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

Bio-Thera Solutions, Ltd. 2019 Annual Report

Janssen Biotech, Inc.
Exhibit 2016
Accord v. Janssen
IPR2026-00256, -00257, -00258, -00259
Ex. 2016-001

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. Major Risk Notice

The Company has elaborated in detail in this report on factors such as the Company's lack of profitability, risks to core competitiveness, operational risks, and industry policy risks. Please refer to Section IV, "Discussion and Analysis of Operating Performance," subsection "2. Risk Factors" of this report. Investors are specifically reminded to pay attention to the following risks:

1. **Products Not Yet Commercially Launched; Company Remains Unprofitable with Ongoing Losses Expected**

As of December 31, 2019, except for BAT1406 which had obtained marketing approval, all of the Company's products were in the research and development stage, and commercial production and sales had not commenced. The Company's products had not generated sales revenue, and the Company was not yet profitable and had cumulative unrecovered losses. In 2019, the net profit attributable to ordinary shareholders of the parent company was RMB -1,022.6218 million. For the foreseeable future, the Company expects to incur cumulative unrecovered losses and to continue operating at a loss.

2. **Substantial Product Pipeline With Expected Need for Continued Large-Scale** R&D Investment in the Future

As of December 31, 2019, the Company invested significant funds in preclinical research, clinical trials, and pre-market preparations for its product pipeline. In accordance with the characteristics of pharmaceutical R&D enterprises and the provisions of the "Accounting Standards for Business Enterprises," the Company expenses all R&D expenditures incurred before the relevant investigational drugs obtain new drug marketing approval. In 2019, the Company's R&D expenses were RMB 636.5111 million. During the reporting period, the Company had 1 product approved for marketing and 20 main products in the pipeline, including 1 product for which an NDA had been submitted, 3 products in Phase III clinical studies, 1 product in Phase II clinical studies, 4 products in Phase I clinical studies, and multiple projects in the preclinical research stage. The Company will continue to require substantial R&D investment in the future to advance R&D activities such as completing preclinical studies, clinical trials, and pre-market preparations for pipeline projects, with more pipeline projects entering Phase III clinical trials. It is expected that the number of the Company's investigational drug projects will increase in the future, and more pipeline products will enter Phase III clinical trials. Therefore, it is anticipated that the Company will continue to incur significant R&D expenses. If R&D expenses exceed the profits generated by commercialized products, it will lead to continued losses for the Company, thereby having a material adverse impact on the Company's daily operations, financial condition, and other aspects.

3. **Drug R&D Risk**

As of December 31, 2019, the Company has 1 product approved for marketing and 20 main products in the pipeline, including 1 product for which an NDA had been submitted, 3 products in Phase III clinical studies, 1 product in Phase II clinical studies, and 4 products in Phase I clinical studies. As of December 31, 2019, the Company had 1 adalimumab biosimilar, BAT1406, approved for marketing, and had submitted an NDA for the innovative drug BAT2094. Among the main pipeline products in clinical trial stages,

Ex. 2016-002

3 were biosimilars and 5 were innovative drugs. Due to the high technical requirements, significant development difficulty, long R&D cycles, and high costs associated with the R&D of innovative drugs and biosimilars, the R&D process is often accompanied by substantial risk of failure.

4. The Company Cannot Guarantee Regulatory Approval Of Its Submitted Drug Marketing Applications

As of December 31, 2019, the Company had only obtained marketing approval for the adalimumab biosimilar BAT1406. If the Company's pipeline drugs fail to obtain marketing approval, or if such approvals include significant restrictions, the Company's target markets may shrink, and the market potential of the pipeline drugs may be diminished.

5. Company Cannot Guarantee Profitability In The Next Few Years And May Face Delisting Risks After Listing

The Company will have continued large-scale R&D investment in the coming years, and its unprofitable status is expected to persist after listing, with cumulative unrecovered losses potentially continuing to expand. If, by the 4th full fiscal year after listing, the Company triggers the financial conditions specified in Article 12.4.2 of the “Shanghai Stock Exchange Sci-Tech Innovation Board Listing Rules”—namely, if the audited net profit before and after deducting non-recurring gains and losses (including retrospective restatements) is negative and operating revenue (including retrospective restatements) is below RMB 100 million, or if the audited net assets at the end of the period (including retrospective restatements) are negative—it may lead to the Company triggering delisting conditions. Although the Company anticipates a low likelihood of continued unprofitability over the next 4 full fiscal years, as of December 31, 2019, the Company had only obtained marketing approval for BAT1406 and submitted an NDA for BAT2094. Other products remain in the drug development stage, and commercial production and sales activities have not commenced. There is a possibility of continued inability to achieve profitability. The Company's unprofitable status may persist or cumulative unrecovered losses may continue to expand, potentially leading to the triggering of delisting conditions. According to the "Measures for the Continuous Regulation of Companies Listed on the Sci-Tech Innovation Board (Trial)," if the Company meets the termination of listing criteria, its shares will be directly delisted without applying suspension, resumption, or relisting procedures.

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

All directors attended.

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

5. 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.

6. Profit Distribution Plan or Capital Reserve to Share Capital Conversion Plan for the Reporting Period Reviewed by the Board of Directors

The Company’s 2019 annual profit distribution plan is as follows: No cash dividends will be distributed, no bonus shares will be issued, 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 Fifteenth Meeting and is pending approval by the Company's General Shareholders Meeting.

