## **3SBio 2018 Full Year Investor Presentation**

March 21, 2019



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## **Agenda**

**1** Welcome and Introduction

**Dr. Lou Jing**, Chairman and CEO

2 R & D Update

**Dr. Zhu Zhenping,** President of R&D and CSO

**3** Operational and Financial Review

Mr. Tan Bo, CFO

4 Q&A



## Welcome and Introduction

**Dr. Lou Jing,** Chairman and CEO

## **2018 Highlights – Strong Operating Performance**

Investment in Innovative R&D Supported by Strong Operating Performance

### Revenue

➤ Revenue increased by approximately RMB 849.5 million or approximately 22.7% to approximately RMB 4,583.9 million.

### **EBITDA**

**EBITDA** increased by approximately RMB 416.0 million or approximately 28.2% to approximately RMB1,892.8 million.

### Rank

➤ Ranked from **42**<sup>nd</sup> (2017) to **27**<sup>th</sup> (2018) among all Chinese pharmaceutical companies according to IQVIA<sup>1</sup>

#### Note:

1 formerly known as IMS Health



### 2018 Highlights - R&D

### Investment in Innovative R&D Supported by Strong Operating Performance

- Well-positioned biologics oncology pipeline (antibodies to HER2, CD20, PD1, VEGF and EGFR)
- Resubmitted NDA application of anti-HER2 antibody Inetetamab (302H) to CDE and achieved priority review status
- Completed patients enrollment for Phase I trials of the anti-EGFR antibody (602) and is planning for advanced trials
- Received an IND approval from the US FDA for phase I trials of an anti-PD1 antibody (609A) in cancer patients
- Completed the Phase III trial of a pre-filled syringe dosage form of Yisaipu (301S), and to file for manufacturing approval in H1 2019
- Completed the phase I clinical trial of a humanized anti-TNF  $\alpha$  antibody (SSS07) in both healthy volunteers and RA patients
- Began patient enrollment of TPIAO in hepatic dysfunction surgery patients at the risk of thrombocytopenia
- Received IND approvals for TPIAO for pediatric ITP indications
- Completed multiple Phase I clinical trials of NuPIAO (SSS06) and obtained approval for Phase II and Phase III clinical trials. Patients enrollment is expected to begin soon
- Completed a phase I trial of RD001 in healthy volunteers, and will begin trials in anemic patients
- Received IND approvals of the anti-VEGF antibody (601A) to conduct clinical trials in patients with macular edema
  following RVO, mCNV and DME; patient enrollment is ongoing for 601A in Phase I AMD trial



## 2018 Highlights (Con'd)

### Investment in Innovative R&D Supported by Strong Operating Performance

#### Products and Sales

- **Bydureon** was launched in May 2018 in China as the first-to-market once-weekly therapy for type 2 diabetes in China
- Fluticasone Propionate Cream obtained manufacturing approval in August 2017 and was launched in March 2018
- <u>Tacrolimus Ointment</u> was approved by NMPA for pediatric indication in February 2018
- TPIAO was listed as one of the top 50 best-selling pharmaceutical products in terms of sales value in China's market
- **EPO** was listed in the 2018 National Essential Drug List (NEDL)
- Leading Commercial Platform with 3,224 sales and marketing employees focusing on oncology, rheumatology, nephrology, metabolic diseases and dermatology

### Strategic Partnering and Licensing

- Refuge Biotechnologies: research collaboration to develop novel programmed cell therapeutics
- Samsung Bioepis: biosimilar collaboration agreement, including bevacizumab for mCRC and NSCLC
- Verseau Therapeutics: an immuno-oncology partnership agreement to develop first-in-class macrophage checkpoint modulators
- Toray: China rights to Remitch (TRK-820); currently approved in Japan for puritis associated with hemodialysis
- Taiwan Liposomes Company: partnership with TLCs' NanoX technology platform to commercialize products
- Acquired NRDL-reimbursed calcium acetate treatment with CKD for hyperphosphatemia in patients



### 2019 Outlook

## Accelerate Product Development through Strong Pipeline and Strategic Partnership and Business Development

### R&D

- New IND applications: Antibodies to PD1, IL17, IL5 and IL4R in China, and begin clinical trials in the US for the anti-PD1 antibody
- New IND applications: TRK-820/Remitch (Toray) and SB8 (Samsung Bioepis) in China
- New pipeline development: preclinical development of a number of new antibodies and bispecific antibodies
- Continue to build up internal clinical development capacity and capability

### **New Products**

- New product launch: Inetetamab (302H) in 2H 2019 as the first therapeutic anti-HER2 antibody in China since Herceptin in 2002
- New product NDA: prefilled syringe dosage form of Yisaipu (301S) in China
- Launch calcium acetate tablet in 2019
- Potential NDRL inclusion of GLP-1 products and others

### **New Development**

- Increase sales of marketed products through further penetration into the already covered hospitals and new hospitals
- Continue to seek M&A and collaboration opportunities to enrich existing product portfolios and pipeline to achieve long term growth



