

A hand holding a 3D model of a DNA double helix structure. The model is rendered in a light gray color with a slight shadow, and the hand is positioned on the right side of the frame, holding the structure. The background is a soft, out-of-focus light blue.

Innovative Pharmaceutical R&D in China: Status and Trends

Peng Wang, Ph.D.

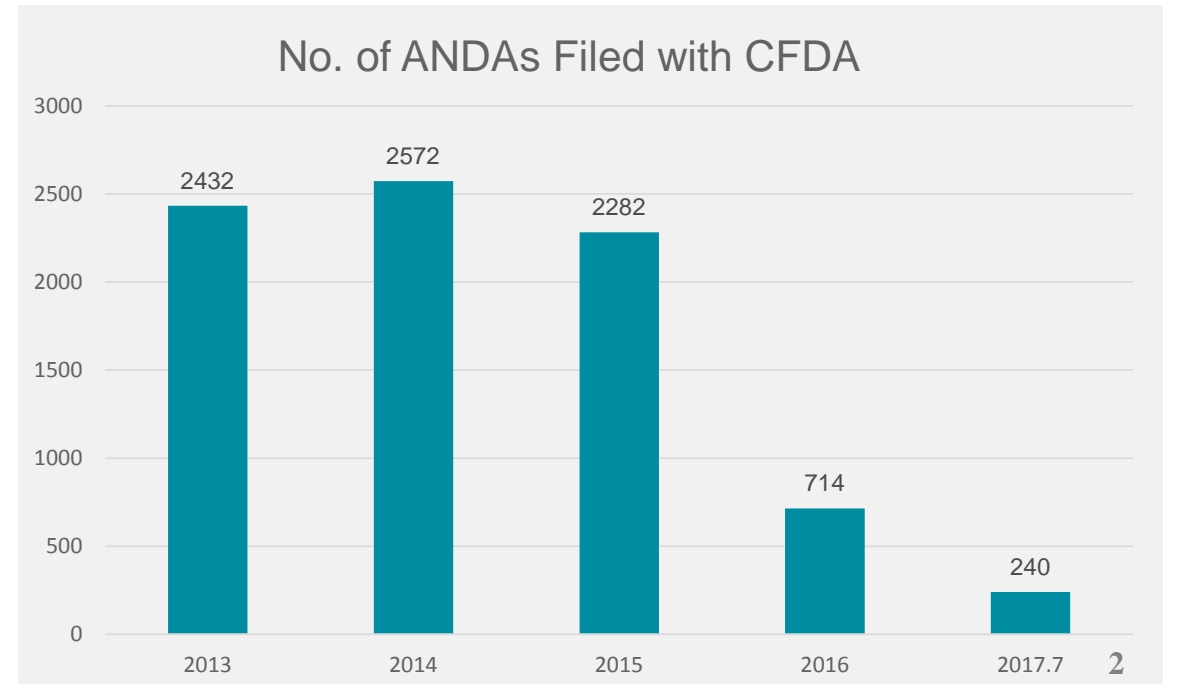
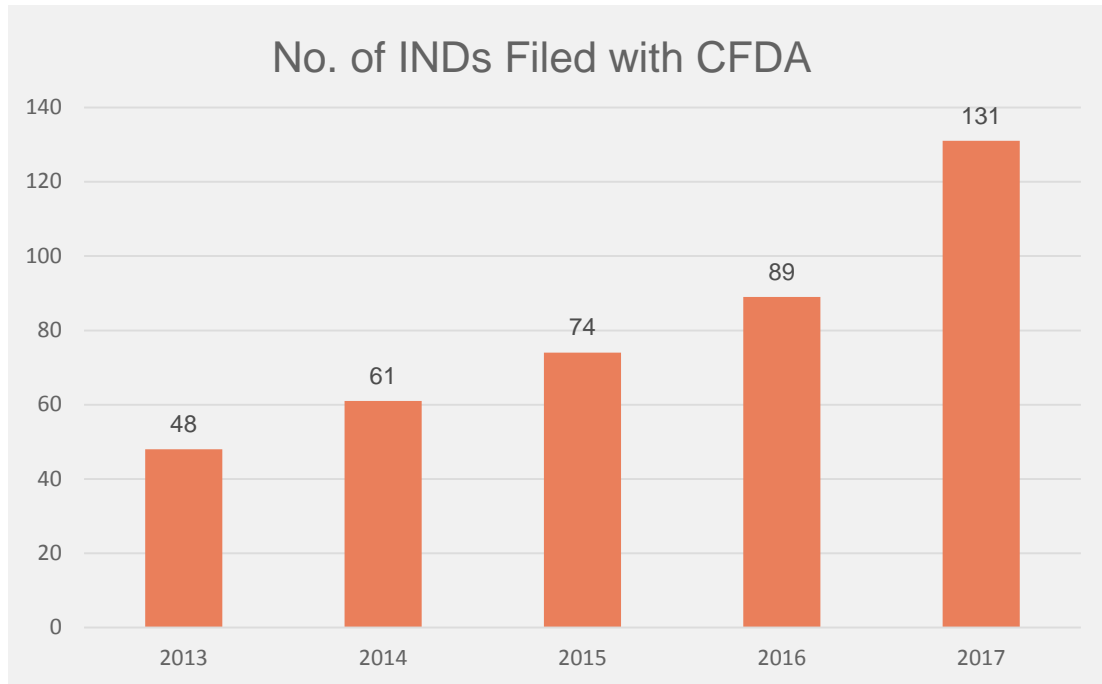
Founder, President and CEO

Suzhou Yabao Pharmaceutical R&D Company

April, 2018

Innovative R&D Boom

- Robust public and private funding
- Smoothed investment exit pathway, including new Hong Kong IPO market for biotechs
- Increasing start-up activity
- CFDA regulatory reform
- A diverse talent pool and well-developed infrastructure



