Company Code: 688177 **Company Abbreviation: Bio-Thera**

Bio-Thera Solutions, Ltd. 2021 Annual Report

Janssen Biotech, Inc.
Exhibit 2020
Accord v. Janssen
IPR2026-00256, -00257, -00258, -00259
Ex. 2020-001

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 Ernst & Young Certified Public Accountants (Special General Partnership) for our company is a standard unqualified audit report.

6. Yi Xianzhong, 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 2021 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 First Board of Directors at its Thirty-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

Ex. 2020-002

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.

Ex. 2020-004

4. Pipeline Project Status

√ Applicable □ Not Applicable

Unit: Thousand RMB

S/N	Item Name	Estimated Total Investment Scale	Amount Invested in Current Period	Cumulative Amount Invested	Progress or Interim Results	Targeted Goals	Technical Level	Specific Application Prospects
1	Peixi® (Bevacizumab Injection)	67,711.29	5,393.36	67,887.74	Approved for marketing in China; marketing applications submitted to the FDA and EMA	Drug Marketing	POBEVCY® (Bevacizumab Injection) is a bevacizumab injection developed by Bio-Thera in accordance with the biosimilar-related guidelines of China's NMPA, the US FDA, and the EU EMA. Its indications include advanced, metastatic, or recurrent non-small cell lung cancer and metastatic colorectal cancer. It is a humanized monoclonal antibody targeting vascular endothelial growth factor (VEGF).	mCRC, nsNSCLC, recurrent glioblastoma, metastatic renal cell carcinoma, persistent, recurrent, or metastatic cervical cancer, epithelial ovarian cancer, fallopian tube or primary peritoneal cancer, hepatocellular carcinoma
2	BAT2094	8,390.30	694.69	8,817.44	Marketing application submitted to the NMPA	Drug Marketing	BAT2094 (Batfibafan) is a synthetic platelet glycoprotein IIb/IIIa (i.e., GPIIb/IIIa) receptor antagonist. BAT2094 is used for anti-thrombosis during the PCI perioperative period, and its clinical dosage form is an injection for intravenous administration. BAT2094 is a Class 1.1 chemical drug independently developed by the Company with self-owned intellectual property.	Anti-thrombosis during the PCI perioperative period and other potential ischemic heart diseases.
3	BAT1806	41,893.84	7,594.19	40,583.23	Marketing application submitted to the NMPA	Drug Marketing	BAT1806 is a tocilizumab injection developed by Bio-Thera in accordance with the biosimilar-related guidelines of China's NMPA, the US FDA, and the EU EMA. It is a recombinant humanized monoclonal antibody targeting the interleukin-6 receptor (IL-6R). It can specifically bind to both soluble and membrane-bound IL-6 receptors (sIL-6R and mIL-6R) and inhibit signal transduction mediated by sIL-6 or mIL-6R. Tocilizumab can treat rheumatoid	RA, sJIA, CRS, GCA, SSc-ILD, PJIA

							systemic juvenile idiopathic arthritis, polyarticular juvenile idiopathic arthritis, giant cell arteritis, and cytokine release syndrome induced by CAR-T therapy.	
4	BAT2506	15,813.49	7,381.02	14,033.51	Clinical Phase III	Drug Marketing	BAT2506 is a biosimilar of golimumab (SIMPONI®) developed by Bio-Thera based on the research of Xian Janssen Pharmaceutical Ltd. Golimumab is an antibody targeting TNF-α. It can specifically bind with high affinity to both soluble and transmembrane human TNF-α, blocking the binding of TNF-α to its receptor TNFR, thereby inhibiting the activity of TNF-α.	RA, PsA, AS, UC, pJIA
5	BAT2206	24,087.21	7,376.86	15,260.00	Clinical Phase III	Drug Marketing	BAT2206 aims to interfere with the triggering of the human inflammatory response by inhibiting several cytokines. It is designed to block interleukins IL-12 and IL-23, thereby helping to activate certain T cells. It is expected to bind to the p-40 subunit of IL-12 and IL-23, preventing them from subsequently binding to their receptors.	Ps, PsA, CD, UC
6	BAT4306F	24,654.52	912.67	4,311.94	Clinical Phase II	Drug Marketing	BAT4306F is a next-generation glycan-modified ADCC-enhanced anti-CD20 monoclonal antibody developed by Bio-Thera. Its initially developed clinical indication is relapsed/refractory CD20-positive B-cell non-Hodgkin lymphoma. BAT4306F binds to a different epitope compared to the currently marketed anti-CD20 antibody rituximab. It can directly induce B-cell apoptosis, and through modification of antibody glycosylation, it further enhances the ADCC effect of BAT4306F.	B-cell leukemia
7	BAT5906	18,864.19	1,709.27	6,746.52	Clinical Phase II	Drug Marketing	Pharmaceutical and pharmacological/toxicological studies indicate that BAT5906 is a next-generation antibody drug with pharmacokinetic, safety, and pharmacodynamic advantages, showing good development prospects. Preclinical studies show BAT5906 has high affinity.	wAMD, DME

