

**ADVANCES IN  
Biopharmaceutical  
Technology in China**  
2nd Ed.



**ADVANCES IN  
Biopharmaceutical  
Technology in China** 2nd Ed.  
**中国生物制药技术进展** 第2版

Society for Industrial Microbiology  
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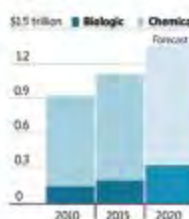
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**China's Biotech Boom**

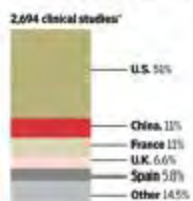
Biotech drugs will account for a quarter of the world's drug sales.

**Drug sales**



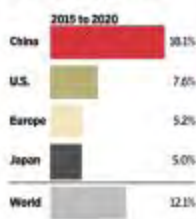
...with China accounting for many biotech drugs in development...

**Open studies involving biologics**



...and its biotech sector capacity growing the fastest.

**Fastest-growing markets**



**Vicky (Qing) Xia and Leo (Yang) Cai**  
**EDITORS**

# **Advances in Biopharmaceutical Technology in China, Second Edition**

*October 2018*

**Editors:**

**Vicky (Qing) Xia, Leo (Yang) Cai**



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Thank you for your efforts, and your recognition of the importance of this study.

Vicky (Qing) Xia and Leo (Yang) Cai  
Managing Editors



## Preface to the Second Edition

This study was undertaken and managed by BioPlan Associates, Inc., a biopharmaceutical management and strategic market analysis consulting firm in Rockville, MD. The genesis of the project, based on our nearly 30 years' experience and knowledge of the market segment, is the growth in the biopharmaceutical segment, including the emerging regions such as China and India. China, in particular, since the publication of the first edition of this study, has advanced relatively more rapidly, and with those advances comes the need for updated perspectives. BioPlan surveyed the industry to identify required content, and then selected subject matter experts to author relevant chapters to this study.

The Society for Industrial Microbiology and Biotechnology (SIMB), in recognizing the importance of applied sciences in biotechnology processes, has lent its name to this endeavor. The Society for Industrial Microbiology and Biotechnology (SIMB) is a nonprofit professional association dedicated to the advancement of microbiological sciences, especially as they apply to industrial products, biotechnology, materials, and processes. Founded in 1949, SIMB promotes the exchange of scientific information through its meetings and publications, and serves as liaison among the specialized fields of microbiology. Membership in the Society is extended to all scientists in the general field of microbiology.

This book, the 2nd edition, is an update from the first published by BioPlan Associates, Inc. over a decade ago. We consider the update very necessary at this time, as so many changes have taken place over the past decade in China's biopharma that the industry has now evolved into a stage few could have imagined back then. Innovation is beginning to deliver profitability for this industry which used to be dominated by generics. Today, many revolutionary changes in bio-manufacturing are occurring, and China is aggressively avoiding legacy technologies in favor of more modern approaches. While the economic situation in China does not always allow adoption of the latest technologies in China, the awareness that future efficiency and productivity depends on using modern techniques is a strong driver. The regulatory authorities in China have also taken on rather substantial reforms to help innovation at all levels, including manufacturing to help achieve parity in line with that of Western peers. China's export ambitions, based on BioPlan's recent analyses, include a strong focus on participating as a commercial partner in Western regulated markets and to meet the quality and performance needs expected of a GMP provider. There are many biopharma fields in China that are energized, and that are beginning to present exciting improvements, and we are fortunate to have dozens of both Chinese and Western industry subject matter experts as our authors who work in these sectors to share their expertise and opinions on this fast-changing industry. We are confident that their insights will help our readers to gain in-depth knowledge and find opportunities in China's booming biopharma industry.

This book contains multiple sections covering innovation, bio-manufacturing, regulatory system and ongoing reforms in China, investment in China's biopharma, clinical trials and contract services,

as well as advances in RNAi, CAR-T, rare disease treatment and projection of future development. It includes appendices of China's biological therapeutics under clinical development and on the market, as well as the Top 60 biopharma companies currently in China.