### **Company Strategy**











### **Innovative Biologics & Core Product Portfolio**



### **China-based Global Leader in Biologics**





In the next 10 years, 3SBio will launch 20+ new products, at least half of which will be innovative biologics products

#### R&D



- To focus on R&D of innovative biologic products
- To further integrate discovery & development of novel antibody and other biologic drugs into the R&D platform
- To prioritize investments in pivotal trials and development of next-generation immuno-oncology therapies

#### **Manufacturing**



- To create opportunity by leveraging existing capacity and to get well-prepared to manufacture new products
- To build up comprehensive quality system to manufacture high quality pharmaceutical products at competitive cost
- To complete construction of new manufacturing facilities in compliance with global standards

#### **Sales and Marketing**



- To build leading team of sales and marketing in designated areas
- To expand market network to achieve deeper penetration within broader market
- To expand product lines leveraging the commercialization platform

#### **Investment and Alliance**



- To introduce in-licensed promising drugs
- To seek targets of equity investments that are aligned with company strategy
- To build up industry ecosystem



## R&D Update

Dr. Zhu Zhenping, President of R&D and CSO

### 3SBio is a Leader in Improving Patient Access to Cutting-Edge Biologics Medicines

- China healthcare reforms over the past 25 years have aimed to bridge the gap in international treatment standard through improved access and affordability
- 3SBio was a pioneer in this first wave of biologics in China, including rhIFN-α2a, rhIL-2, rhEPO, rhTNFR:Fc and rhTPO, and more recently with advanced antibody programs targeting HER2, CD20, PD1, VEGF and EGFR to provide biological oncology therapies with the greatest unmet demand in China
- With a fully integrated and proven R&D, manufacturing and commercial capabilities, 3SBio is an attractive partner for international companies large and small seeking to advance innovative programs in China which address the global need for safe, effective and affordable disease treatments
- 3SBio's early-stage R&D efforts focus on novel, next generation therapies, including programmed cell therapeutics, immune checkpoint inhibitors, macrophage checkpoint modulators, bispecific antibodies and combination therapies anchored by 3SBio's comprehensive antibody pipeline.



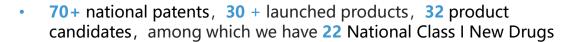
## **3SBio Integrated R&D Centers and Platforms**



4 R&D Centers with Biologics & Chemical Drugs Platforms

National Engineering Research Center for Antibody Drugs

Multiple Research Topics Supported by 13th Five-Year Major Drug Development Project



- 330 experienced scientists under the leadership of Dr. Zhu Zhenping, the Chief Scientific Officer
- Covering oncology, auto-immune diseases, nephrology, metabolic, dermatology and other areas

### **R&D Centers in 3SBIO**





















Research & Discovery

**Process** Development & Pilot Manufacturing

Registration Affairs

Clinical Development

Intellectual Property

Project Management

International **Business and** Sales

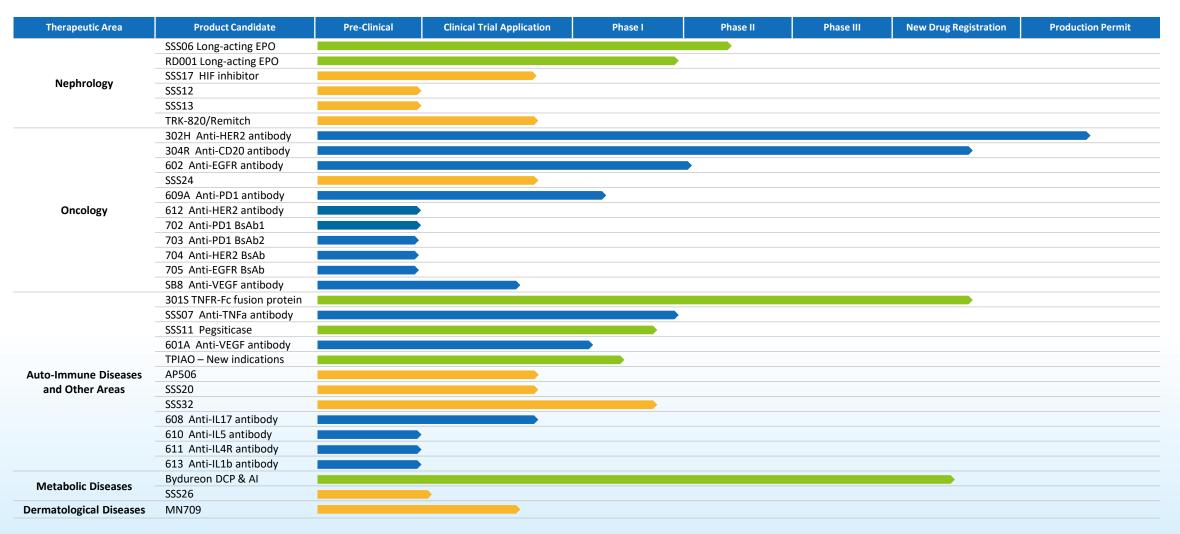
**Business** Development & External Alliance

