enterprise based on the outstanding performance of QLETLI®.

The Company's independently developed bevacizumab (Chinese brand name: POBEVCY®; US & European brand name: Avzivi®; Brazilian brand name: Bevyx®) has been approved for marketing in four major global markets: China, the US, Europe, and Brazil. It is currently the only domestically produced bevacizumab biosimilar that has undergone global multi-center registrational clinical studies. It is the first and currently only domestically produced bevacizumab biosimilar approved by the FDA, EMA, and ANVISA. It is currently the only domestically produced bevacizumab biosimilar with a 400mg/16mL specification.

The Company's independently developed tocilizumab biosimilar (Chinese brand name: TOFIDENCE®; US brand name: TOFIDENCE®) has been approved for marketing in three major global markets: China, the US, and Europe. TOFIDENCE® is the first monoclonal antibody drug independently developed and produced by a Chinese domestic pharmaceutical company to receive marketing approval from the US FDA. It is the first and currently only domestically produced tocilizumab biosimilar approved by the FDA and EMA.

The Company's independently developed and self-owned Class 1 chemical drug Bevifibatide Citrate Injection (BETAGRIN®) with proprietary intellectual property received marketing approval from the National Medical Products Administration (NMPA) in June 2024. BETAGRIN® is the first domestically developed dual-function anti-thrombotic β3 integrin receptor inhibitor in China. It is indicated for acute coronary syndrome patients undergoing percutaneous coronary intervention (including intracoronary stent placement) to reduce the risk of acute occlusion, stent thrombosis, no-reflow, and slow-flow. On New Year's Day 2025, BETAGRIN® officially commenced its first batch of shipments, bringing a new antiplatelet therapy option for acute coronary syndrome patients undergoing percutaneous coronary intervention (PCI).

TRANSPERFECT

I, Paris Zhou, hereby certify that I am competent to translate from Chinese to English and that the attached translation is, to the best of my knowledge and belief, a true and accurate translation of the document entitled "Document Date - 2024-Dec-30 - 688177.SS - Bio-Thera Solutions Ltd - ANNUAL FULL REPORT - 百奥泰 2024 年年度报告 - cn07817339" from Chinese to English.

I declare that all statements made herein on my own knowledge are true and that all statements made on information and belief are believed to be true, and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 or Title 18 of the United States Code

Paris Zhou

NAME

May 21, 2026

DATE