The intended audience for this study includes decision-makers at biopharmaceutical research organizations, biotherapeutic manufacturers, contract manufacturing organizations, suppliers to the industry, policy-makers, and international entities evaluating this market. We plan to keep this study current by assessing the segment regularly as technologies, and the industry advance.

We thank all of our writers, reviewers, and the Society for Industrial Microbiology and Biotechnology (SIMB) for making the publication of this book possible.

*China's Food and Drug Administration changed its name to China National Drug Administration/State Drug Administration.*

*Some Chapters in our Report retain the former name. Exchange rates: 1 CNY = 0.15 USD (July 2018)*

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## SECTION 1

# **Introduction to Advances in China Biopharmaceuticals**

## 1

# Introduction: A China Biopharmaceutical Strategy

**Andrew D. Skibo**

Head of Global Biologics Operations  
AstraZeneca (MedImmune)  
Gaithersburg, MD USA

## ABSTRACT

**C**hina aspires to become one of, if not the leading, country contributor to the global pharmaceutical and biopharmaceutical industry by 2030. Large companies in this sector—both international firms expanding their own footprint within China and indigenous Chinese firms establishing both their internal and their global footprints—have witnessed double-digit growth for much of the past five to seven years. The major successful pharmaceutical firms operate their business as a unified whole. Strategies for growth may be and are tailored to suit the dynamics of a particular region, but all of the elements of that strategy are also part of a coordinated overall plan. The factors driving the overall pharmaceutical and biopharmaceutical industry are uniform and apply to every company doing business in this sector, with some companies being further ahead (or behind). The development curve in certain key areas such as the creation of new product pipelines or the establishment of operations in emerging markets may differ from company to company, but the driving factors behind those changes apply to all companies. The global pharmaceutical and biopharmaceutical industry itself, not just that within China, has entered a period of substantial change. Drivers for success in the past decade will not in all

cases be the drivers for success for the future. Some factors that drove success for our industry in the past decade may indeed be factors that could contribute to failure in the future if they are managed without considering the new context of the industry. Changes that our industry is dealing with include factors that have a material impact on our risk versus value structures and strategies. Our supply structures that were designed for the realities of the past 10 to 15 years have to be adapted for the expected realities of the next 10 to 15 years. Enterprise and supply chain strategies based upon old paradigms may well fail in this new future. The changes most affecting the industry today include:

- Robust research and development pipelines and increasing new product launches
- A shift to biologics from small molecules
- A shift from a focus on primary care to specialty care product segments
- Continued growth of emerging market sectors
- High patient population specialty care markets
- Largely aligned global quality standards applied to products and raw materials
- Growth of the oncology, especially the immuno-oncology therapy area

While the impact of each of these changes has a unique origin, many of them have in common the fact that they potentially drive a substantial increase in the risk of supply versus cost equation used to set strategy for pharmaceutical and biopharmaceutical manufacturing supply chain design. Old models now may be high-risk models. This trend will be exacerbated through the next decade.