## **Major Progress in Pipeline Development in 2018**

- Well-positioned biologics oncology pipeline (antibodies to HER2, CD20, PD1, VEGF, and EGFR)
- > Resubmitted NDA application of the anti-HER2 antibody Inetetamab (302H) to CDE and achieved priority review status
- Completed the Phase III trial report of a pre-filled syringe dosage form of Yisaipu 301S, to file for manufacturing approval in H1 2019
- Initiated phase I PK study of the anti-CD20 antibody 304R, in comparison to Rituximab
- > Completed a phase I trial of the anti-EGFR antibody **602**, and is planning for advanced trials in patients with colorectal cancer
- Completed multiple Phase I clinical trials of NuPIAO SSS06, phase II trial to begin soon
- Completed a phase I trial of RD001 in healthy volunteers, and will begin trials in anemic patients soon
- Began patient enrollment of TPIAO in hepatic dysfunction surgery patients at the risk of thrombocytopenia
- Received an IND approval for TPIAO for pediatric ITP indication, patient enrollment to begin soon
- Received IND approvals of the anti-VEGF antibody 601A to conduct clinical trials in patients with macular edema following RVO, mCNV and DME; patient enrollment is ongoing for 601A in phase I AMD trial
- > Received an IND approval from the US FDA for phase I trials of an anti-PD1 antibody 609A in cancer patients



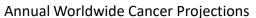
## Robust and Innovative Product Pipeline Supported by Integrated R&D Platform

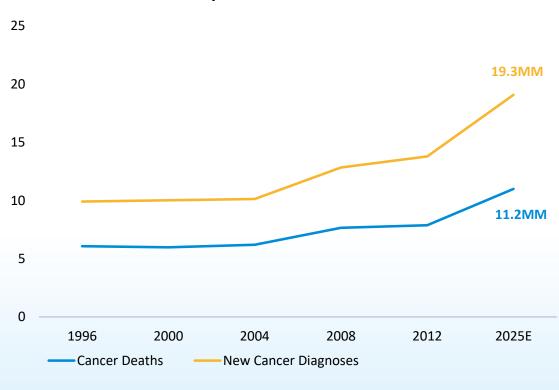




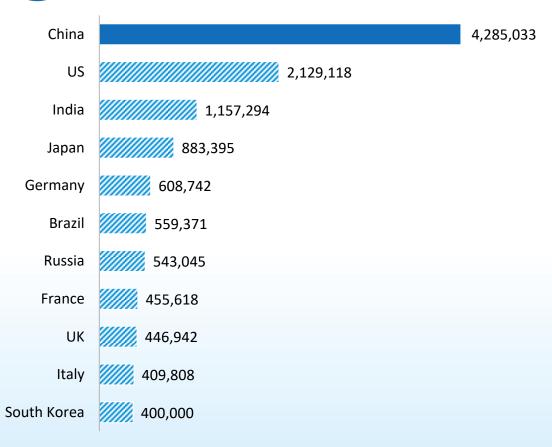
## **Growing Cancer Patient Population Globally and in China**







## Estimated Number of New Cases in 2018



Source: WHO, GLOBOCAN

Source: WHO, GLOBOCAN

## **Oncology Market in China**

### Top 10 Oncology Drugs by Generic Name Globally and in China



## Globally (2018 Forecast)

Generic Name	Brand Name of Patented Drug	Market Size (Billion USD)
Lenalidomide	Revlimid <sup>®</sup>	9.7
Nivolumab	Opdivo®	7.6
Pembrolizumab	Keytruda®	7.2
Trastuzumab	Herceptin®	7.1
Bevacizumab	Avastin®	7.0
Rituximab	Mabthera <sup>®</sup>	6.9
Ibrutinib	Imbruvica®	5.6
Palbociclib	Ibrance®	4.1
Abiraterone Acetate	Zytiga®	3.5
Enzalutamide	Xtandi <sup>®</sup>	3.2

Source: GlobalData



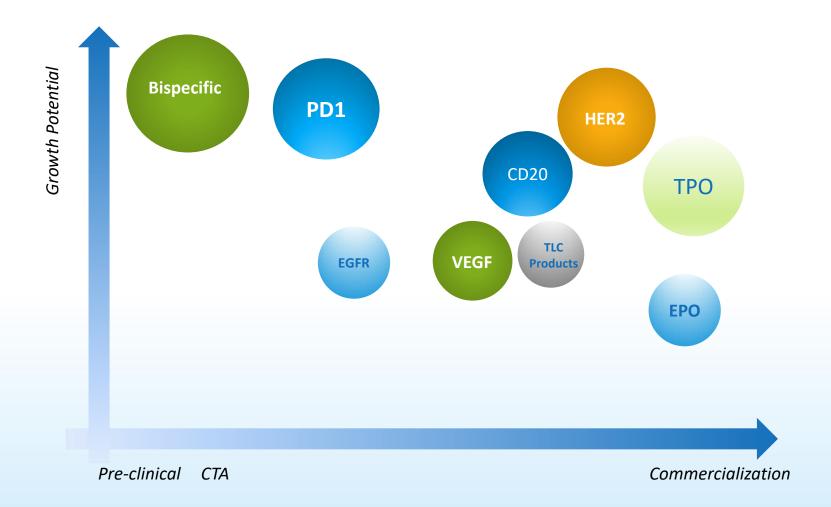
### China (2018 Q1-Q3 Sales from Sample Hospitals)

