Company Code: 688177

Company Abbreviation: Bio-Thera

Bio-Thera Solutions, Ltd

2025 Semi-Annual Report

Janssen Biotech, Inc.
Exhibit 2024
Accord v. Janssen
IPR2026-00256, -00257, -00258, -00259
Ex. 2024-001

Important Notice

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

2. 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."

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

4. This semi-annual report is unaudited.

5. 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 semi-annual report.

6. Profit distribution plan or capital reserve conversion plan for the reporting period approved by the Board resolution None

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

□ Applicable √ Not Applicable

8. 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.

9. Existence of non-operating fund occupation by the controlling shareholder and other related parties No

10. Existence of external guarantees provided in violation of prescribed decision-making procedures No

11. Existence of more than half of the directors being unable to guarantee the truthfulness, accuracy, and completeness of the disclosed semi-annual report No

12. Other

□ Applicable √ Not Applicable

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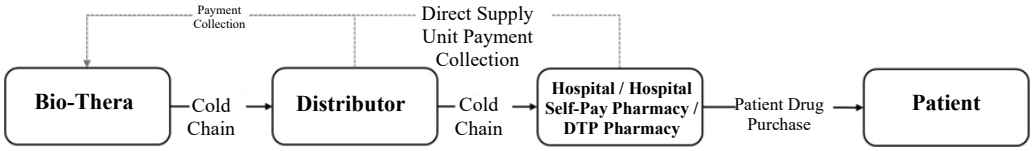
List of Documents for Reference	Financial report bearing the signatures and seals of the legal representative of the Company, the person in charge of accounting work, and the person in charge of the accounting establishment.
	Original copies of all publicly disclosed Company documents and announcement drafts during the reporting period.

etc. All functional teams under the commercialization department possess extensive experience in promoting and commercializing innovative drugs and related products. Specifically, the National Sales Directors of the domestic sales team each have over 10 years of professional experience 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.

Newly Added Important Non-Main Business Operations

□ Applicable √ Not Applicable

II. Discussion and Analysis of Operations

The Company adheres to the philosophy of "Innovation for Life," committed to developing next-generation innovative drugs and biosimilars for treating tumors,

autoimmune diseases, cardiovascular diseases, ophthalmological conditions, and other major diseases that threaten human life or health. In the first half of 2025, 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） Efficient Advancement of R&D Pipeline and Continuous Breakthroughs in Innovation

During the reporting period, STARJEMZA® (ustekinumab) received marketing approval from the U.S. FDA. As the Company's fifth approved product and third product approved by the U.S. FDA, the approval of STARJEMZA® strongly validates Bio-Thera's outstanding R&D capabilities and production capacity as a leading global biopharmaceutical company.

Company R&D projects progressed steadily. During the reporting period, marketing applications for BAT2506 (golimumab) submitted to the NMPA, FDA, and EMA were all accepted. The marketing authorization application for BAT2306 (secukinumab) submitted to the NMPA was accepted. BAT2206 (ustekinumab) received a positive opinion from the European CHMP. The clinical trial application for BAT1006 for Injection in combination with trastuzumab and chemotherapy for treating breast cancer was approved. The clinical trial application for the Class 1 new drug BAT7111 for Injection (PD-1/4-1BB) for treating advanced solid tumors was approved. BAT5906 achieved positive results in its pivotal registrational Phase III clinical study for wAMD. The pivotal registrational Phase III clinical study for BAT8006 in treating platinum-resistant ovarian cancer completed enrollment of its first subject.

At the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, clinical progress and interim data for BAT8006 (FRα ADC) were presented in an oral presentation. This study included dose-escalation and expansion phases, enrolling a total of 133 ovarian cancer patients. Among all ovarian cancer patients (regardless of FRα expression level or prior lines of therapy), the median PFS was 7.63 months. In patients evaluable for tumor response, the ORR was 40.7% and the DCR was 80.5%. Studies for BAT8006, including combination therapy studies, have enrolled over 200 patients, with no ocular toxicity or interstitial lung disease (ILD) observed. Clinical progress or interim data for BAT8008 (Trop-2 ADC), BAT8010 (HER2 ADC) in combination with the ADCC-enhanced BAT1006 (HER2 monoclonal antibody), and BAT1308 (PD-1) in combination with chemotherapy ± bevacizumab were presented in poster presentations. These project data demonstrate Bio-Thera's strong R&D capabilities and mark significant breakthroughs in the Company's innovative drug development in recent years.

（2） Revenue grew steadily, and global market coverage continued to expand.