Recent CFDA Regulatory Reform

OBJECTIVE

Solving the backlog of registration applications

Encouraging innovation, and improving quality of generic drugs

Improving quality and transparency of review and approval

REFORM

Personnel expansion

Clinical data verification

Registration classification

Priority review

MAH

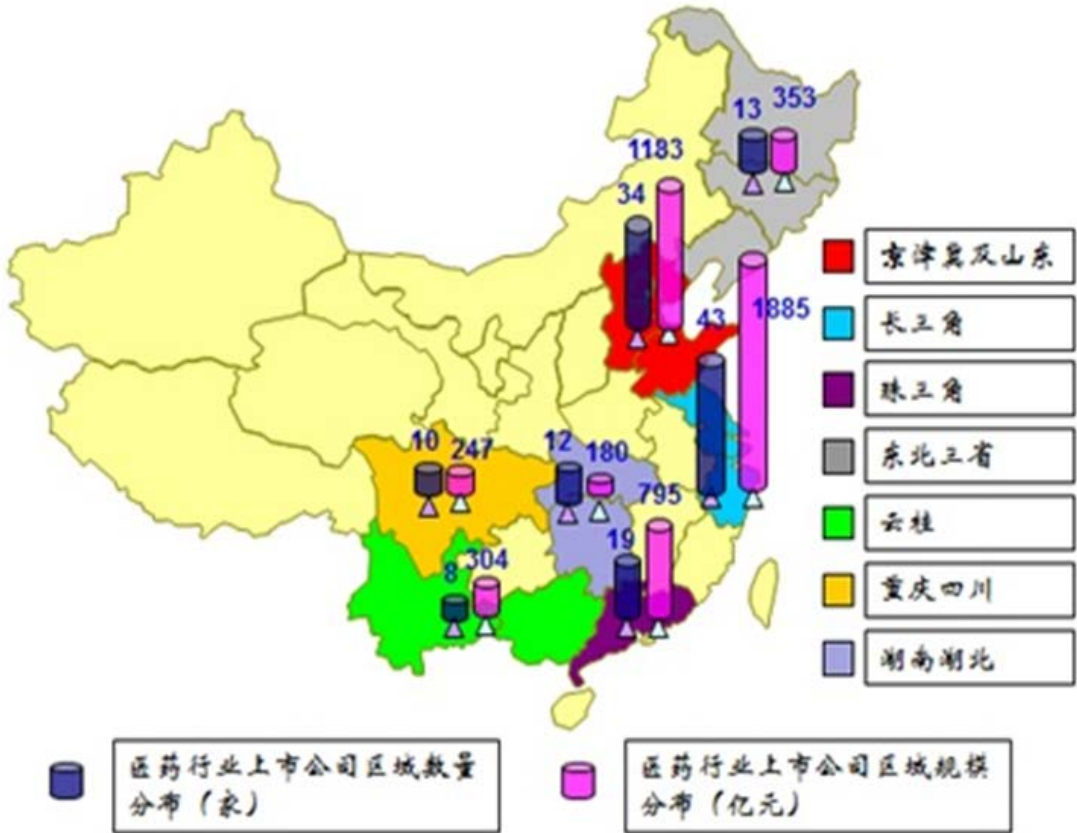
Joining ICH

ACHIEVEMENT

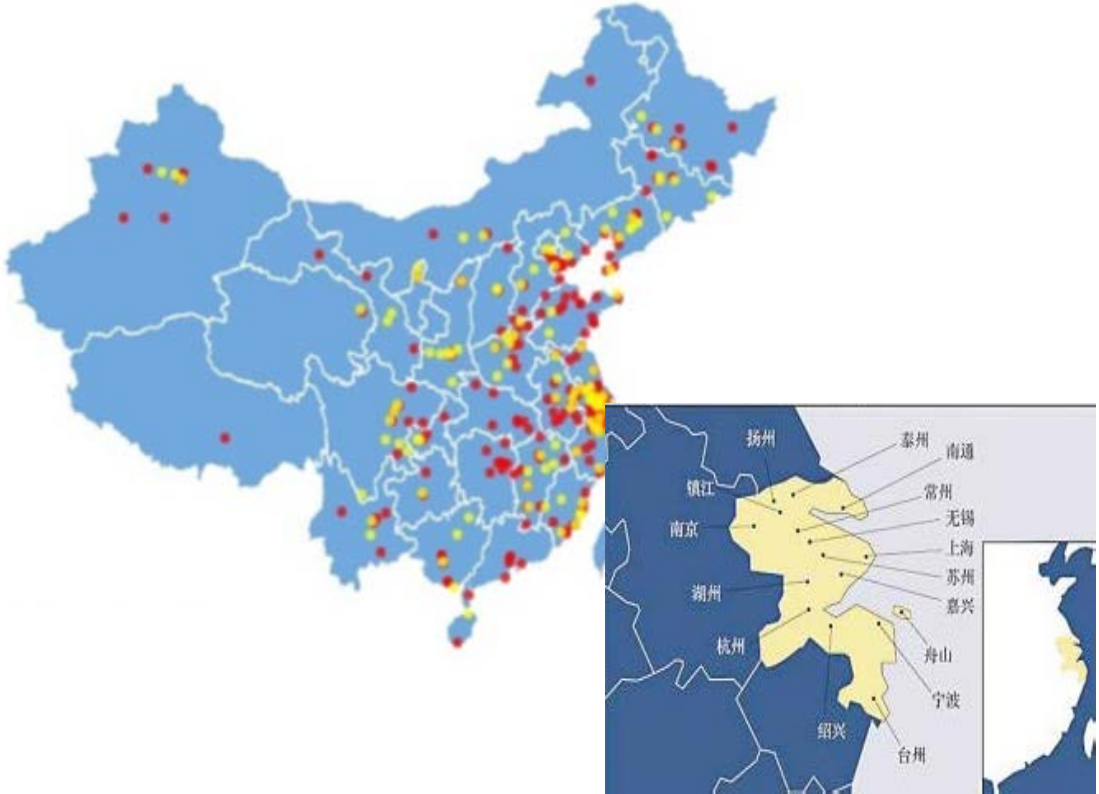
- Dramatical change in the numbers of INDs and ANDAs filed with CFDA
- 40 NDA approvals in 2017, compared to 9 in 2016
- Accelerated regulatory approvals for innovative drugs, targeting no delay versus US/EU
- Priority review and accelerated regulatory approvals (e.g. NDA review time for AstraZeneca's Osimertinib was 1.5 months, compared to previous average timeline of 5.3 years)