Generic Name	Brand Name of Patented Drug*	2018 Q1-Q3 Sales (Billion RMB)
Paclitaxel	Taxol®	1.6
Pemetrexed	Alimta®	1.2
Docetaxel	Taxotere®	1.0
Tegafur Gimeracil Oteracil Potassium	Ai Si Wan®	1.0
Rituximab	Mabthera®	0.9
Trastuzumab	Herceptin <sup>®</sup>	0.9
Oxaliplatin	Eloxatin®	0.8
Capecitabine	Xeloda®	0.8
Bevacizumab	Avastin®	0.7
Imatinib	Gleevec®	0.6

Source: PDB



## **3SBio Position in Addressing Cancer Challenge**





## Inetetamab (302H, 伊尼妥单抗)



• From 2009 to 2013, the Company successfully conducted an open label, multi-center, perspective Phase III trial in China for Inetetamab (302H), a humanized anti-HER2 antibody for injection, in patients with HER2 over-expressing metastatic breast cancer



- In September 2018, the Company completed a thorough clinical re-inspection and audited of the phase III trial sites/data, and resubmitted New Drug Application (NDA) to the NMPA for Inetetamab (302H) to treat patients with HER2 over-expressing metastatic breast cancer
- The NDA has been granted a priority review status by the NMPA



• Granted innovative generic name Inetetamab(伊尼妥单抗) by Chinese Pharmacopoeia Commission in 2019



• If approved, Inetetamab will be the **first** therapeutic anti-HER2 antibody approved in China since Herceptin in 2002



## Positioned to be the Leader in Next Generation Immuno-Oncology Programs

### Macrophage Targeting Immunotherapies



- First-in-class macrophage checkpoint modulators (MCMs) to benefit patients with cancer, immune and inflammatory diseases.
- While PD-1 inhibitors have provided great clinical successes, they are only effective in 15-20% of cancer patients.
- Macrophages demonstrate one of the highest infiltration rates in human tumors (~75%).
- MCMs cause tumors to turn highly inflammatory and stimulate multiple immune cell types, including T cells.
- MCM therapies have the potential to significantly expand the number of patients benefitting from immunotherapy, including those unresponsive to PD-1 inhibitor therapies.

### **Bispecific Antibodies**

- 3SBio has multiple bispecific antibody programs, each constructed recombinantly based on the comprehensive internal antibody pipeline
- 702: anti-PD1 x anti-tumor target 1 bispecific antibody
- 703: anti-PD1 x anti-tumor target 2 bispecific antibody
- 704: anti-HER2 x anti-tumor target bispecific antibody
- 705: anti-EGFR x anti-tumor target bispecific antibody
- And others

### **CAR-T Cell Therapy**



- Partnership leverages gene engineering technologies CRISPR interference (CRISPRi) and CRISPR activation (CRISPRa) through Refuge's receptor-dCas platform to develop therapeutic cells that are programmed to make cancerfighting decisions inside the patient's body.
- Refuge's receptor-dCas platform combines multiple therapeutic approaches in a single cell, such as repression or activation of checkpoint targets and cytokine genes, with greater potency and reduced side effects

#### Other Novel Immuno-oncology Program

- Continue to seek licensing and partnership opportunities to further enrich and advance novel immuno-oncology programs
- Leverage existing assets including anti-PD1, inetetamab, anti-VEGF, anti-EGFR and others



### **Integrated Strategic Collaborations**



Exclusive License Agreement for the commercialization of short-acting and long-acting GLP-1 products in China



- Will jointly design and carry out research programs focusing on developing Programmed Therapeutic Cells
- Exclusive license to develop and commercialize the programmed therapeutic cells in Greater China



 Exclusive License Agreement for distribution and promotion of insulin products namely, Humulin Cartridges, Humulin Kwikpens and reusable pens in China



- Partnership focused on the development and commercialization of novel monoclonal antibodies in the field of immuno-oncology for a broad range of cancers
- first-in-class macrophage checkpoint modulators ("MCM(s)") to benefit patients with cancer and other diseases.