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

Ex. 2016-003

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. Other

□ Applicable √ Not Applicable

Ex. 2016-004

Table of Contents

Section I	**Definitions**	**6**
Section II	**Company Profile and Key Financial Indicator**	**10**
Section III	**Overview of Company Business**	**15**
Section IV	**Discussion and Analysis of Operations**	**34**
Section V	**Important Matters**	**62**
Section VI	**Share Changes and Shareholder Information**	**95**
Section VII	**Information Related to Preferred Shares**	**106**
Section VII	**Information Related to Directors, Supervisors, Senior Management, and Employees**	**107**
Section IX	**Corporate Governance**	**118**
Section X	**Information Related to Corporate Bonds**	**121**
Section XI	**Financial Report**	**122**
Section XII	**List of Reference Documents**	**236**

Ex. 2016-005

In recent years, with the successive introduction of policies such as national drug price negotiations, adjustments to the National Reimbursement Drug List, consistency evaluations, and volume-based procurement, the terminal bidding and procurement prices for some drugs have gradually decreased, and competition among companies has intensified. The Company's future marketed drugs may face risks of price reduction, which could pose certain potential negative impacts on the Company's future drug revenue.

3. Risk of Adjustments to the National Reimbursement Drug List

Drugs included in the National Reimbursement Drug List can have all or part of their costs covered by social insurance, making listed drugs more competitive in the market. The National Reimbursement Drug List is adjusted periodically based on factors such as therapeutic needs, frequency of drug use, efficacy, and price, but increasingly emphasizes the clinical therapeutic value of drugs. The drugs developed by the Company will also actively respond to national policies and seek inclusion in the National Reimbursement Drug List while considering patient accessibility. If the Company's newly developed products or new indications for existing products fail to be successfully included in the list, or if products or indications already included in the list are removed, it may result in slower sales growth or a decrease in sales for the relevant products.

(VII) Risks Related to Depositary Receipts

□ Applicable √ Not Applicable

(VIII) Other Significant Risks

√ Applicable □ Not Applicable

Risk of Control by the Actual Controller

The Company's actual controllers, Mr. Yi Xianzhong, Ms. Guan Yuchan, and Mr. Yi Liangyu, collectively control 59.27% of the Company's shares through indirect holdings and possess actual control over the Company. The Company has established a series of rules and systems aimed at protecting the rights of minority investors, including rules for shareholders' meetings, board of directors meetings, supervisory board meetings, an independent director system, an affiliated transaction management system, and an external guarantee management system. However, if the Company's actual controllers in the future improperly intervene in major matters such as business decisions, profit distribution, and external investments by exercising their voting rights based on their controlling position, it may harm the interests of other shareholders of the Company.

III. Main Operating Performance During the Reporting Period

Please refer to the relevant statements in the subsection "I. Discussion and Analysis of Operating Performance" of this chapter.

(I) Analysis of Main Business Operations

1. Analysis Table of Changes in Related Items of the Income Statement and Cash Flow Statement

Unit: Yuan Currency: RMB

Item	Amount for Current Period	Amount for Same Period Last Year	Change Percentage (%)
Operating Revenue	700,000.00	0	Not Applicable
Operating Cost	127,750.00	-	Not Applicable
Selling Expenses	15,424,835.75	-	Not Applicable
Administrative Expenses	385,946,116.17	26,179,338.12	1,374.24
R&D Expenses	636,511,058.15	541,689,370.95	17.50
Financial Cost	-981,281.91	27,828.17	-3,626.22
Net Cash Flow from Operating Activities	-597,975,664.90	-528,249,563.33	Not Applicable
Net Cash Flow from Investing Activities	-74,805,751.44	-339,340,487.95	Not Applicable
Net Cash Flow from Financing Activities	599,326,979.67	932,980,339.97	-35.76

Ex. 2016-006

Note: 1. Administrative expenses increased by 1,374.24% compared to the same period last year, primarily due to RMB 349,800,000.00 in share-based payment expenses incurred during this reporting period.

2. Financial cost decreased by 3,626.22% compared to the same period last year, primarily due to interest income generated from shareholder investment funds received during this reporting period.

3. Net cash flow from financing activities decreased by 35.76% compared to the same period last year, primarily due to reduced transactions with the controlling shareholder during this reporting period.

2. Analysis of Revenue and Cost

□ Applicable √ Not Applicable

(1). Analysis Table of Production and Sales Volume

□ Applicable √ Not Applicable

Company's Top 5 Customers

□ Applicable √ Not applicable Other Explanation

As of December 31, 2019, the Company had no products commercially sold.

B. **Company's Major Suppliers**

Procurement amount from the top five suppliers was RMB 220.2762 million, accounting for 38.87% of total annual procurement. Among the procurement amounts from the top five suppliers, procurement from affiliated parties was RMB 0 million, accounting for 0% of total annual procurement.