Distribution of Innovative R&D

Domestic Public Pharmas



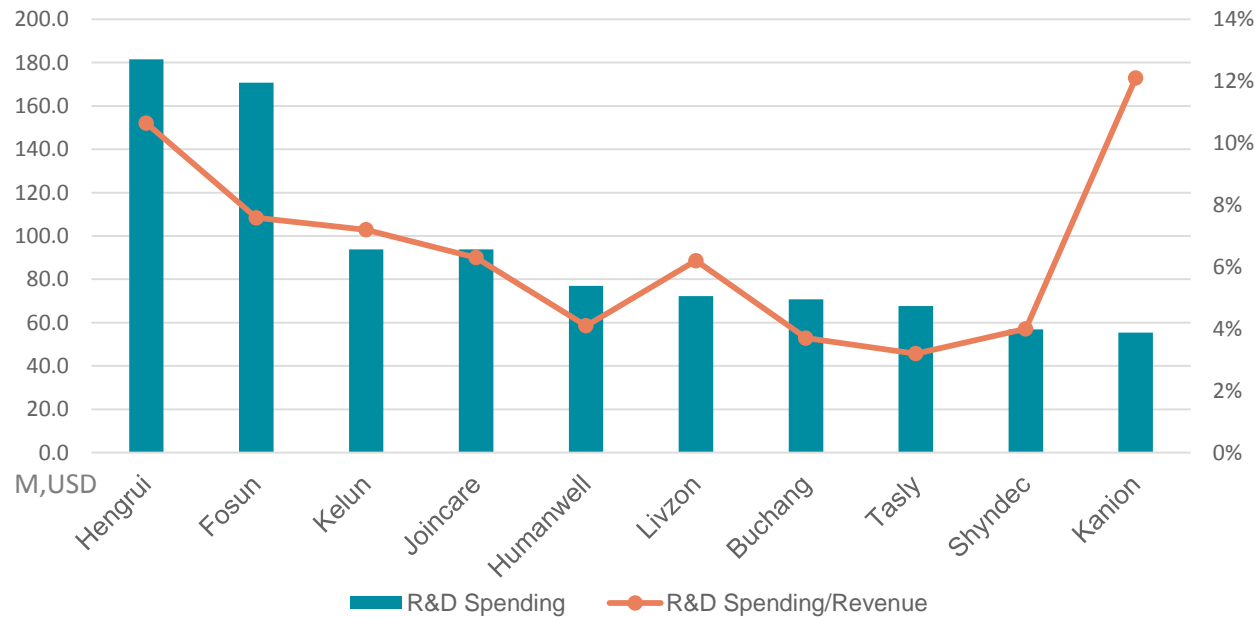
Biomedical Science Parks (~500)



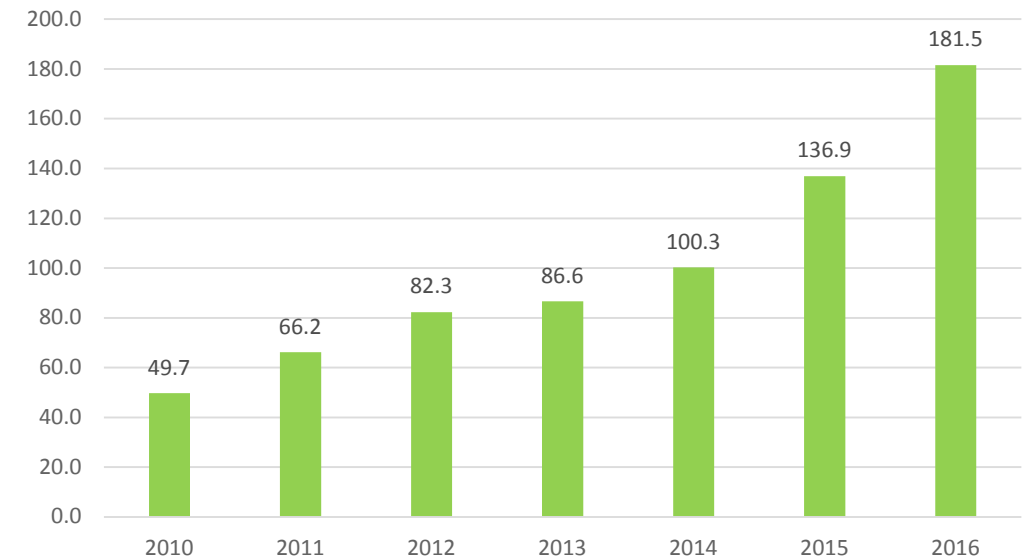
Source: CBCA

Growing R&D Spending by Large Domestic Pharmas

R&D Spending of the TOP 10 Domestic Public Pharmas in 2016



R&D Spending of HengRui since 2010 (M, USD)