- Collaboration for clinical development, regulatory registration and commercialization of multiple biosimilar in China
- Samsung Bioepis will be responsible for manufacturing and supply of the products



- Exclusive right to develop and commercialize TRK-820/Remitch in China
- Will submit IND application to CDE in 2019



- Exclusive partnership to commercialize in mainland China two liposomal products utilizing TLC's proprietary NanoX™ technology.
- Will cooperate to obtain regulatory approvals



- Research collaboration and product license
- Partnership focused on novel small molecule oncology drugs



## **Comprehensive Manufacturing Platform with Strategic CMO Capabilities**

### Complete Quality System Voluntarily in Compliance with Global Standards

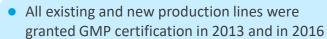
- All 10 production lines for different dosage forms are certified by GMP in 2010
- QA personnel represent 20%+ of all manufacturing employees at the site
- General manager has 10+ years' experience of pharmaceutical R&D, manufacturing and quality control





- QA personnel represent 20%+ of all manufacturing employees at the site
- QA director has 20+ years' experience of pharmaceutical manufacturing and quality control, taking leading roles in MNCs and engaging in drafting national pharmaceutical guidelines and standards
- Pegsiticase, manufactured at Shenyang facility, can be used for clinical trials in the US

- Serves world-renowned companies such as Mylan and Sanofi
- QA personnel represent nearly 40% of all manufacturing employees at the site
- EU GMP certified production lines in Italy



- QA personnel represent 20%+ of all manufacturing employees at the site
- QA director has 10 years' experience of pharmaceutical R&D, manufacturing and quality control







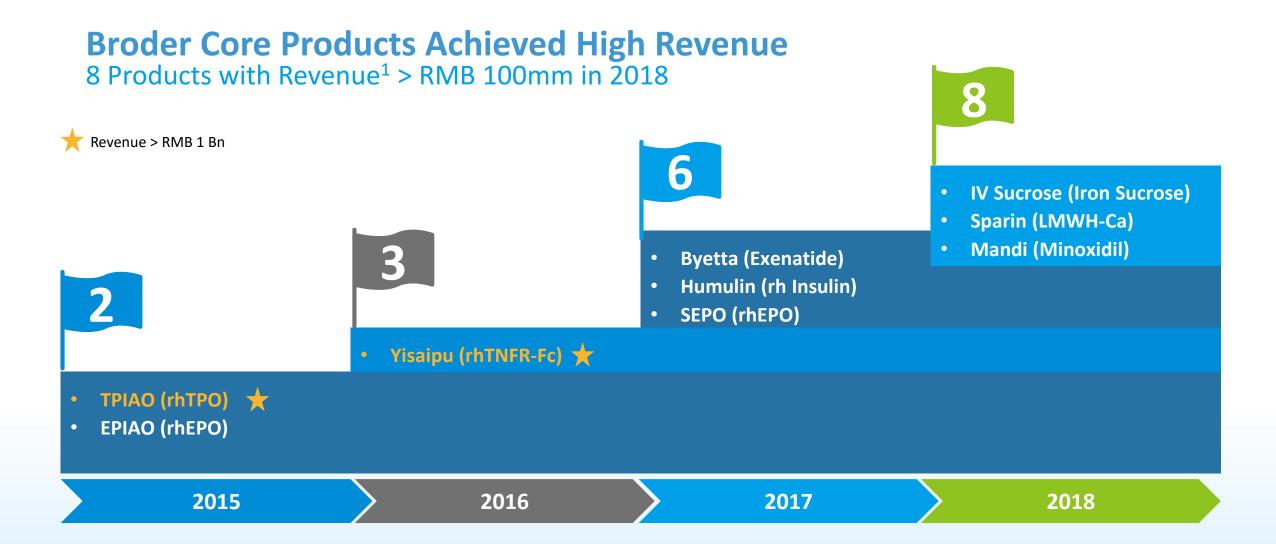
Shenyang

- Plant certified by countries including Colombia, Brazil, Mexico and Ukraine
- Passed EU QP audit
- QA personnel represent 20%+ of all manufacturing employees at the site
- QA director has 30+ years' experience of pharmaceutical R&D, manufacturing and quality control, and serves as the current Vice Chairman of the Biomedicine Committee of Shanghai Pharmaceutical Association and the Director of Shanghai Association for Quality



## Operational Review

Mr. Tan Bo, CFO



Note:

1 Revenue based on in market sales

## Market-Leading Products with Significant Growth Potential Attractive Products with Unique Value Positions and Significant Growth Potential

TPIAO rhTPO	<ul> <li>Self-developed and the only commercialized rhTPO product in the world</li> <li>Achieved a market share of 65.3% in 2018¹.</li> <li>Inclusion in 2017 NRDL as a class B drug</li> <li>INDs approved for surgery patients with hepatic dysfunction at the risk of thrombocytopenia and pediatric ITP indication</li> </ul>	
<b>Yisaipu</b> rhTNFR-Fc	<ul> <li>Launched in 2005 as a first-to-market drug</li> <li>Indicated for the treatment of rheumatoid arthritis, plaque psoriasis and ankylosing spondylitis</li> <li>Boasts a dominant market share of 64.0%<sup>2</sup> in China in 2018</li> <li>Inclusion in 2017 NRDL as a class B drug</li> </ul>	
EPIAO rhEPO	<ul> <li>Consistently ranked #1 in the PRC rhEPO market in terms of sales and volume since 2002</li> <li>Market share reached 41.0%<sup>2</sup> in 2018 (together with SEPO)</li> <li>The only rhEPO product approved for all three indications by SDA in China</li> </ul>	
SEPO rHuEPO	<ul> <li>Second brand rhEPO of the Group</li> <li>Increased our penetration into Grade II and Grade I hospitals</li> </ul>	
Byetta/Bydureon Exenatide/Long-acting exenatide	<ul> <li>GLP-1 products in-licensed from AstraZeneca in Oct 2016</li> <li>The first to market long-acting GLP-1 product in China</li> </ul>	
<b>Humulin</b> rHu Insulin	<ul> <li>Insulin products in-licensed from Eli Lilly in May 2017</li> <li>Better leverage existing diabetes marketing and promotion team to improve productivity</li> <li>Further penetrate into broad market and achieve the synergy with existing products</li> </ul>	
IV Sucrose Iron Sucrose	For all patients requiring IV iron treatment when oral therapy has failed or not likely to be effective.	
Sparin LMWH-Ca	• Used in the prevention of blood clots and treatment of venous thromboembolism (deep vein thrombosis and pulmonary embolism) and in the treatment of myocardial infarction.	
<b>Mandi</b> Minoxidil	<ul> <li>The only topical drug recommended by the guideline for diagnosis and treatment of androgenetic alopecia</li> <li>Achieved a market share of 71.7%<sup>2</sup> in 2018</li> </ul>	