Company's Top 5 Suppliers

√ Applicable □ Not Applicable

Unit: Unit: Thousand RMB; Currency: RMB

S/N	Supplier Name	Procurement Amount	Percentage of Total Annual Procurement (%)
1	Supplier No.1	9,111.54	16.08
2	Supplier No.2	6,276.78	11.08
3	Supplier No.3	2,406.33	4.25
4	Supplier No.4	2,237.27	3.95
5	Supplier No.5	1,995.70	3.52
Total	/	22,027.62	38.87

Other Explanation: None

3. Expenses

√ Applicable □ Not Applicable

Unit: Yuan

Item	2019	2018	Change Percentage (%)
Selling Expenses	15,424,835.75	-	Not Applicable

Administrative Expenses	385,946,116.17	26,179,338.12	1374.24
R&D Expenses	636,511,058.15	541,689,370.95	17.50
Financial Cost	-981,281.91	27,828.17	-3626.22

4. Cash Flow

√ Applicable □ Not Applicable

Cash Flow

Unit: Yuan

Item	2019	2018	Change Percentage (%)
Net Cash Flow from Operating Activities	-597,975,664.90	-528,249,563.33	Not Applicable
Net Cash Flow from Investing Activities	-74,805,751.44	-339,340,487.95	Not Applicable
Net Cash Flow from Financing Activities	599,326,979.67	932,980,339.97	-35.76

(II) Explanation of Significant Changes in Profit Due to Non-Main Business Operations

√ Applicable □ Not Applicable

In 2019, the consolidated financial statements and the Company's financial statements recognized a one-time share-based payment expense of RMB 352,000,000.00, resulting in increased losses compared to the previous year.

(III) Analysis of Assets and Liabilities

√ Applicable □ Not Applicable

1. Asset and Liability Status

Unit: Yuan

Item Name	Amount at End of Current Period	Percentage of Total Assets at End of Current Period (%)	Amount at End of Previous Period	Percentage of Total Assets at End of Previous Period (%)	Change Percentage Compared to End of Previous Period (%)	Explanation
Cash and Cash Equivalents	39,074,061.97	3.85%	112,355,238.10	11.01%	-65.22%	Mainly due to ongoing R&D expenditures, leading to a decrease in cash and cash equivalents
Construction in Progress	117,139,643.44	11.54%	69,659,688.52	6.82%	68.16%	Mainly due to newly added production line equipment under construction
Accounts Payable	153,462,499.35	15.12%	99,142,612.78	9.71%	54.79%	Mainly due to an increase in unpaid technical service fees
Employee Compensation Payable	23,096,553.52	2.28%	17,408,474.15	1.71%	32.67%	Mainly impacted by an increase in company personnel
Taxes Payable	785,714.14	0.08%	5,137,433.40	0.50%	-84.71%	Mainly due to a decrease in VAT requiring withholding and collection
Deferred Income	3,208,822.69	0.32%	6,220,426.82	0.61%	-48.41%	Mainly due to deferred income transferred to other income

Ex. 2016-008

Other Explanation: None

2. Major Assets Restricted as of the End of the Reporting Period

√ Applicable □ Not Applicable

Item	Book Value as of December 31, 2019	Reason for Restriction
Cash and Cash Equivalents (Note 1)	13,696,945.50	Performance guarantee under the land use right transfer contract
Other Non-current Assets (Note 1)	20,545,418.25	Performance guarantee under the land use right transfer contract
Fixed Assets (Note 2)	107,778,772.02	Mortgage for bank loans
Construction in Progress (Note 2)	18,195,716.45	Mortgage for bank loans
Total	160,216,852.22	

Note 1: As of December 31, 2019, and December 31, 2018, cash and cash equivalents with book values of RMB 34,242,363.75 and RMB 33,780,000.00, respectively, were used as performance guarantees for the letter of guarantee related to the state-owned land use right transfer contract entered into between the Company and the Guangzhou Municipal Land Resources and Planning Commission. The guarantee period is from August 30, 2018, to December 31, 2022.

Note 2: As of December 31, 2019, fixed assets with a book value of RMB 107,778,772.02 and construction in progress with a book value of RMB 18,195,716.45 were mortgaged to obtain bank loans. The mortgage period is from August 21, 2019 to August 30, 2020.

3. Other Explanation

□ Applicable √ Not Applicable

(IV) Analysis of Industry Operating Information

√ Applicable □ Not Applicable

According to the industry directory and classification principles of the "Classification and Codes of Listed Companies" (2012 revision) issued by the China Securities Regulatory Commission, the Company belongs to the "Pharmaceutical Manufacturing Industry (C27)." Analysis of industry operating information during the reporting period is detailed in "Section III Company Business Overview," subsection "I. Description of the main business, operating model, industry situation, and R&D status during the reporting period," subsection "(III) Industry Situation." Specific industry segmentation is detailed in the subsection "Analysis of Operating Information for the Pharmaceutical Manufacturing Industry" of this section.