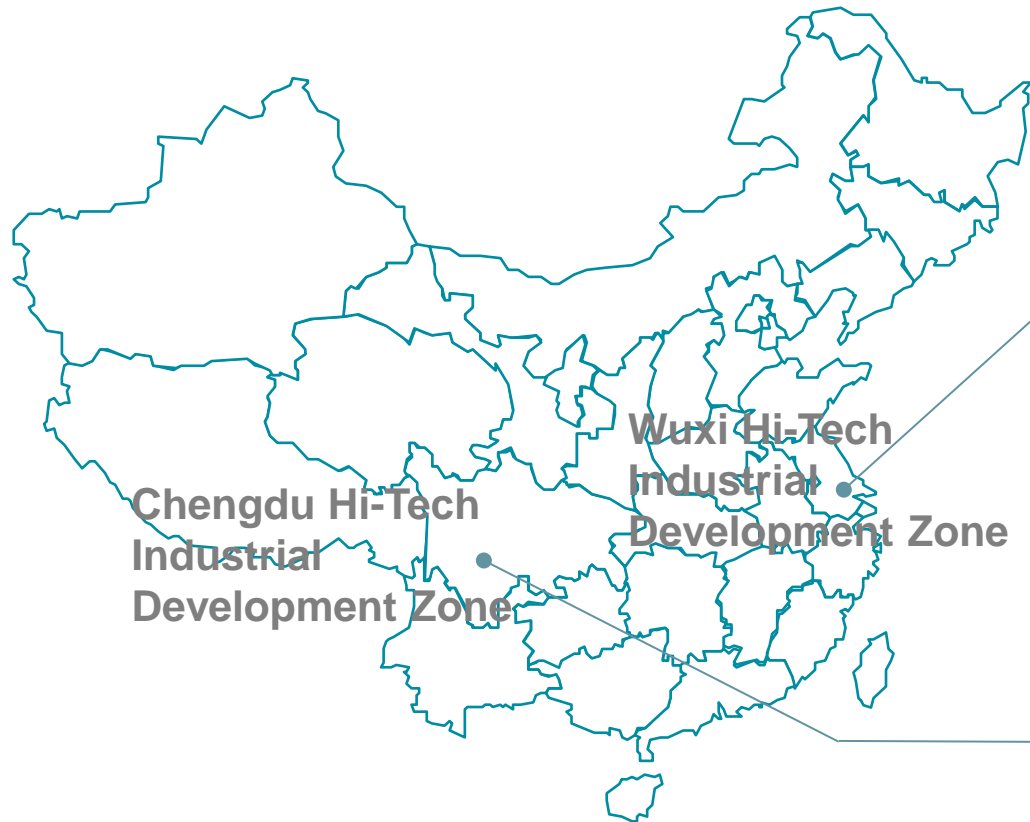


bioBay: A Best Pharmaceutical Innovation Cluster

- Within bioBay located in SIP (Suzhou Industrial Park, a district of Suzhou City), there are **437** resident companies (as of March, 2018)
- Total INDs approved by CFDA
 - **61** Small molecule drugs
 - **20** Biologics
- Total medical device certificates obtained
 - **34** Manufacturing certificates
 - **256** Product registrations
 - **15** CE certifications
 - **1600+** Invention patents
- SIP: There are >1,000 companies



Emerging Leading Service Providers



WuXi Biologics
Global Solution Provider

- An integrated service provider for discovery, development and manufacturing of biologics
- FDA-approved commercial manufacturing
- Partners including 13 of the TOP 20 MNCs
- Listed on Hong Kong in June 2017; Market value: >10 billion USD

HITGEN
先导药物

- DNA-encoded library technology for small molecule drug discovery
- Partners including MSD, Pfizer, J&J, Boehringer Ingelheim, Takeda, etc.