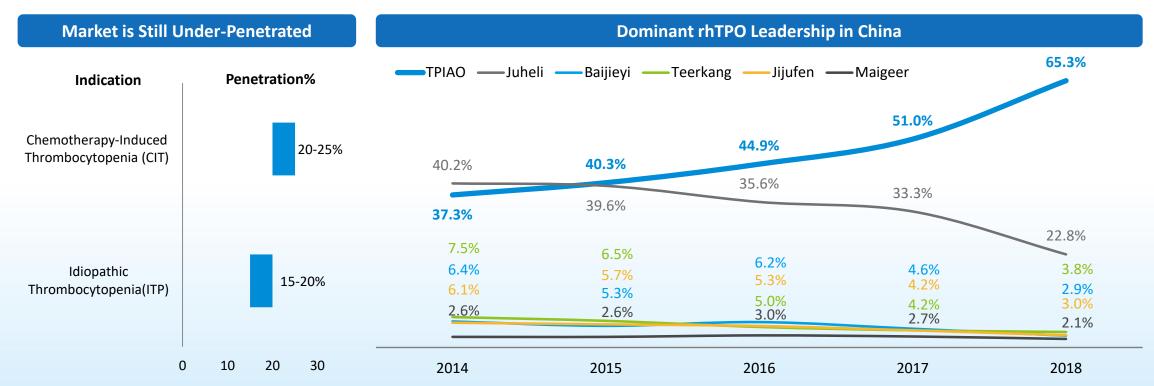
#### Notes

- 1 Treatment for thrombocytopenia category in IQVIA data
- 2 IQVIA data



## Market-Leading Products with Significant Growth Potential (cont'd) TPIAO

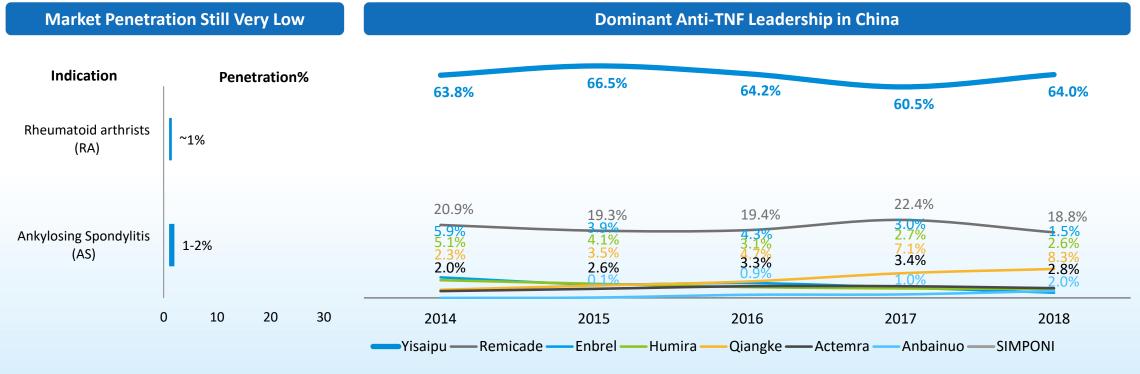
- First to market
- Achieved a market share of 65.3% in 2018
- Higher efficacy, faster platelet recovery and fewer side effects compared to alternative treatments for CIT and ITP
- The first choice in second tier treatments list per PRC ITP Experts Consensus
- Inclusion in 2017 NRDL as a class B drug
- INDs approved for surgery patients with hepatic dysfunction at the risk of thrombocytopenia and pediatric ITP indication