Analysis of Operating Information for the Pharmaceutical Manufacturing Industry

1. Industry and Major Pharmaceutical Product Overview (1). Industry Overview

√ Applicable □ Not Applicable

Development Overview of the Biologics Industry

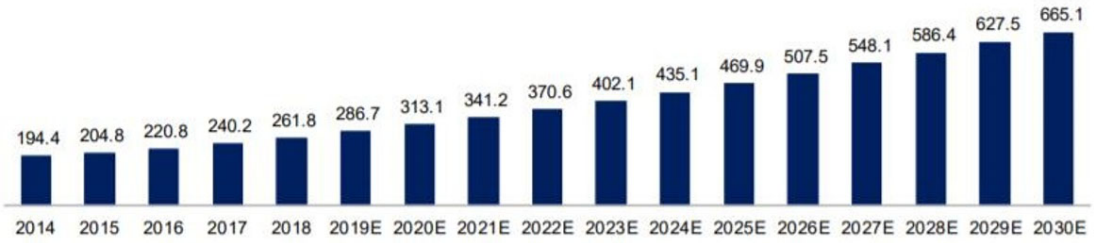
Ex. 2016-009

Compared to chemical drugs, the development of biologics started relatively late, only entering the stage of large-scale industrialization in the past 40 years. Despite its late start, the biologics industry has become the segment within the global pharmaceutical industry most likely to produce blockbuster products with annual revenues exceeding USD 1 billion. According to statistics from various pharmaceutical companies' annual reports, among the top 10 best-selling drugs globally in 2018, 9 were biologics, with only 1 being a chemical drug. Humira® ranked first in global drug sales for seven consecutive years. According to a Frost & Sullivan report, the global biologics market size reached USD 194.4 billion in 2014 and increased to USD 261.8 billion in 2018. Continuous breakthroughs in pharmaceutical R&D technologies

Global Biologics Market Size, 2014-2030E

Period	CAGR
2014-2018	7.7%
2018-2023E	9.0%
2013E-2030E	7.5%

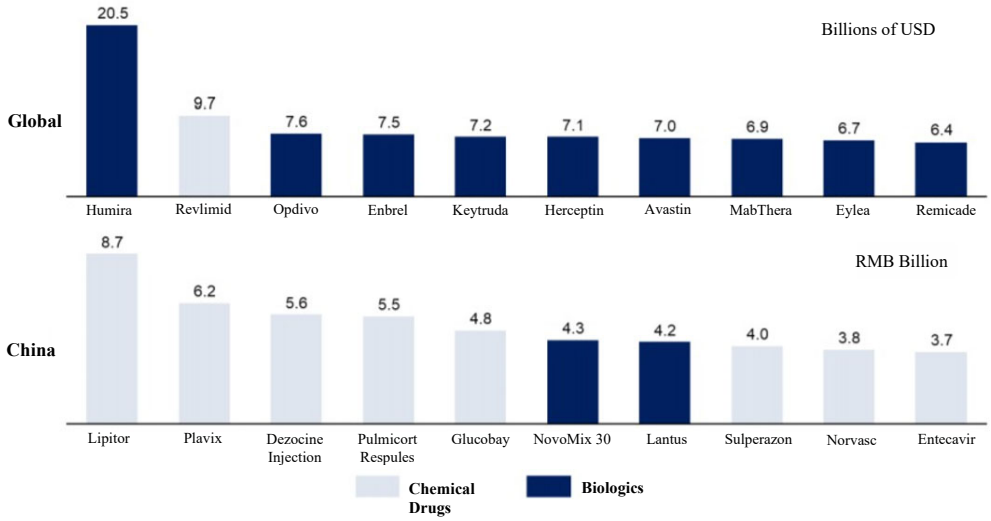
Unit: Billions of USD based on winning bid prices



within the biopharmaceutical field are the main growth drivers for the biologics industry market. Data Source: Frost & Sullivan Report

Due to differences in industrial structure, the best-selling drugs in the Chinese pharmaceutical market differ significantly from the global market. Among the top 10 best-selling drugs in China in 2018, only two were biologics (insulins), while the other eight were chemical drugs. In the future, the structure of China's best-selling drugs

Global and China Top 10 Best-Selling Drugs, 2018



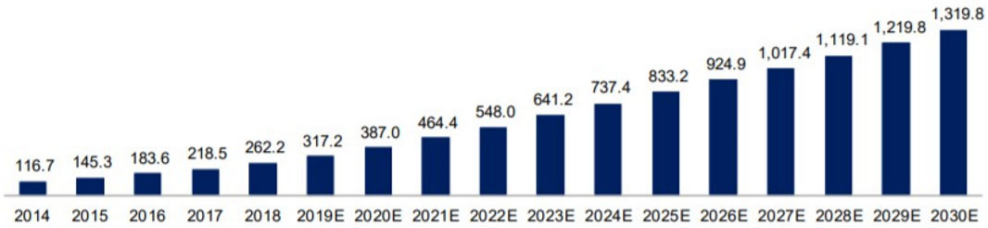
will develop towards the global trend, with more biologics becoming leading blockbuster products in terms of sales. Data Source: Frost & Sullivan Report

The development of China's biologics industry lags behind the global market, thus China's biologics market has broader growth potential. The Chinese biologics market has grown rapidly in recent years at a rate several times that of the global biologics market. Driven by factors such as technological innovation, increased public health awareness, and the superior efficacy of biologics, the future Chinese biologics market size

Global Biologics Market Size, 2014-2030E

Period	CAGR
2014-2018	22.4%
2018-2023E	19.6%
2023E-2030E	10.9%

Unit: RMB Billion
based on winning bid prices



is expected to expand rapidly, reaching RMB 1.3 trillion by 2030. Data Source: Frost & Sullivan Report