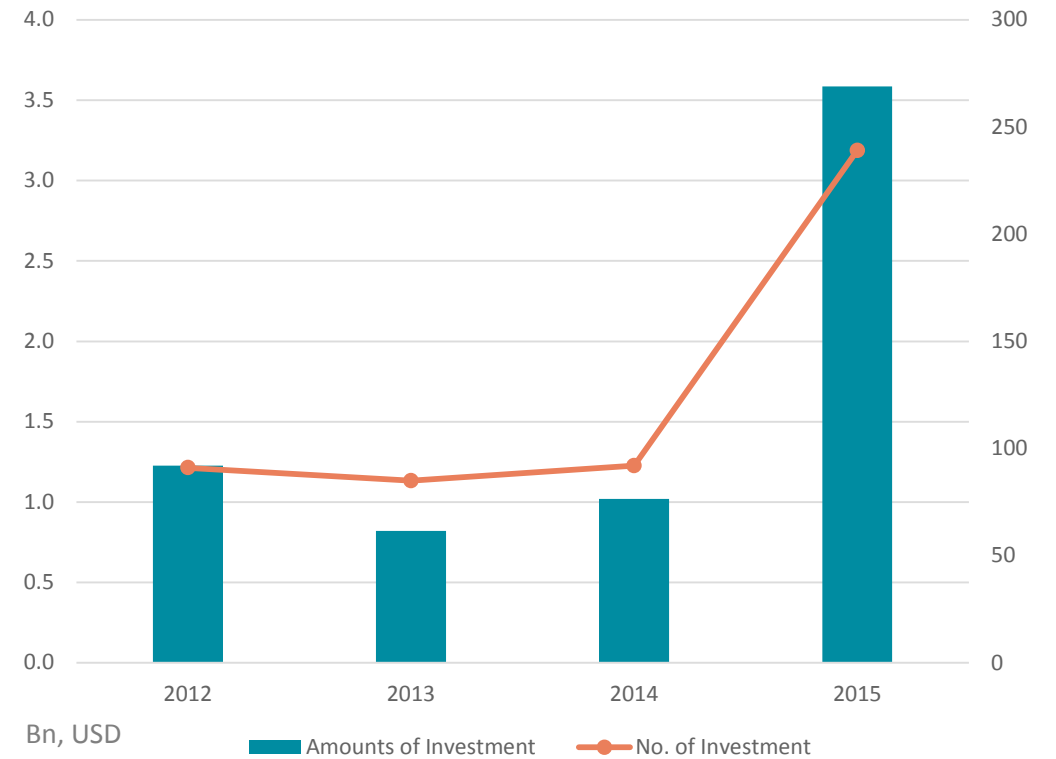
2017 Life Science Investment

■ Key numbers in 2017 vs 2016:

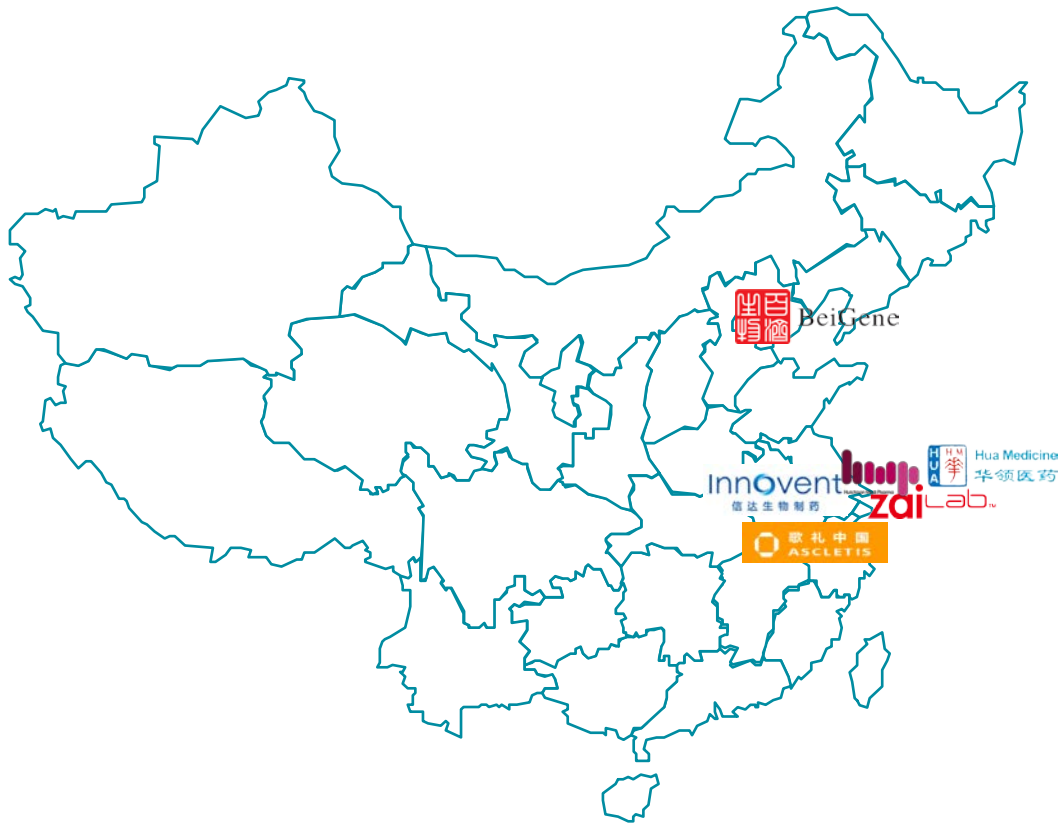
- New VC/PE funds raised – doubled to \$40B
- VC investment – doubled to \$12B
- Partnering deals – doubled to \$8B
- M&A activity – tripled to \$65B
- IPOs – record 53 IPOs raising \$5B

■ These numbers were close to those in US

VC/PE Investment in 2012-2015



Emerging Leading Biotech Companies



BeiGene

- In-house discovery, with programs out-licensed to Merck Serono and Celgene
- Focused on oncology
- Listed on Nasdaq in 2016
- Market value: ~\$9B

Innovent

信达生物制药

- Combined In-house biologics discovery and collaboration, with programs out-licensed to Eli Lilly via strategic partnership
- Total capital raised to date: \$600M
- Corporate valuation: ~\$1.5B,
- IPO planned



Hutchison Medi Pharma

- In-house discovery, with programs out-licensed to Eli Lilly and AstraZeneca
- Focused on oncology and immunology
- Listed on Nasdaq in 2016
- Market value: ~\$4.5B



Hua Medicine
华领医药

- Key asset: One GKA program in phase III for diabetes
- Total capital raised to date: \$125M
- \$400M HK IPO planned