3

## Market-Leading Products with Significant Growth Potential (cont'd) Yisaipu

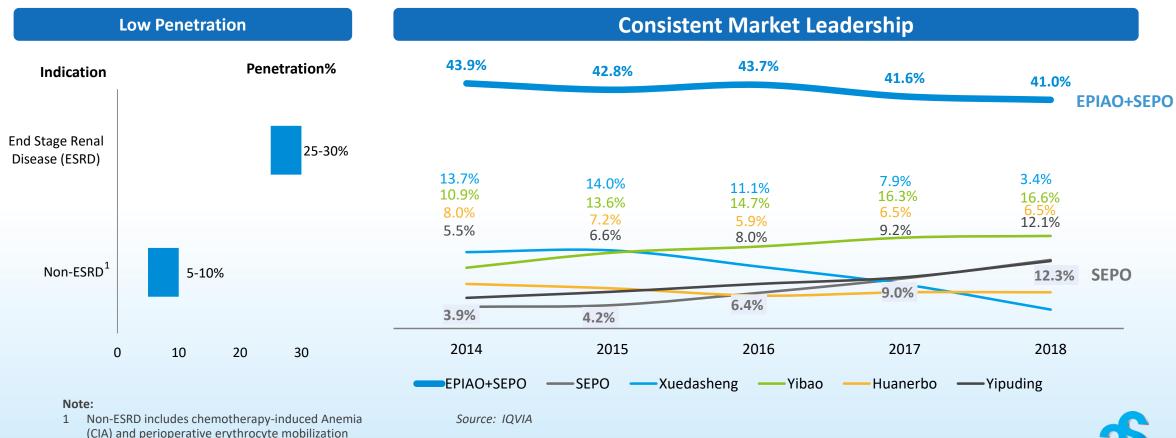
- First-to-market Anti-TNF drug
- Indicated for the treatment of rheumatoid arthritis, ankylosing spondylitis and plaque psoriasis
- Boasted a dominant market share of 64.0% in China in 2018 and demonstrated strong hospital sales in 2018
- Inclusion in 2017 NRDL as a Class B drug
- Completed phase III trial for prefilled syringe of Yisaipu and is expecting to apply for manufacturing approval in 2019



Source: IQVIA

## Market-Leading Products with Significant Growth Potential (cont'd) EPIAO and SEPO

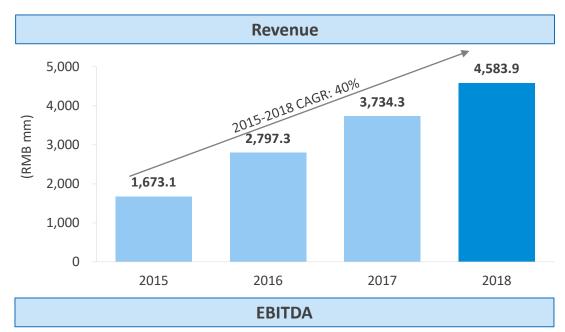
- EPIAO has been market leader in China's rhEPO market for over a decade, continuously ranked as #1 in terms of revenue and volume since 2002
  - ➤ Market share reached 41.0% in 2018 (together with SEPO)
- SEPO is our second brand rhEPO product and expanded our market coverage, especially in Grade II and Grade I hospitals
  - Market share reached 12.3% in 2018, compared to 3.3% in 2013