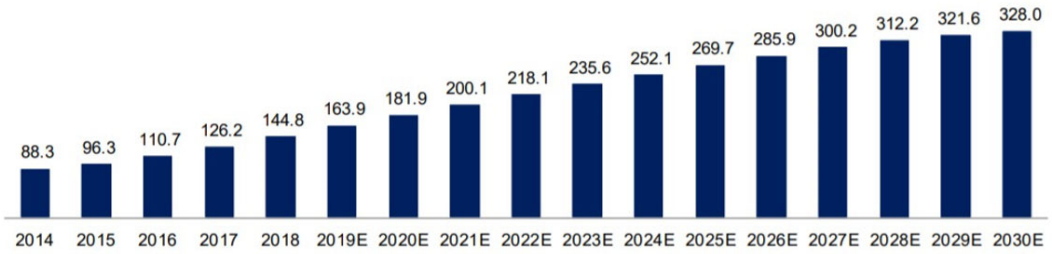
Development Overview of the Monoclonal Antibody Drug Industry

Biologics include monoclonal antibodies, recombinant therapeutic proteins, vaccines, blood products, cell and gene therapies, and other biological

Global Monoclonal Antibody Drug Market Size (2014-2030E)

Period	CAGR
2014-2018	13.2%
2018-2023E	10.2%
2023E-2030E	4.8%

Unit: Billions of USD
based on winning bid prices



Data Source: Frost & Sullivan Report

therapies. Among these, due to their strong targeting, good efficacy, and low side effects, monoclonal antibody drugs are widely used

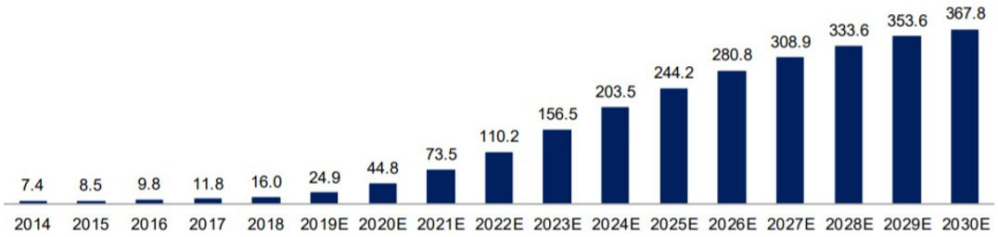
in various therapeutic areas such as autoimmune diseases and cancer. In 2018, monoclonal antibody drugs occupied 7 positions on the global top ten best-selling drug ranking. Monoclonal antibody drugs have also become the most popular research area within the biologics industry. According to a Frost & Sullivan report, with the increasing number of monoclonal antibody drugs approved in Europe and the US, the global monoclonal antibody drug market grew from USD 88.3 billion in 2014 to USD 144.8 billion in 2018, with a CAGR of 13.2%. This market is expected to reach USD 235.6 billion by 2023 and USD 328 billion by 2030.

China's monoclonal antibody drug market is still in its early stages, with many drugs currently marketed in Europe and the US not yet approved in China. According to a Frost & Sullivan report, China's monoclonal antibody drug market size was only RMB 16 billion in 2018. As more monoclonal antibody drugs enter the market and are gradually included in the reimbursement drug list, this market is expected to grow at a CAGR of 57.9% over the next five years. China's monoclonal antibody drug market is projected to grow to RMB 156.5 billion by 2023 and RMB 367.8 billion by 2030.

China Monoclonal Antibody Drug Market Size (2014-2030E)

Period	CAGR
2014-2018	21.1%
2018-2023E	57.9%
2023E-2030E	13.0%

Unit: RMB Billion
based on winning bid prices



Data Source: Frost & Sullivan Report **Development Overview of the Biosimilar Industry**

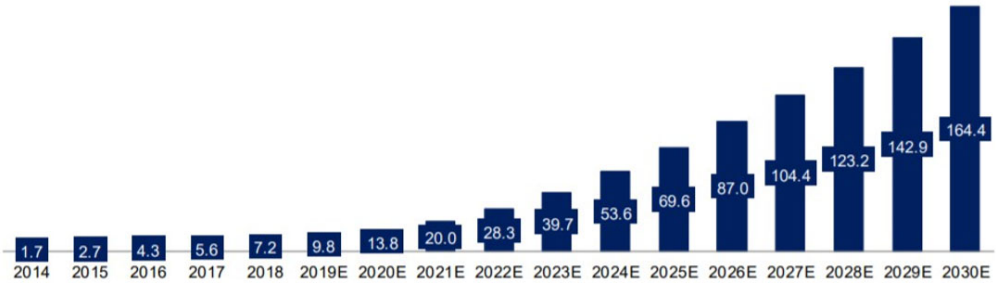
According to the "Technical Guidelines for the Development and Evaluation of Biosimilars (Trial)" issued by China's NMPA, a biosimilar is a therapeutic biological product that is similar to an already approved reference drug in terms of quality, safety, and efficacy. Biosimilars are copies of originator drugs and can only be approved after the originator drug's patent protection expires. The global biosimilar market size is in a phase of rapid growth. As more biosimilars gain approval, the market growth rate is expected to show a sustained increasing trend. According to a Frost & Sullivan report, the global biosimilar market size reached USD 1.7 billion in 2014, increased to USD 7.2 billion in 2018, and is projected to reach USD 164.4 billion by 2030.