zaiLab™

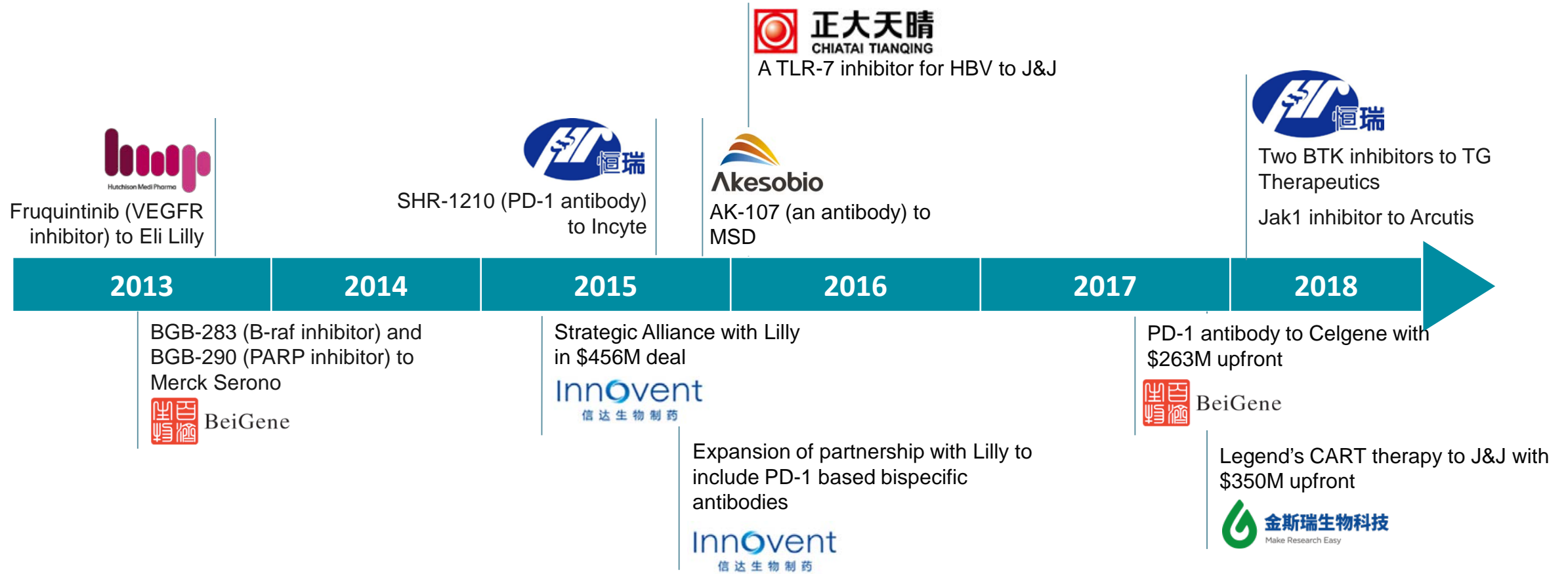
- All programs were in-licensed
- Focused on oncology and immunology
- Listed on Nasdaq in 2017
- Market value: ~\$1B



歌礼中国
ASCLETIS

- Key asset: One HCV program in NDA stage
- Total capital raised to date: \$255M
- Corporate valuation: ~\$1.5B
- IPO planned

“China Innovations” Out-licensed to Western Companies



Hong Kong IPO: A New Booster for China Biotechs

- IPO on Hong Kong Stock Exchange has become possible for pre-profit or pre-revenue biotech companies

Principles Underlying Biotech Issuer Suitability



Product regulated by Competent Authority

- US Food and Drug Administration (FDA), China Food and Drug Administration (CFDA), European Medicines Agency (EMA)
- Other authorities will be considered on a case-by-case basis



Past concept stage

- Completed Phase I and received no objection to commence Phase II (or later)
- Product subject to human testing



Meaningful investment from at least one Sophisticated Investor

- To provide a level of validation from an experienced third party investor

Proposed Listing Eligibility

SUITABILITY FOR LISTING

PRODUCT

At least one Core Product⁽¹⁾ beyond concept stage

RESEARCH AND DEVELOPMENT

Primarily engaged in R&D of its Core Product(s) for a minimum of 12 months

IPO

Primary reason for listing is to raise capital for R&D to bring its Core Product(s) to commercialisation

PATENTS

Durable patent(s), registered patent(s), patent application(s) and/or intellectual property in relation to its Core Product(s)

SOPHISTICATED INVESTOR⁽²⁾

Meaningful investment⁽²⁾ for at least 6 months before IPO (which must remain at IPO)

Specific guidance for Biotech Issuers



Pharmaceutical (small molecule drugs)

- completed Phase I or, for previously approved products (e.g. FDA's 505(b)(2)) – at least one trial on human subjects; and
- no objection to commence Phase II



Biologics

- completed Phase I, or for biosimilar – at least one trial on human subjects; and
- no objection to commence Phase II (or later)



Medical Devices (including diagnostics)

- Class II medical device (or equivalent) or above;
- at least one trial on human subjects;
- endorsed or no objection to proceed to further clinical trials or commence sales of the device



Other Biotech Products

- will be considered on a case-by-case basis;
- need to demonstrate it is beyond concept stage;
- appropriate framework or objective indicator for investors to make an informed investment decision

- Chinese biotech companies targeting Hong Kong IPO:

- Announced: Hua Medicine, Ascleptis, Henlius (Fosun's biotech arm), Shanghai Tasly (Tasly's biopharma unit), Innovent
- Many others are considering

Overview of Suzhou Yabao Pharmaceutical R&D Company



Suzhou Yabao is located in Suzhou bioBAY, half hour from Shanghai by train, which is globally recognized as a best pharmaceutical innovation cluster in China

FACTS

- Founded in 2014 as an innovative R&D-focused subsidiary of Yabao Pharmaceutical Group
- A clinical-stage biopharmaceutical company
- Strong capabilities for pharmaceutical R&D and international collaboration

- To develop transformative medicines
- Collaboration-based
- Leveraging “China Advantages”

MISSION & STRATEGY

Our Achievements Over Last 3 Years

International Collaboration

- A total of 8 license deals signed, possibly as many as any company did in China over last 3 years
- Collaborations established with multinational pharma company (Eli Lilly), world-leading organization (MRC Technology, UK), and first class academic labs (UBC, Lawson Institute, and University of South Australia)

Pipeline

- A pipeline of 9 drug candidates: 2 in Phase I, 2 INDs filed, and 1 IND being filed
- All being first-in-class or best-in-class on new targets