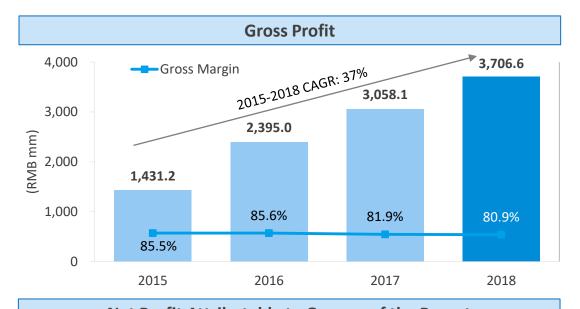


# Financial Review

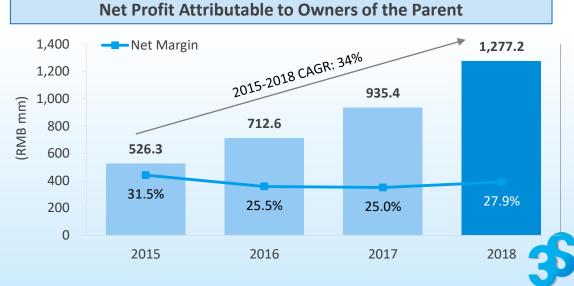
Mr. Tan Bo, CFO

## **Consistent Strong Growth Since IPO**

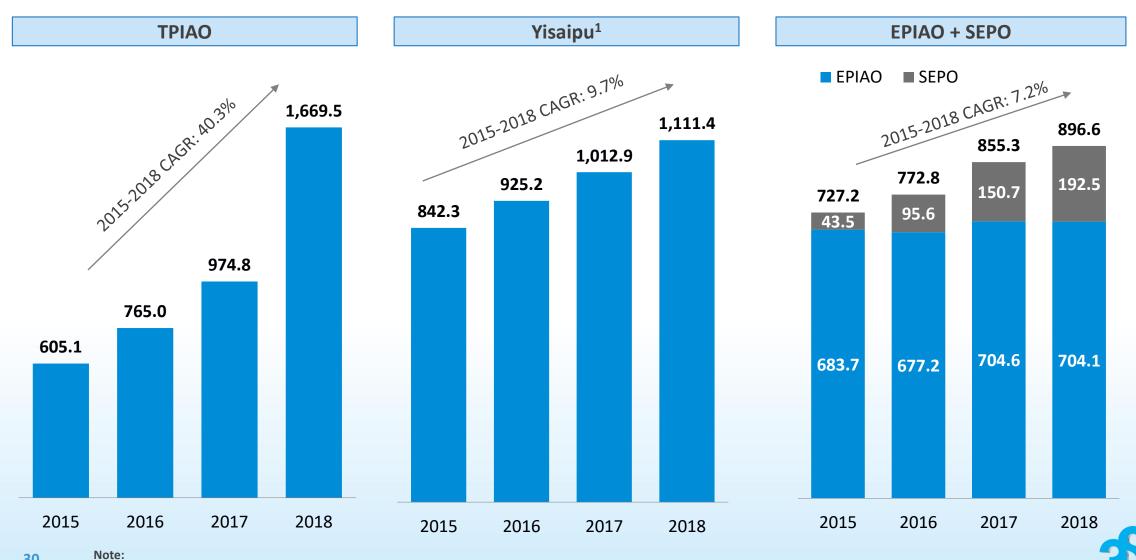








## **Market-Leading Products with Strong Growth Momentum**



30

Yisaipu was consolidated since 1 April 2016.

### **Investment Highlights**











Thanks!

珍爱生命 美注生存 创造生活 Cherish life Care for life Create life



## **Experienced and Visionary Management Team Leading the Growth**



**Dr. Lou Jing** *Co-founder, Chairman, Executive Director and Chief Executive Officer* 

- Joined Shenyang Sunshine as director of R&D in 1995
- Led the manufacturing process development and manufacturing of EPIAO and TPIAO
- Obtained Ph.D from Fordham University in 1994 and completed post-doctor training at the US National Institute of Health in 1995
- M.D from Second Military Medical University in 1985 and EMBA from CEIBS, Shanghai in 2008



**Mr. Kevin Xiao** *Chief Operating Officer* 

Extensive experience within PRC's pharmaceutical industry, including serving as Chief Executive Officer for Hisun Pfizer Pharmaceutical from 2012 to 2015 where he was in charge of the strategy and operations of Hisun and Pfizer joint venture



**Dr. Zhenping Zhu**President of R&D and

Chief Scientific Officer

- Served as EVP for Global Biopharmaceuticals, Kadmon Corporation and served as the president for Kadmon China
- Served as VP and Global Head of Protein Sciences and Design for Novartis and VP of Antibody Tech and Immunology for ImClone Systems
- Led discovery and early development of several FDA-approved novel antibodies for various oncology indications



**Mr. Bo Tan** *Chief Financial Officer* 

- Extensive experience within the financial and pharmaceutical industries
- Worked across private equity, equity research and corporate functions



**Ms. Su Dongmei**Director and Senior Vice President

- Served as director of R&D
- Co-inventor of four patents of the Company



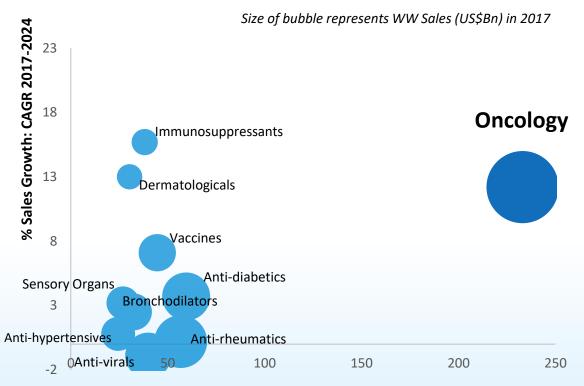
**Dr. James Zhang**Vice President of Manufacturing and
Head of CMO

- Served as vice president of Yuanda, the head of Yuanda Wuhan Pharmaceutical Research Institute and the chief science officer of Huadong Pharmaceutical Company
- Served as executive director on the board of directors of Huadong Medicine and China Grand Pharmaceutical and Healthcare Holdings



## Well Positioned to Meet the Needs of Patients in Oncology



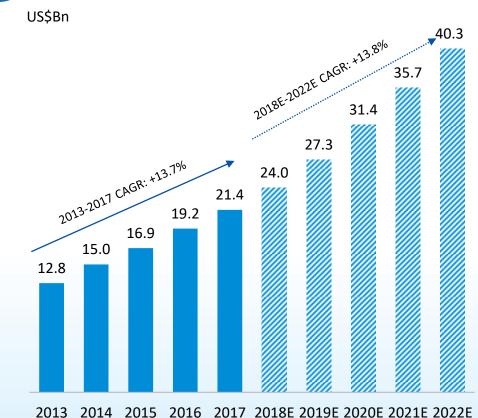


Estimated Sales (US\$Bn) in 2024

Source: EvaluatePharma



### China Oncology Market Forecast (2013-2022E)



Source: Frost & Sullivan