							In vivo pharmacodynamic test results indicate that BAT5906 is more effective than the marketed drug ranibizumab in inhibiting neovascularization in monkey eyes.	
8	BAT4406F	4,850.04	451.95	2,278.84	Clinical Phase I	Drug Marketing	BAT4406F is a next-generation glyco-optimized fully human anti-CD20 antibody developed by Bio-Thera. Its indication is autoimmune diseases such as neuromyelitis optica spectrum disorders. The mechanism of action of BAT4406F is to specifically bind to the CD20 molecule on the surface of B cells and precursor cells. Through the antibody's Fc region, in the presence of complement, NK natural killer cells, phagocytes, etc., it induces biological effects such as ADCC and CDC (complement-dependent cytotoxicity), thereby achieving the goal of eliminating B cells.	NMOSD and other potential autoimmune diseases
9	BAT1308	8,878.70	879.37	2,606.96	Clinical Phase I	Drug Marketing	BAT1308 Injection is a monoclonal antibody drug independently developed by Bio-Thera. Its active ingredient is an antibody targeting human programmed cell death protein-1 (PD-1) expressed by Chinese hamster ovary cells. It belongs to the immunoglobulin IgG4κ subtype and can specifically bind with high affinity to human PD-1, thereby blocking the interaction between PD-1 and its ligands PD-L1 and PD-L2. BAT1308 can bind to PD-1 on the surface of T cells, relieving the inhibitory effect of the PD-1 pathway on T cells, thereby restoring and enhancing the immune-killing function of T cells and inhibiting tumor growth.	Various solid tumors
10	BAT1006	13,169.00	228.79	1,848.61	Clinical Phase I	Drug Marketing	BAT1006 Injection is a monoclonal antibody drug independently developed by Bio-Thera. Its active ingredient is an antibody targeting human epidermal growth factor receptor-2 (HER2) expressed by Chinese hamster ovary cells. It belongs to the immunoglobulin IgG1κ subtype and can specifically bind with high affinity to the extracellular protein domain II of human HER2, blocking the heterodimerization	of HER2 with other HER family receptors