Data Source: Frost & Sullivan Report

Global Biosimilar Market Size (2014-2030E)

Period	CAGR
2014-2018	44.2%
2018-2023E	40.6%
2023E-2030E	22.5%

Unit: Billions of USD



High prices are the main reason for the low penetration of originator drugs in China. Biosimilars have lower R&D costs compared to originator drugs, giving them a price advantage. As of December 31, 2019, multiple manufacturers in China have applied for clinical trials or marketing applications for rituximab biosimilars, bevacizumab biosimilars, and adalimumab biosimilars. China's first rituximab biosimilar and first adalimumab biosimilar have already been approved. With increased medical insurance coverage, patients' payment ability will be significantly enhanced, providing strong support for the development of biosimilars in China and accelerating market expansion. According to a Frost & Sullivan report, China's biosimilar market is expected to experience explosive growth in the coming years, with the market size reaching RMB 58.9 billion by 2030.

Data Source: Frost & Sullivan Report

(2). Overview of Major Pharmaceutical Products

√ Applicable □ Not Applicable

Overview of Major Pharmaceutical Products by Segment

√ Applicable □ Not Applicable

Segment	Product Name	Indication	Registration Classification	Traditional Chinese Medicine Protected Variety?	Prescription Drug?	New Product Launched During Reporting Period?
Biopharmaceuticals	QLETLI	Ankylosing Spondylitis, Rheumatoid Arthritis, and Psoriasis	Therapeutic Biological Product Category 2	No	Yes	Yes

Overview of Major Pharmaceutical Products by Therapeutic Area

√ Applicable □ Not Applicable

Main Therapeutic Area	Product Name	Product Registration Classification	New Product Launched During Reporting Period?	Production Volume During Reporting Period	Sales Volume During Reporting Period
Autoimmune Diseases	QLETLI	Therapeutic Biological Product Category 2	Yes	13,318 vials*	0

Note*: This data represents only the production volume for the single month of December 2019, after QLETLI received marketing authorization in November 2019. **(3).**Major Pharmaceutical Products Newly Entering or Exiting the Essential Drug List and Reimbursement Drug List During the Reporting Period

√ Applicable □ Not Applicable

The Marketing Authorization Application for adalimumab BAT1406 was officially accepted by the CDE on August 17, 2018, and received marketing approval in November 2019, with the brand name "QLETLI." The approved indications are ankylosing spondylitis, rheumatoid arthritis, and psoriasis. Adalimumab injection was included in the National Reimbursement Drug List, with a reimbursement standard of RMB 1,290 per 40mg.

(4).Company's Well-Known or Famous trademark

□ Applicable √ Not Applicable

2. Company Pharmaceutical Product R&D Status

(1). Overall R&D Status

√ Applicable □ Not Applicable

The Company is committed to developing next-generation innovative drugs and biosimilars for the treatment of cancer, autoimmune diseases, cardiovascular diseases, and other major diseases critical to human health.

In the autoimmune disease field, the Company's main products are biosimilars, including BAT1806, which has entered international Phase III clinical trials, BAT2506, which has completed Phase I patient recruitment, and BAT2206, which has received clinical trial approval. Additional biosimilar candidates are at various stages of preclinical research, with at least one candidate expected to file a clinical trial application in 2020.

In the oncology field, the Company focuses on both biosimilar and innovative drug development. The biosimilar BAT1706 entered the final stages of its international Phase III clinical trial at the end of 2019, with submissions planned in China, the US, and Europe in 2020.

Among innovative candidates, the ADC candidate BAT8001 is in Phase III, and BAT8003 is in the dose-escalation phase of Phase I. The Company is also developing next-generation ADC technology for more follow-on targets.

Additionally, the Company has BAT4306F and BAT4406F targeting the hematological oncology target CD20, which were in Phase I dose-escalation and Phase I initiation stages, respectively, in 2019.

Tumor immunotherapy is an area the Company has focused on in recent years. BAT1306 is already in Phase II clinical trials, with several other candidates in the preclinical safety evaluation stage. Bispecific antibodies have also shown promising efficacy in animal studies. In the cardiovascular and other disease areas, BAT2094 has submitted an NDA application. BAT5906 successfully completed its dose-escalation trial in 2019 and will initiate Phase II clinical studies for both wAMD and DME indications in 2020.

(2). R&D Investment Status

R&D Investment for Major Pharmaceutical Products

√ Applicable □ Not Applicable

Unit: Thousand RMB; Currency: RMB

Ex. 2016-014

Product	R&D Investment Amount	Expensed R&D Investment Amount	Capitalized R&D Investment Amount	R&D Investment as a Percentage of Operating Revenue (%)	R&D Investment as a Percentage of Operating Cost (%)	Percentage Change in Amount Compared to Same Period Last Year (%)	Explanation
QLETLI	4,220.66	4,220.66	Not Applicable	Not Applicable	Not Applicable	-46.84%	Note 1*
BAT1706	19,326.76	19,326.76	Not Applicable	Not Applicable	Not Applicable	15.69%	
BAT8001	9,972.70	9,972.70	Not Applicable	Not Applicable	Not Applicable	98.07%	Note 2*
BAT1806	12,364.01	12,364.01	Not Applicable	Not Applicable	Not Applicable	59.91%	Note 3*
BAT2094	1,371.84	1,371.84	Not Applicable	Not Applicable	Not Applicable	93.74%	Note 4*
BAT8003	897.78	897.78	Not Applicable	Not Applicable	Not Applicable	-58.11%	Note 5*
BAT1306	1,191.74	1,191.74	Not Applicable	Not Applicable	Not Applicable	5.37%	
BAT4306F	625.35	625.35	Not Applicable	Not Applicable	Not Applicable	0.49%	
BAT5906	817.76	817.76	Not Applicable	Not Applicable	Not Applicable	-16.15%	
BAT2506	2,041.88	2,041.88	Not Applicable	Not Applicable	Not Applicable	68.63%	Note 6*
BAT4406F	532.42	532.42	Not Applicable	Not Applicable	Not Applicable	66.60%	Note 7*