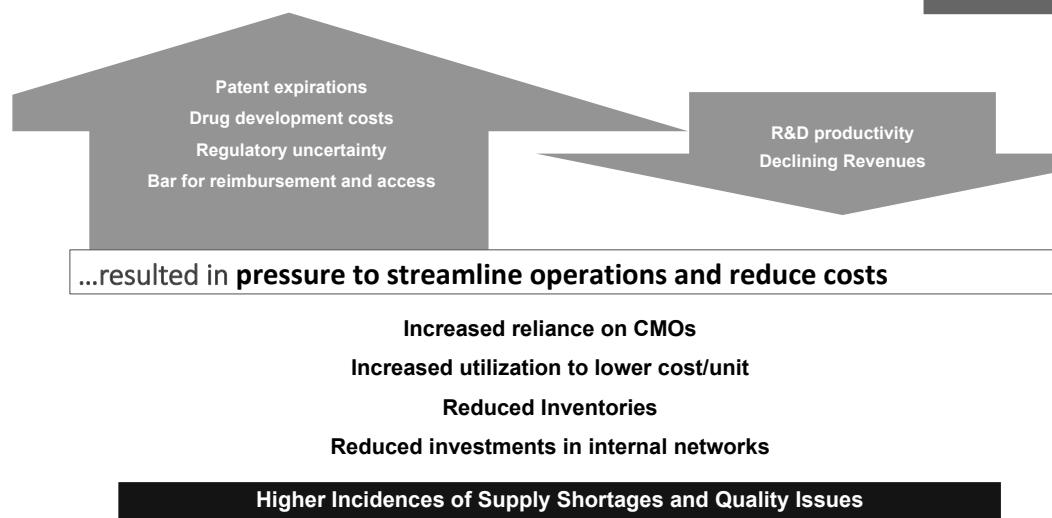
## Changes And Trends In The Global Pharmaceutical/ Biopharmaceutical Industry

Changes and trends in the global pharmaceutical and biopharmaceutical industry can significantly inform the industry's strategy in China. As stated earlier, China aspires to become one of if not the leading country contributors to the global pharmaceutical and biopharmaceutical industry by 2030. The business factors that drive success in this industry on a global scale are common to all firms. Differences that exist on a regional basis should be optimized to take advantage of regional strengths and unique markets, but overall global success will be achieved only if a company is fully aware of the most impactful future trends poised to drive the industry over the next 10 to 15 years. Those most impactful pharmaceutical industry trends have changed significantly from those of the past decade. The factors affecting the industry during the period between 2000 and 2015 have been referred to as a “perfect storm” (Figure 1) of negative changes for the industry and include:<sup>1</sup>

- Patent expirations
- Significantly increased drug development costs
- Lower research and development (R&D) productivity
- Greater regulatory uncertainty
- Higher hurdles for product reimbursement and patient access
- Trends towards R&D externalization to share risk and reduce costs
- Uncertainty in the American healthcare market (which still drives more than 50% of all major drug reimbursements)
- Ex-American price controls
- Uncertainty regarding biosimilar market entry and penetration

**“Success in China, as an integral part of this global biopharmaceutical business, requires an understanding of not only the changes occurring in the industry but also the driving forces behind those changes.” Andrew D. Skibo, Head of Global Biologics Operations, AstraZeneca / MedImmune**