							(EGFR/HER3/HER4) and inhibiting the proliferation and survival of tumor cells related to HER2 receptor activity. The antibody glycosylation modification of BAT1006 lacks fucose. Compared to ordinary IgG1κ antibodies, it has a stronger effect in recruiting immune cells like NK cells to kill tumor cells.	
11	BAT2306	9,229.00	1,665.68	3,491.26	Clinical Phase I	Drug Marketing	Secukinumab (BAT2306) Injection is a biosimilar developed by Bio-Thera Solutions, Ltd. Its active ingredient is a monoclonal antibody of the IgG1 kappa subtype expressed by Chinese hamster ovary cells. It can specifically bind with high affinity to human interleukin-17A (IL-17A) and human interleukin-17A/F (IL-17A/F), thereby inhibiting the autoimmune inflammatory response mediated by interleukin-17.	Ps, PsA, AS, nr-axSpA, ERA
12	BAT4706	15,161.00	233.53	2,789.83	Clinical Phase I	Drug Marketing	BAT4706 is a fucose-free glyco-optimized IgG1 class fully human monoclonal antibody candidate drug developed by Bio-Thera. Its target is CTLA-4, for the treatment of advanced solid tumors. CTLA-4 is an immune checkpoint expressed on regulatory T cells (Tregs) and activated CD4+ and CD8+ T cells. BAT4706 can specifically bind to the CTLA-4 molecule, restoring the activation of T cells. Simultaneously, its enhanced antibody-dependent cellular cytotoxicity (ADCC) effect can lead to the apoptosis of Tregs in the tumor microenvironment, thereby enhancing the body's immune response to cancer.	Various solid tumors
13	BAT6026	10,881.00	639.50	1,705.68	Clinical Phase I	Drug Marketing	BAT6026 is a fucose-free fully human anti-OX40 monoclonal antibody developed by Bio-Thera for the treatment of advanced solid tumors. OX40 is an activating immune checkpoint expressed on activated immune cells (primarily CD4+ and CD8+ T cells, as well as intratumoral Treg cells). When OX40 is activated, its	Cancer

							downstream signaling pathways promote T cell division, survival, and cytokine production. While the mechanism of action of the OX40 target still requires in-depth research, it is generally believed that the potential mechanisms of OX40 antibodies in tumors include the following three. First, directly activating CD4+ and CD8+ T cells, enhancing their proliferation and survival capabilities. Second, inhibiting the suppressive function of Tregs, reducing their inhibition of the immune system. Third, directly depleting intratumoral Tregs through effects such as Fcγ receptor-mediated ADCC. BAT6026 enhances ADCC activity through defucosylation modification, enabling more effective depletion of intratumoral Tregs.	
14	BAT6005	17,176.00	443.88	2,510.38	Clinical Phase I	Drug Marketing	BAT6005 is an anti-TIGIT monoclonal antibody of the IgG1 subtype with normal Fc effector function developed by Bio-Thera, intended for development in tumor treatment. TIGIT is an immunoglobulin superfamily protein highly expressed on the surface of activated NK cells, CD4+ T cells, CD8+ T cells, and immunosuppressive Tregs cells. The main ligand of TIGIT, PVR, is highly expressed on the surface of various solid tumor cells and dendritic cells. BAT6005 can block the binding of TIGIT to CD155 (PVR), thereby restoring the function of T cells and NK cells. Additionally, BAT6005 has normal ADCC effector function and can eliminate immunosuppressive Tregs cells via its ADCC function.	Cancer
15	BAT6021	17,166.00	960.08	2,314.20	Clinical Phase I	Drug Marketing	BAT6021 is a differentiated anti-TIGIT monoclonal antibody developed by Bio-Thera, intended for development in tumor treatment. TIGIT is an immunoglobulin superfamily protein highly expressed on the surface of activated NK cells, CD4+ T cells, CD8+ T cells, and immunosuppressive Tregs cells. The main ligand for TIGIT,	Cancer

							PVR, is highly expressed on the surface of various solid tumor cells and dendritic cells. BAT6021 can block the binding of TIGIT to CD155 (PVR), thereby restoring the function of T cells and NK cells. The differentiated BAT6021 has enhanced ADCC function. It can eliminate immunosuppressive Tregs cells via its enhanced ADCC function and strengthen the binding between T cells and DC cells, thereby enhancing antigen-specific T cell responses and improving the efficacy of tumor immunotherapy.	
16	BAT7104	17,576.00	787.16	2,197.33	Clinical Phase I	Drug Marketing	BAT7104 is a bispecific antibody targeting PD-L1 and CD47 developed by Bio-Thera, intended for development in tumor treatment. BAT7104 activates macrophage phagocytosis of tumor cells by blocking the CD47/SIRPα pathway. BAT7104 relieves the inhibition of T cells by tumor cells via the PD-L1/PD-1 pathway by blocking the PD-L1/PD-1 pathway, achieving combined anti-tumor effects by T cells and macrophages. Through differentiated affinity design, the CD47-targeting arm of BAT7104 has moderate affinity, reducing the potential for toxic side effects. Simultaneously, its PD-L1-targeting arm has high affinity, improving the antibody's selectivity for tumor cells and enhancing targeted tumor cell toxicity.	Cancer
TOTAL	/	315,501.58	37,352.00	179,383.47	/	/	/	/