Note 1: The adalimumab BAT1406 (QLETLI) project received clinical trial approval in December 2015 and commenced clinical trials. It completed Phase III clinical trials and submitted the Marketing Authorization Application in July 2018, and received the drug registration approval in November 2019. With the conclusion of clinical trials, the Company began pilot production. R&D expenses decreased in 2019 compared to 2018.

Note 2: BAT8001 received clinical trial approval in September 2016 and is currently in Phase III clinical trials. As the clinical trial progresses, clinical expenses in each period will gradually increase.

Note 3: Tocilizumab BAT1806 received clinical trial approvals in China (November 2017), Georgia (November 2018), Bulgaria (January 2019), Poland (March 2019), and Ukraine (May 2019). As the clinical trial progressed, expenses increased significantly in 2019.

Note 4: The batifiban BAT2094 project received clinical trial approval in July 2012. All subjects in the Phase III clinical trial completed the study in the second half of 2016. Follow-up of subjects was completed in 2017. The Marketing Authorization Application was submitted in November 2019.

Note 5: BAT8003 applied for clinical trial approval in October 2018 and received approval in January 2019. Large-scale clinical trials have not yet commenced; it is currently in Phase I studies.

Note 6: BAT2506 started clinical trial application in January 2019 and received approval in April 2019. As of now, the project is in Phase I clinical trials. Patient recruitment has gradually begun, and small-scale clinical trials are underway. R&D expenses incurred during the clinical trial period in 2019 increased compared to 2018.

Note 7: BAT4406 received clinical trial application approval in July 2019 and is currently preparing to initiate Phase I clinical trials. As the research progresses, monthly R&D expenses in 2019 increased compared to 2018.

Comparison with Industry Peers

√ Applicable □ Not Applicable

Unit: Unit: Thousand RMB; Currency: RMB

Comparable Companies in the Same Industry	R&D Investment Amount	R&D Investment as a Percentage of Operating Revenue (%)	R&D Investment as a Percentage of Net Assets (%)
Hengrui Pharma	389,633.60	16.73	15.73
Betta Pharmaceuticals	67,458.50	43.41	27.42
Shenzhen Chipscreen Biosciences	7,823.90	45.02	5.41
Suzhou Zelgen Biopharmaceuticals	18,384.15	/	249.28
Average R&D Investment Amount in the Same Industry		120,825.04	
Company's R&D Investment Amount During Reporting Period		63,651.11	
Company's R&D Investment as a Percentage of Operating Revenue During Reporting Period (%)		/	
Company's R&D Investment as a Percentage of Net Assets During Reporting Period (%)		100.93	

Explanation of Significant Changes in R&D Investment and the Rationality of R&D Investment Ratio

□ Applicable √ Not Applicable

(3). Overview of Major R&D Projects

√ Applicable □ Not Applicable

Unit: Thousand RMB; Currency: RMB

R&D Projects (including consistency evaluation projects)	Basic Product Information	R&D (Registration) Stage	Progress Status	Cumulative R&D Investment	Number of Manufacturers Who Have Submitted Applications	Number of Approved Domestic Generic Manufacturers
BAT2094	Chemical Drug, Indication: Perioperative Antithrombosis for PCI	Clinical Research Stage	Phase III clinical, NDA Application	7,363.20	/	/
BAT1706	Biosimilar, Indication: Non-squamous Non-Small Cell Lung Cancer	Clinical Research Stage	Phase III Clinical	46,690.77	/	/
BAT8001	ADC Drug, Indication: HER2-positive Breast Cancer	Clinical Research Stage	Phase III Clinical	19,495.39	/	/
BAT1806	Biosimilar, Indication: Rheumatoid Arthriti	Clinical Research Stage	Phase III Clinical	23,509.86	/	/
BAT1306	Biologic Drug, Indication:	Clinical Research Stage	Phase II Clinical	4,859.26	/	/

R&D Projects (including consistency evaluation projects)	Basic Product Information	R&D (Registration) Stage	Progress Status	Cumulative R&D Investment	Number of Manufacturers Who Have Submitted Applications	Number of Approved Domestic Generic Manufacturers
	EBV-positive Gastric Cancer ADC Drug Indication: Trop2-Positive Advanced Epithelial Carcinoma					
BAT8003		Clinical Research Stage	Phase I Clinical	5,439.76	/	/
BAT2506	Biosimilar, Indication: Autoimmune Diseases	Clinical Research Stage	Phase I Clinical	3,760.44	/	/
BAT4306F	Biologic Drug, Indication: Relapsed/Refractory CD20-positive B-cell Non-Hodgkin Lymphoma	Clinical Research Stage	Phase I Clinical	2,800.63	/	/
BAT5906	Biologic Drug, Indication: Wet Age-related Macular Degeneration	Clinical Research Stage	Phase I Clinical	3,900.01	/	/