Development Expertise

- Management team with rich and full pharmaceutical R&D experience in both US and China
- China IND track record: completing tech transfer and CFDA IND-filing package within 10 months (new CFDA policies should further expedite this process)

Near-term Strategic Plans

- **To collaborate with external investors, we are in a process of spinning-off Suzhou Yabao**
- **Continuing to enhance our pipeline through collaboration and leveraging “China Advantages” to accelerate drug approval and maximize China market potential**
- **Leadership team expansion, including C-level executives with Western clinical development, business development and management experience**
- **Implementing global development strategy and initiating clinical development in US/Australia**

Our Team



Dr. Peng Wang, Founder, President and CEO

- **1990, Ph.D. in Biochemistry from the University of Tokyo, School of Pharmaceutical Sciences**
- **1990 - 2008, Allergy/Immunology/Inflammation, Schering-Plough, Research Fellow**
 - Major contribution to discovery and early development of 9 development candidates
- **2008 - 2009, WuXi AppTech, Corporate VP and Head of Discovery Biology**
 - Business development: established collaboration on >30 projects with >10 Western companies
- **2009 - 2013, Simcere Pharmaceutical Group, Corporate VP and CSO**
 - International collaboration: Major contribution to 5 deals (3 R&D, 1 import drug, and 1 commercial JV deal)
 - Innovative R&D in China: 7 INDs approved, with the most advanced program in NDA filing and completing a phase 1 in Australia
- **2013 - 2017, Yabao Pharmaceutical Group, President of R&D and CEO of Suzhou Yabao**
 - International collaboration: 11 deals signed (including 8 R&D, 1 import drug, and 2 development/manufacturing/commercialization deals)
 - Innovative R&D in China for global, with 2 INDs approved
- **2017 – current, Yabao Pharmaceutical Group, CSO, and CEO of Suzhou Yabao**
- **2015 - current, Adjunct Professor at University of South Australia; 2017 - current, AIMBE Fellow**

Other Team Members (1/2)

Dr. Bing Yan, Chief Medical Officer

- MD in Clinical Endocrinology/Immunology from Shanghai JiaoTong University Medical School
- Post-doctoral Clinical Fellow (Endocrinology & Immunology) at Johns Hopkins Medical School (1992-1998)
- 16 Years clinical development experience with major pharma companies in US, including J&J (2000-2004) and Wyeth (2004-2009)
- Working in China for Wyeth then Pfizer since 2009, mostly as Vice President (since 2011)



Dr. Lin Zhu, VP, Pharmacology, Toxicology and ADME/PK

- Ph.D. in Biotechnology from Tsinghua University
- Head of Pharmacology and Toxicology at Simcere Pharma Group (2008-2013)
- Led preclinical development and obtained IND approval of 9 innovative drug candidates



Dr. Fei Zhang, VP, CMC Development

- Ph.D. from China Pharmaceutical University
- 12 years drug development experience at Simcere Pharma Group (2004-2016) with increasing responsibilities, including head of analytical development and head of CMC development
- Made significant contributions to 1 NDA approval and 8 other NCE programs to IND approval



Dr. Yan Xia, Head of Medicinal Chemistry

- Ph.D. in Organic Chemistry from University of Pittsburgh, post-doctoral training at NIH
- Former Senior Principal Scientist with 21-year medicinal chemistry experience at Schering-Plough and Merck
- Major contributions to discovery and early development of 8 development candidates (including 1 launched)



Other Team Members (2/2)

Dr. Yang Song, Director, Medicinal Chemistry

- Ph.D. from Tsinghua University
- 11 years experience in medicinal chemistry, including leading several lead optimization programs collaborated with MNCs

Mr. Yiqun Xu, Executive Director, Clinical Development

- MS from Southeast University
- Over 15 years experience in clinical development, including project management, clinical operation and monitoring, protocol development, etc.

Ms. Zhixin Wang, Director, Clinical Development

- MS from Capital Medical University
- 4 years experience as hospital physician and 8 years experience in managing clinical operation at multinational companies

Dr. Xiarui Dou, Chief Patent Counsel

- Ph.D. in Pharmacology from Beijing Traditional Chinese Medicine University; Certified lawyer and patent attorney
- 6 years patent experience with large pharma and 2 years with law firm

Dr. Zhongping Fu, Director, Biologics Development

- Ph.D. from Macao Science and Technology University
- 8 years experience in analytical development and quality control for biologics, including 3 therapeutic antibody programs (1 in phase I and other 2 filed as INDs)

Dr. Caixia Sun, Director, Clinical Development

- MD from Nanjing University
- 6 years experience in clinical development, including protocol design, clinical operation, medical support, etc.

Mr. Lei Yang, Director, Project Management

- MS from Zhongnan University
- 6 years experience in drug discovery and early development, former protein kinase team leader at Genscript and head of in vitro pharmacology and project manager (the BMS-Simcere collaboration program) at Simcere Pharma (2007-2011)

Ms. Weina Liu, Director, Business Development

- MS from China Pharmaceutical University
- 6 years business development experience and made contributions to 10 international collaboration deals