**Fig. 1 The Perfect Storm**

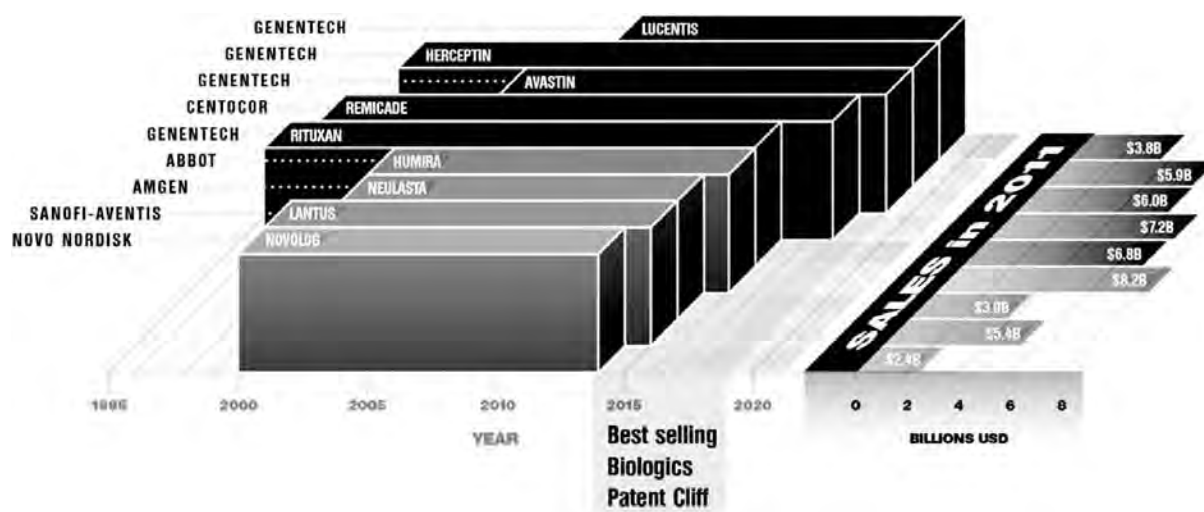


Source: A.D. Skibo, AstraZeneca, (2015) AstraZeneca ISPE/FDA/PQRI Quality Manufacturing Conference

## Patent Expiries

Each of these factors alone would have had a material impact on the industry. As a collective whole, their combined impact affected and continues to affect the underlying fundamentals of the pharmaceutical industry. Figure 2 shows just the cliff of major biologics product patent expiries in just the six years of 2014 through 2019.<sup>2</sup> Nine of the major global pharmaceutical companies will witness the expiration of approximately USD \$50 billion in this time period alone. The impact of patent expiries for the small-molecule portion of the pharmaceutical industry was much greater. Individual companies lost as much as almost USD \$20 billion in annual sales revenue in the 13 years of 2005 to 2018.<sup>35</sup>

**Fig. 2 Patent Expiry Adds to Market Uncertainty**



Source: Pharmaceuticals, 2012

Figure 3 shows the success rate by R&D phase from product concept through registration and approval for both large- and small-molecule product development.<sup>3</sup> The overall success rate for small-molecule research and development during this same period was approximately 2%. The real number for some companies might have been less than 1%. That very low success rate was not allowing for the production of potential new products, especially new products with large market revenue potential, at a rate remotely close to that required to offset patent expiries. Had that trend continued, large pharmaceutical companies would have dwindled away to shadows of their former selves.