Impact of R&D Projects on the Company

√ Applicable □ Not Applicable

During the reporting period, the Company had 1 product approved for marketing and 20 main products in the pipeline, including 1 product for which an NDA had been submitted, 3 products in Phase III clinical studies, 1 product in Phase II clinical studies, 4 products in Phase I clinical studies, and multiple projects in the preclinical research stage. The Company will continue to require substantial R&D investment in the future to advance R&D activities such as completing preclinical studies, clinical trials, and pre-market preparations for pipeline projects, with more pipeline projects entering Phase III clinical trials. It is expected that after the initial public offering, the number of the Company's investigational drug projects will increase, and more pipeline products will enter Phase III clinical trial stages. Therefore, it is anticipated that the Company will continue to incur significant R&D expenses in the future. If R&D expenses exceed the profits generated by commercialized products, it will lead to continued losses for the Company, thereby having a material adverse impact on the Company's daily operations, financial condition, and other aspects.

(4). Pharmaceutical Products Submitted for Regulatory Approval, Completed Registration, or Obtained Production Approval During the Reporting Period

√ Applicable □ Not Applicable

Submitted for Regulatory Approval in 2019:China: BAT2506, BAT4406F, BAT2206, BAT5906 (additional indication), all for Clinical Trial Applications.

Completed Registration and Obtained Approvals in 2019: China: BAT8003, BAT2506, BAT4406F, and BAT2206 approved for clinical trials; BAT1406 approved for marketing. US FDA: BAT1706 Investigational New Drug (IND) application.

Ex. 2016-017

(5). R&D Projects Canceled or Pharmaceutical Products Not Approved During the Reporting Period

□ Applicable √ Not Applicable

(6). Important R&D Projects Planned for the New Year

√ Applicable □ Not Applicable

Please refer to subsection "Analysis of Operating Information for the Pharmaceutical Manufacturing Industry," section 2 (3) "Overview of Major R&D Projects" in this section.

3. Company Pharmaceutical Product Production and Sales Situation

(1). Overview of Company's Main Business Operations by Therapeutic Area

□ Applicable √ Not applicable Other Explanation

□ Applicable √ Not Applicable

(2). Analysis of Company's Main Sales Models

□ Applicable √ Not Applicable

(3). Bidding Results in Centralized Drug Procurement

□ Applicable √ Not Applicable

□ Applicable √ Not Applicable

(4). Analysis of Selling Expenses Detailed Breakdown of Selling Expenses

√ Applicable □ Not Applicable

Unit: Unit: Thousand RMB;
Currency: RMB

Specific Project Name	Amount for Current Period	Percentage of Total Selling Expense for Current Period (%)
Employee Compensation	931.39	60.38
Conference and Training Expenses	195.83	12.70
Travel Expenses	234.75	15.22
Business Entertainment Expenses	116.59	7.56
Service Fees	34.54	2.24
Office Expenses	2.99	0.19
Other Expenses	26.39	1.71
Total	1,542.48	100.00

Comparison with Industry Peers

□ Applicable √ Not Applicable

Explanation of Significant Changes in Selling Expenses and the Rationality of Selling Expenses

□ Applicable √ Not Applicable

Other Explanation

□ Applicable √ Not Applicable

(V) Analysis of Investment Status

1. Overall Analysis of External Equity Investments

□ Applicable √ Not Applicable

(1) Significant Equity Investments

□ Applicable √ Not Applicable

(2) Significant Non-Equity Investments

□ Applicable √ Not Applicable

(3) Financial Assets Measured at Fair Value

□ Applicable √ Not Applicable

(VI) Sale of Major Assets and Equity

□ Applicable √ Not Applicable

(VII) Analysis of Major Controlled and Participated Companies

√ Applicable □ Not Applicable

Unit: Thousand RMB

Name	Registered Location	Business Nature	Shareholding Percentage	Registered Capital	Total Assets	Net Assets	Net Profit
BTS BIOPHARMA INC.	United States	Clinical Trials, Drug Registration, and Business Development Consulting	100%	USD 1 million	60.75	60.40	-114.56

(VIII) Structured Entities Controlled by the Company

□ Applicable √ Not Applicable

IV. Company's Discussion and Analysis Regarding Future Development

(I) Industry Landscape and Trends

√ Applicable □ Not Applicable

The biopharmaceutical industry is an important sector highly focused on by the economic development of countries worldwide. Countries and regions such as the United States, Europe, and Japan have all regarded the biopharmaceutical industry as the next new economic growth point. China's biopharmaceutical industry started relatively late. However, with the increasing influence of the biopharmaceutical industry globally, China also places great emphasis on its development. Biotechnology was first listed as a key development target in the 863 Plan. In the "11th Five-Year Plan," it proposed "focusing on biotechnology and pharmaceutical technology." In the "12th Five-Year Plan," the biopharmaceutical industry was again listed as one of the seven strategic emerging industries. The "13th Five-Year Plan" established three specific target systems: "enhancing the originality level of biotechnology," "building biotechnology innovation platforms," and "strengthening the industrialization of biotechnology."

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 - 2019-Dec-30 - 688177.SS - Bio-Thera Solutions Ltd - ANNUAL FULL REPORT - 百奥泰：2019年年度报告 - cn04212595” 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