During the reporting period, the Company's operating revenue achieved steady growth, with a year-on-year increase of 9.84% in the first half of 2025. The Company actively optimized resource allocation and continuously expanded sales channels. Its sales network now covers all provinces, municipalities, and autonomous regions in China except Xizang, Hong Kong, Macao, and Taiwan, with collaborative product agreements established with over 3,000 prescription hospitals and over 2,000 pharmacies. Market demand continues to rise.

The Company has a global presence and is actively advancing its internationalization strategy to explore overseas markets. During the reporting period, the Company engaged in global collaborations for multiple products across various regions: The Company granted World Medicine exclusive distribution and sales rights for BAT2206 (ustekinumab) in the Turkish market; granted Intas exclusive commercialization rights for BAT2506 (golimumab) in the U.S. market; executed licensing and commercialization agreements with Dr. Reddy’s for BAT2206 (ustekinumab) and BAT2506 (golimumab) in Southeast Asian markets; and granted SteinCares exclusive distribution and sales rights for BAT2406 (dupilumab) in Brazil and other Latin American regions.

（3） Consistently Meeting Highest Quality Standards, with Continuously Improving Commercial Production Capacity

The Company's industrial production base located in the Yonghe Development Zone, Huangpu District, Guangzhou, has successfully passed multiple on-site inspections by major global regulators including China's NMPA, the U.S. FDA, Europe's EMA, and Brazil's ANVISA. The total capacity of the Company's drug substance production lines has now reached 66,500L, possessing mature commercial production capabilities for biological products.

Since first receiving the GMP certificate from the NMPA in December 2019, the base has achieved commercial production of QLETLI®, POBEVCY®, TOFIDENCE®, and BETAGRIN®. In August 2023, the base successfully passed the FDA Pre-License Inspection (PLI) and was approved to supply commercial batches of bevacizumab and tocilizumab injection for the U.S. market. In January 2025, it passed another FDA PLI inspection and was approved to produce and supply ustekinumab injection for the U.S. market. In July 2023, it passed the on-site inspection by Brazil's ANVISA and received the corresponding GMP certificate for producing bevacizumab for the local market. In October 2023, it passed the on-site inspection by the EU's EMA and received the corresponding GMP certificate for producing bevacizumab and tocilizumab for the local market.

The Company has established a pharmaceutical quality management system that continuously complies with domestic and international regulatory requirements. Through a quality system audit and continuous improvement mechanism combining self-inspections and external audits, the Company ensures products meet the highest quality standards throughout their lifecycle. During the reporting period, the base successfully passed multiple external inspections, including pre-marketing on-site inspections of biological products by the National Medical Products Administration, compliance inspections by the Guangdong Medical Products Administration, and audits by key customers. The audit scope comprehensively covered the complete quality and safety spectrum of pharmaceuticals, including key areas such as: Production Management, Quality Management, Laboratory Management, Supplier Management, Material and Warehouse Management, Equipment Management, Contract Testing, Drug Safety, and Pharmacovigilance. All inspections were passed successfully, fully validating the compliance and effectiveness of the base's quality management system.

（4） Continuously Improving Corporate Governance and Standardized Operations, Strengthening the Talent Pipeline

The Company places high importance on the soundness of its governance structure and the effectiveness of its internal control system. It earnestly implemented the new “Company Law” and its supporting reform measures. During the reporting period, the Company completed revisions to the “Articles of Association of Bio-Thera Solutions, Ltd.“, legally and orderly advanced procedures for amending the duties of the Audit Committee and the Supervisory Board, and completed revisions to several corporate systems, including the rules of procedure for shareholders' meetings and board meetings. Furthermore, in accordance with the new “Company Law“ and relevant laws, regulations, and normative documents, the Company completed the board re-election and training for newly appointed directors and senior management. This further enhanced the compliance awareness and performance capabilities of the Company's directors and senior management, safeguarding the Company's sustained high-quality development.

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 June 30, 2025, the Company had a total of 418 R&D personnel, accounting for 33.02% of total staff. Among R&D personnel, 26 hold doctoral degrees and 152 hold master's degrees. The Company will continue to deepen team building, optimize the performance management system, improve employee career progression pathways, and provide comprehensive support for the Company's sustained growth and expansion.

Analysis and Outlook on Changes in Non-IFRS Financial Indicators

□ Applicable √ Not Applicable

Significant changes in the Company's operations during the reporting period, and matters that occurred during the reporting period which have had, or are expected to have, a significant impact on the Company's operations.

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 “3-250R1133544 (1)” 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