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18	Gan & Lee Pharmaceuticals
19	Chongqing Zhifei Biological Products Co., Ltd. / Beijing
20	Yantai RC-Pharmaceutical Co., Ltd. / MabPlex International (Note: MabPlex is the contract manufacturing arm of Yantai Rongchang)
21	Shanghai Henlius Biotech
22	MabTech Ltd. (HK)
23	Shanghai Junshi Biosciences Co., Ltd. / Jiangsu
24	Genor Biopharma Co., Ltd., subsidiary of Walvax Biotech / Shanghai
25	3SBio Inc.
26	JHL Biotech
27	GlaxoSmithKline China (GSK China) / Hangzhou
28	Zhejiang TeruSipharm Co., Ltd.
29	Shenzhen Sanofi Pasteur Biological Products Co., Ltd.
30	Biotech Pharmaceutical Co., Ltd. (Biotech Pharma)
31	Shanghai Pharmaceuticals Holding Co., Ltd. (including former Shanghai Jiailian Pharmaceutical)
32	Sinovac Biotech, Ltd. / Dalian
33	Xiamen Amoytop Biotech Co., Ltd. (Xiamen Amoytop)
34	Livzon Mabpharm, Inc. (Zhuhai IMAB Biological Technology Company Ltd.)
35	Harbin Pharma Bio (Harbin Pharmaceutical Group Bioengineering Co., Ltd.)
36	Lunan Pharma Group
37	Zhejiang Hisun Pharmaceutical Co., Ltd.
38	CSPC Pharmaceutical Group Ltd.
39	Pacific Meinuoke
40	AlphaMab Co. Ltd.
41	North China Pharmaceutical Co., Ltd.
42	Shanghai United Cell Biotechnology Co., Ltd.
43	TOT Biopharm Company Limited
44	Anhui Anke Biotechnology (Group) Co., Ltd. (Anhui Anke)
45	Zhuhai Essex Bio-Pharmaceutical Co., Ltd. (Zhuhai Essex)
46	Minhai Biotechnology Co., Ltd.
47	Jiangsu Hengrui Medicine Co., Ltd. / Suzhou
48	Genor Biopharma Co., Ltd., subsidiary of Walvax Biotech / Yuxi
49	Sichuan Kelun Pharmaceutical Co., Ltd.
50	BioThera Solutions (Guangzhou) Ltd.
51	Chia Tai Tianqing Pharmaceutical Co., Ltd.
52	T-Mab Biopharma
53	Beijing Eastern Biotech, Co., Ltd.
54	Beijing Four Rings Biopharmaceutical Co., Ltd.
55	Celgene Biopharma / Shanghai
56	Simcere Pharma Group / Yantai
57	Tasty Pharmaceutical Group Co., Ltd.
58	Northland Bio
59	Akeso Biopharma
60	Jiangsu Hengrui Medicine Co., Ltd. / Shanghai
61	Synermore Inc/ Suzhou facility
62	Boehringer Ingelheim Biologics China
63	Shanghai Jingfeng Pharmaceutical Co., Ltd.
64	Chongqing Zhifei Biological Products Co., Ltd.
65	Beijing Tri-Prime Gene Pharmaceutical Co., Ltd.
66	YZT Biopharma
67	Sinobioway Biomedicine Co., Ltd. / Tianjin
68	Chengdu Kanghong Pharmaceutical Group
69	Clover Pharma
70	ShangPharma Group (including ChemPartner and China Gateway Pharmaceutical Development CMO/CRO divisions)
71	Lee's Pharmaceutical Holdings Limited / Hefei Zhaokao
72	Simcere Pharma Group / Changzhou
73	Zhejiang Huahai Pharmaceutical Co., Ltd. (Huahai Pharma)
74	Changchun High & New Technology Industries (Group) Inc. / BCHT
75	BelGene (Beijing), Co., Ltd.
76	Generon (Shanghai) Corporation
77	Sinocelltech Ltd. (Majority owned by Sino Biological, Inc.)
78	Pfizer Biological Pharma (Hangzhou) Ltd.
79	Jiangsu Hengrui Medicine Co., Ltd. / Lianyungang
80	SL Pharma / Beijing
81	Shanghai Junshi Biosciences Co., Ltd. / Jiangsu, Suzhou
82	Shanghai Benemae Pharmaceutical Co.
83	Zensun (Shanghai) Sci & Tech Co., Ltd.
84	C-Mab Biopharma, Inc.
85	Hangzhou Just Biotherapeutics Inc
86	Walvax Biotechnology Co., Ltd. / Kunming
87	Hualan Biological Engineering Inc.
88	Walvax Biotechnology Co., Ltd. / Taizhou
89	Harbin Gloria Pharma





## Advances in Biopharmaceutical Technology in China

A great opportunity exists in working with Chinese companies to establish scientific partnerships and effective company strategies. However, success in Asia in the new millennium will require changes in partnerships between Western and Asian companies. Every company faces the question "What should our China strategy be?" This volume provides an overview of the biopharmaceutical industry, and the state of technology in China. It will help the reader assess the state of biopharmaceutical development in China, understand general business practices, analyze business opportunities and identify potential partners. It also provides a ready reference for all aspects of biopharmaceuticals in China, including a general understanding, detailed technical and business descriptions, and comprehensive information on all types of organizations involved in biopharmaceuticals in China, whether they are state owned or privately held companies, universities, or government institutions.

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- Beijing University
- Betta Pharma Co., Ltd.
- Boehringer Ingelheim China
- CanSino Biologics Inc.
- Celgene Pharma
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- China Technology Exchange
- Chinese Academy of Sciences
- Chinese Pharmacopoeia Commission
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- CStone Pharmaceuticals
- Dacheng LLP
- Doer Bio
- Fudan University
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- Hengrui Pharma
- Hua Medicine
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