Our Pipeline

Program	Indication	Mechanism of Action	D	P	IND	PI	Progress	Partner
Metabolite Disease								
SY-004	Diabetes	Glucokinase activator	■	■	■	■	China phase Ib on-going, four global (including US) phase I studies completed	Eli Lilly
SY-008	Diabetes	SGLT1 inhibitor	■	■	■	■	China phase I initiated, one US phase I study completed	Eli Lilly
SY-009	Diabetes	SGLT1 inhibitor	■	■	■	■	China IND filed	Eli Lilly
CNS								
SY-007	Stroke	PTEN inhibitor	■	■	■	■	China IND filed, US IND filing planned	A team at University of British Columbia
SY-006	Parkinson's disease	Undisclosed	■	■	■	■	Lead optimization	MRC Technology
Oncology and Autoimmune/Inflammation								
SY-003	Oncology	PLK/PI3K/Ras inhibitor	■	■	■	■	Preclinical development on-going	Professor at University of South Australia
SY-010	Oncology	Undisclosed immuno-oncology target	■	■	■	■	Lead optimization	University of South Australia
SY-012	Autoimmune/Inflammation	Antibody on undisclosed target	■	■	■	■	Candidate discovery	Undisclosed
Other Areas								
SY-005	Sepsis	Recombinant human Annexin 5 protein	■	■	■	■	IND to be filed in Q2 2018	Lawson Health Research Institute

D = Discovery, P = Preclinical Development, PI = Phase I

Finished

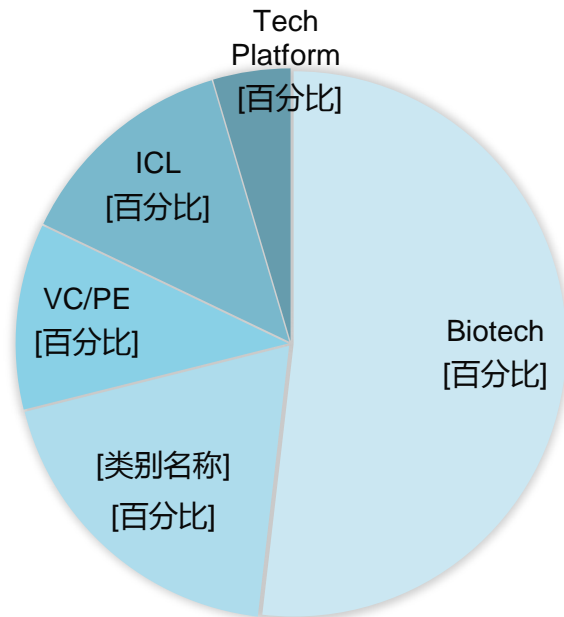
On-going

Brief Introduction to New Drug Founders Club (1/2)

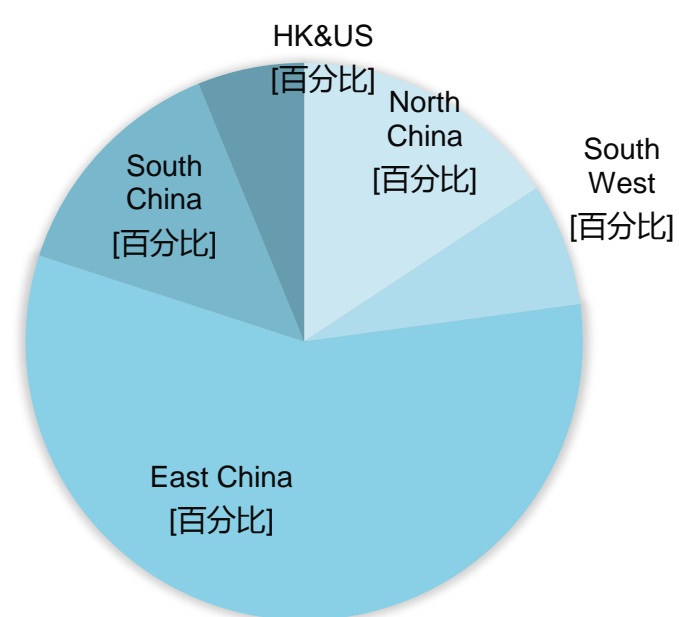


- Founded in April 2015
- Members are FOUNDERS of companies focusing on innovative pharmaceutical R&D or providing relevant services
- Mission: To advance communication and collaboration among all founders of the relevant companies in China
- Currently there are **218** members

Industries of Members

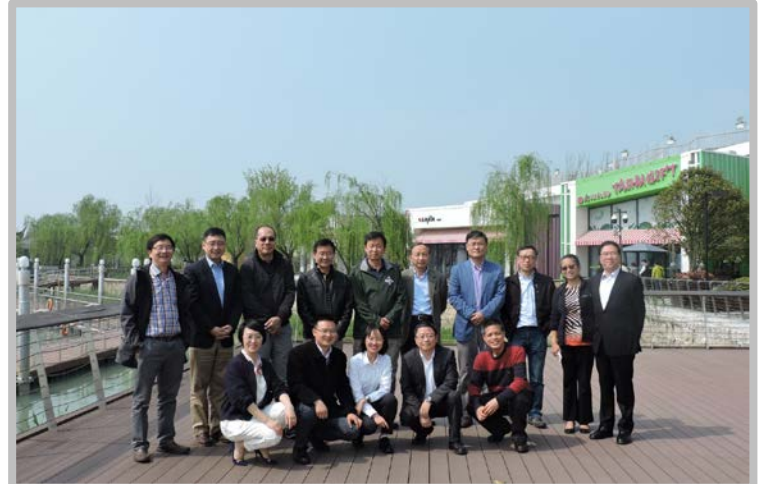


Location of Members



Brief Introduction to New Drug Founders Club (2/2)

Club activities: annual conference, symposium, salon, member gethering, etc.



How to Establish Drug Discovery Ecosystem in Asia?

- **A key to establishing drug discovery ecosystem in Asia would be information exchange and learning**
- **China is emerging as a pharmaceutical innovation center in the world**
- **China industry will have more and more assets for license-out, and will need to license-in more and more assets**
- **A major challenge is the shortage of collaboration partnerships, resulting from shortage of information exchange and learning.**
- **Everyone should learn harder to gain full information, and to correct misunderstanding**

THANK YOU