Situation Description None

3. Actively responding to the government's pandemic prevention policies, and encouraging Party members within the Company to actively engage with their residential communities, proactively cooperating with community neighborhood committees in pandemic prevention, control, and publicity work. Providing ideological guidance to Party members unable to work due to community control requirements, and actively cooperating with the relevant Company departments to ensure smooth work handover.

4. Actively participate in public opinion guidance. The current international situation is extremely complex and volatile, the public opinion landscape is intricate, information is difficult to verify, and various voices emerge one after another. The Party branch requires all Party members to consistently align with the central authorities, lead by example, comply with laws and regulations on social platforms, and express themselves rationally.

(ii) Investor Relations and Protection

Type	Frequency	Relevant Details
Holding Performance Briefings	2	During the reporting period, the Company held the 2020 Annual Performance Briefing and the 2021 Semi-Annual Performance Briefing.
Utilizing New Media for Investor Relations Management Activities	0	Not Applicable
Setting up an Investor Relations Section on the Official Website	√Yes □No	Please refer to the Company's official website: www.bio-thera.com

Specific Details of Investor Relations Management and Protection

√ Applicable □ Not Applicable

During the reporting period, the Company strictly complied with relevant laws, regulations, and internal systems such as the "Information Disclosure Management System" and the "Investor Relations Management System", completing information disclosure work in a truthful, accurate, complete, timely, and fair manner.

The Company actively established effective communication channels with investors to protect their legitimate rights and interests. By organizing performance briefings, the Company communicated and exchanged information with investors regarding its operations and performance. It responded to investor inquiries promptly and conscientiously on the SSE E-Interaction Platform. It set up an investor relations email, with dedicated personnel responsible for timely replies to investor emails. It established an investor hotline with dedicated personnel answering investor calls throughout the day, addressing investor questions earnestly and patiently.

Description of Other Methods of Communication with Investors

□ Applicable √ Not Applicable

(iii) Information Disclosure Transparency

√ Applicable □ Not Applicable

The Company has established a comprehensive information disclosure management system, set up a functional department responsible for information disclosure, defined work standards for information disclosure, and ensured the truthfulness, accuracy, completeness, timeliness, and fairness of information disclosure. The Company strengthens the information disclosure capabilities of relevant staff through internal and external training. The Company has set up a dedicated investor hotline and investor relations email, and established good communication with investors through platforms like the investor interaction platform and performance briefings, continuously improving information disclosure transparency and maintaining accurate and timely information exchange and transmission.

(iv) Intellectual Property and Information Security Protection

√ Applicable □ Not Applicable

Intellectual property is crucial to the success of the Company's business. The Company's commercial success depends partly on its ability to obtain and maintain patents and other intellectual property rights, as well as patent protection, for commercially important technologies, inventions, and know-how related to its business, to maintain and enforce patents, to keep trade secrets confidential, and to operate its business without infringing, misappropriating, or otherwise violating the valid and enforceable intellectual property rights of third parties.

The Company places high importance on intellectual property and information security protection. The Company has an experienced intellectual property team responsible for maintaining the Company's IP portfolio (including patents and trademarks), protecting intellectual property rights, and improving the Company's intellectual property system. Simultaneously, the Company has a dedicated intellectual property department responsible for the application and maintenance of domestic and international patents. The Company will continuously improve its intellectual property protection system, apply for patent protection globally for core technological achievements, and reasonably utilize legal means to safeguard its independent intellectual property rights.

(v) Participation of Institutional Investors in Corporate Governance

□ Applicable √ Not Applicable

(vi) Other Corporate Governance Matters

□ Applicable √ Not Applicable

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 - 2021-Dec-30 - 688177.SS - Bio-Thera Solutions Ltd - ANNUAL FULL REPORT - 百奥泰 2021 年年度报告 - cn05875254" 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